# A CRITICAL EXPLORATION OF REGULATION OF MEDICAL DEVICES IN INDIA IN COMPARISON WITH THE WHO MODEL FRAMEWORK AND REGULATIONS IN THE US AND EU

*Liji Samuel*[*]

**ABSTRACT**

In the context of evidence-based medical practice, medical and diagnostic devices play a pivotal role in enhancing the quality of healthcare services. The 21st century digital health solutions have revolutionised the entire healthcare concept, where personal devices offer a wide range of healthcare services outside the settings of healthcare establishments. Thus, the medical device regulations have to oversee the safety standards and performance of both traditional and high-end medical devices. In this context, this study analyses the recently adopted Medical Device Rules, 2017, in India in the light of the WHO Model Regulations to examine how far the standards and performance requirements stipulated under Medical Device Rules, 2017, conform with international standards. The study will also review the regulations in the United States of America and the European Union to make a comparative analysis of the laws and will suggest amendments, if any, to the Medical Device Rules, 2017.

***Keywords****: Medical devices, Post-market surveillance, Adverse event reporting, Digital health solutions, WHO Model Regulations, Regulatory changes, International standards*



∗ Associate Professor, Department of Law, Central University of Kerala, Kerala.

## I. Introduction

MEDICAL DEVICES are instruments used by medical professionals to diagnose, treat, monitor, alleviate diseases or support or modify a physiological process. Medical devices are quintessential for modern evidence-based medical practice. The quality and performance of medical devices deeply affect the quality of medical diagnosis and treatment. On the other hand, medical devices that do not conform to manufacturing and safety standards are detrimental to the health and safety of patients and users. Thus, countries have devised various measures to ensure the quality and safety of medical devices. The earliest attempt was made in the United States in 1936 by establishing the Food and Drug Administration.

Later in 1976, legal regulations for medical devices were introduced in the United States by amending the Federal Food, Drug and Cosmetic Act, 1938. Later, other countries also developed their regulatory norms for medical devices. Due to the divergence of regulatory norms adopted by various countries, a Global Harmonisation Task Force (GHTF) was constituted. The GHTF started to function in 1992 with the representatives of five founding members to harmonise the regulations on medical devices.[1] The successor to GHTE is the International Medical Device Regulatory Forum (IMDRF), born in 2011 when representatives from the medical device regulatory authorities of Australia, Brazil, Canada, China, Japan, the European Union, and the United States, as well as the World Health Organization (WHO), met in Ottawa.[2]

Consequent to the efforts taken at the international level to harmonise the norms for regulating medical devices, the WHO Global Model Regulatory Framework for Medical Devices Including *in vitro* Diagnostic Medical Devices, 2017 (WHO Model Regulation, 2017) was introduced to enable the WHO state parties to adopt a uniform regulatory framework for medical devices.[3] In parity with international regulations, India introduced the Medical Devices Rules in 2017 with stringent regulatory norms for the manufacturing and sale of medical

[1] Global Harmonisation Task Force, *available at:* https://web.archive.org/web/20061006200045/http://www.ghtf.org/index.html (last visited on December 20, 2021).
[2] International Medical Device Regulatory Forum, *available at:* https://www.imdrf.org/about (last visited on December 21, 2021).
[3] Medical Devices: WHO Response, *available at*: https://www.who.int/health-topics/medical-devices#tab= tab_2 (last visited on December 29, 2021).

devices. Though the Medical Devices Rules 2017 launched a new regulatory paradigm, some flaws are visible when it is compared with international standards.

Thus, this study strives to analyse the Medical Device Rules, 2017 against the backdrop of the WHO Model Framework. The study also makes a comparative study of regulations in the US and EU for ensuring the quality, safety, and performance of medical devices. The study limits its scope to regulations that are in force to ensure the quality and performance of medical devices. Laws relating to imports, exports, IPR rights, clinical research, and taxation are not within the purview of this research paper.

## II. Growth of the Global Medical Device Industry

The availability and accessibility of essential drugs and medical devices are the hallmarks of sound healthcare systems. Due to the increased demand and use of medical devices and the advancement in medical and communication technologies, the medical devices industry has grown and diversified substantially over these years. The medical device industry includes establishments manufacturing simple band-aids to sophisticated surgical robots. It integrates various industrial segments and medical technologies, including nanomedicine, nuclear medicine, digital medical technologies, etc. Different regulatory norms exist in different jurisdictions for minimising the adverse impact of medical devices. The diversity in industrial standards and regulatory norms in other countries are the major hurdles in expanding the medical device industry.[4]

The growth of the global device industry was USD 432.23 billion in 2020.[5] Though the market declined by 3.7 per cent in 2020, it was predicted to grow from USD 455.34 billion in 2021 to USD 657.98 billion in 2028.[6] Among the global medical-industrial players, the United States remains the largest medical device market globally, accounting for 40 per cent of the total

[4] Medical Devices Market - Opportunities And Strategies – Global Forecast To 2030, *available at:* https://www.globenewswire.com/news-release/2020/10/27/2114984/0/en/Global-Medical-Device-Market-2020-Size-To-Increase-Due-To-Rising-Infectious-And-Chronic-Disease-Cases-As-Per-The-Business-Research-Company-s-Medical-Devices-Global-Market-Opportuni.html (last visited on December 15, 2021).
[5] Medical Devices Market Size, Share and COVID Impact Analysis, *available at:* https://www.fortunebusinessinsights.com/industry-reports/medical-devices-market-100085 (last visited on December 18, 2021).
[6] *Ibid.*

global medical device market.[7] Germany, France and China are other global leaders in the medical device industry. The rapid growth of the medical device industry is attributed to many factors, such as the growth of healthcare facilities, the increasing number of elderly populations, technological innovations and increased health expenditure.[8] The outbreak of the COVID-19 pandemic was a major driving force in increasing the demand for hospital supplies and respiratory care devices in affected regions.[9]

The major market segments are *in vitro* diagnostic devices (IVD), cardiology, orthopedic, diagnostic imaging, endoscopy, ophthalmology and diabetic care devices. Of these segments, the *in-vitro* diagnostic devices account for the largest share, at 17.1 per cent.[10] The convergence of medical and digital technologies has led to innovation and investment in new medical products and technologies intended to support telemedicine services and the digitalisation of healthcare services[11]. Devices that can be used for home-based care and devices that can be operated with limited professional assistance, including remote patient monitoring devices, are fast-moving medical devices nowadays in the market.

## III. Indian Medical Device Industry: An Overview

With the introduction of industrial liberalisation policies during the 1990s, the Indian healthcare industry grew sporadically. India is the fourth largest medical device market in the Asia Pacific Region and holds the 20$^{th}$ position globally.[12] The Indian market is valued at USD 5.2 Billion and is growing at a 15.8 per cent compound annual growth rate.[13] It is predicted to grow to USD 50 billion industry by 2025.[14] Though the Indian medical industry is emerging as a leading medical device market, it still holds import dependency, ranging from 75-80 per cent. India had a total export of USD 2.1 billion in 2019.[15] Gujarat, Maharashtra, Karnataka, Haryana, Andhra Pradesh, Telangana and Tamil Nadu are the manufacturing hubs for medical

[7] Medical Technology Spotlight, SELECTUSA, *available at:* https://www.selectusa.gov/medical-technology-industry-united-states (last visited on December 18, 2021).
[8] *Supra* note 4.
[9] *Ibid.*
[10] *Ibid.*
[11] FICCI & Deloitte, *Indian Medical Electronics Industry: Outlook 2020*, 26 (2011).
[12] Nishith Desai Associates, "The Indian Medical Device Industry: Regulatory, Legal and Tax Overview" 1 (March, 2020).
[13] *Ibid.*
[14] Indian Band Equity Foundation (IBEF), "Medical Devices" 3 (November, 2021).
[15] *Ibid.*

devices in India.[16] Due to the reduced number of indigenous manufacturers, nearly 40 global device companies have a presence in India, with a share of 50 to 90 per cent of the medical device industry in India.[17] Most multinational companies have no houses in India, and they only primarily import devices.[18]

The Indian medical device industry is influenced by various factors such as public-private health expenditure, the country's GDP, disease patterns, demand for different treatment options, regulatory environment, taxation and reimbursement options.[19] Imports presently meet 75 per cent of the need for medical devices. This leads to a mismatch in the design and use of some medical devices as India's healthcare structure and clinical conditions differ. To encourage the indigenous medical device industry, the Government introduced various schemes such as 'Production Linked Incentives (PLI) Schemes for Medical Devices' in 2020.[20]

The Government is also trying to set up a Centre of Excellence (CoE) in collaboration with the Indian Council of Medical Research (ICMR) and the Indian Institutes of Technology (IITs). The 100% in Foreign Direct Investment (FDI) is also intended to ensure the participation of multinational companies in the Indian medical device industry.[21] The Government also launched Medical Device Parks in states like Delhi, Himachal Pradesh and Uttar Pradesh.[22] Above all, a National Medical Devices Promotion Council to promote local manufacturing of high-end medical devices was also established in 2020.[23]

India was an active player in the medical device industry but lacked a proper regulatory framework and was largely unregulated until 2017. The lack of a robust regulatory structure hampered the growth of the indigenous device industry, which, on the other hand, proved beneficial to international manufacturers. Industrial regulations are necessary to ensure product safety and quality and to fix liability. It also affects our nation's economy by reducing the demand for products manufactured under less regulatory supervision.

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[16] *Ibid.*
[17] Deloitte & NATHEALTH, *Medical Devices Making in India-A Leap for Indian Healthcare* 6 (March, 2016).
[18] *Ibid.*
[19] Infosys, "Indian Medical Industry – Current State and Opportunities for Growth" 4 (2018).
[20] Guidelines for the Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices, Ministry of Chemicals and Fertilizers, October 29, 2020, *available at:* https://plimedicaldevices.ifciltd.com/docs/Guidelines_Medical%20Devices.pdf (last visited on January 10, 2022)
[21] *Supra* note 14.
[22] *Ibid.*
[23] *Ibid*.

## IV. Medical Device Adverse Event and need for Regulation

Innovation and research have led to the introduction of several life-saving and enhancing medical devices. However, reports and studies have unveiled the adverse events of medical devices on the flip side. Medical device adverse events are unexpected events occurring during or after the use of medical devices. It may result in permanent impairment, injury or even death.[24] Such adverse events are reported in all jurisdictions, including in the US, where a robust regulatory regime exists. The main reason for this is the outdated or lack of evaluation procedures to ensure the safety of medical devices. 'The Implant Files', a project sponsored by the International Consortium of Investigative Journalism with the support of 250 journalists in 36 countries, reveals the database of 12000 medical device recalls due to safety and security issues.[25] In 2018, it was reported that adverse medical events caused 83000 deaths and 1.7 million injuries globally.[26] Since 1968, the FDA has received more than 16 million reports of adverse events in the US. In 2018, the FDA identified that 9 million reports were of a serious nature of the total reports received.

In contrast to the US, the adverse event reports in India before 2018 were nil due to a lack of a regulatory mechanism for medical devices. Also, the patients in India were not aware of the adverse events of the medical device. However, the Johnson & Johnson (DePuy) hip implant recall was an eye-opening incident. Nearly 100000 patients from different parts of the world were implanted with the device (DePuy ASR) developed by the subsidiary of J&J.[27] Around 4600 patients from India were also implanted with the device.[28] The health authorities had to initiate a criminal investigation against them as they did not respond to repeated requests to recall defective devices. The regulatory authority (CDSCO) also issued a recall of DePuy ASR and directed all medical professionals to abstain from ASR hip replacements.[29] Thus, a proper regulatory mechanism was sorely needed to ensure the safety and security of patients and to

[24] Chiho Yoon, Ki Chang Nam, *et. al*., "Differences in Perspectives of Medical Device Adverse Events: Observational Results in Training Program Using Virtual Cases" 34 *J Korean Med Sci*. 2 (2019).
[25] International Medical Device Database, *available at*: https://medicaldevices.icij.org/ (last visited on December 18, 2021).
[26] Pat Anson, Faulty Medical Devices Blamed for Thousands of Deaths, *available at:* https://www.painnewsnetwork.org/stories/2018/11/26/faulty-medical-devices-blamed-for-thousands-of-deaths (last visited on December 10, 2021).
[27] Peter Cronau, India Issues Recall, Commences Criminal Investigation into Defective ASR Hip Implant, *available at:* https://www.abc.net.au/news/2014-05-26/4pm-publication-embargo3a-four-corners-hip-replacement-story-u/5478424?nw=0&r=Interactive (last visited on January 10, 2022).
[28] *Ibid.*
[29] *Ibid.*

effectively implement the recall of defective medical devices without delay. Consequent to such incidents, India introduced a materiovigilance programme and a new regulatory regime for medical devices.

## V. Regulation of Medical Devices: An exploration of the Indian Legal Landscape in comparison with WHO Guidelines

Concerning medical devices, regulations are imperative at various levels, including quality assurance, performance, sale, exporting, importing, taxing and price fixation. India had no specific legislative framework for regulating medical devices, though a definition for medical devices was included in the definition of drugs provided in section 3(b) (iv) of the Drugs and Cosmetics Act, 1940. However, early in 2005, the manufacturing of medical devices was brought under the Central Licensing Approving Authority. It notified ten medical devices to be considered as drugs in 2005 and later, in 2009, included 19 more medical devices in the list.[30] And in 2006, the Department of Science and Technology drafted a Medical Device Regulation Bill with a proposal to establish a Central Drug Authority.[31] On the other hand, the Ministry of Health and Family Welfare proposed the Drugs and Cosmetics Amendment Bill.[32] However, these draft Bills lapsed, and Schedule M -III was adopted to regulate the quality standards of notified medical devices under the Drugs and Cosmetic Rules, 1945.[33]

Realising the need to regulate the medical device industry, the National Health Policy 2017 recommended adopting sustainable measures to ensure the availability, affordability and regulation of medical devices. To ensure the availability of medical devices, it proposed encouraging and incentivising the local manufacturers to provide customized indigenous medical devices under the 'Make in India' programme. It also recommended adopting a price control mechanism for essential diagnostics and equipment similar to the National List of Essential Medicines (NLEM). More importantly, it proposed strengthening the regulation of medical devices and establishing a regulatory body to maintain the innovation and entrepreneurial spirit of the medical device industry by harmonising the domestic regulatory

[30] Pooja Gupta, Manthan D Janodia, *et. al*, "Medical device vigilance systems: India, US, UK, and Australia", 3 *Med Devices* 67-79 (2010), *available at:* https://www.academia.edu/4426547/Medical_device_vigilance_systems_India_ US_UK_ and_Australia (last visited on January 15, 2022).
[31] Updates on the Medical Device Regulations in India, *available at:* https://www.pacificbridgemedical.com/publication/updates-on-the-medical-device-regulations-in-india/ (last visited on December 15, 2021).
[32] *Ibid*.
[33] *Ibid.*

standards with the international norms for medical devices. The post-market surveillance and measures for preventing adverse effects of medical devices are also suggested in the policy. In 2017, India adopted the Medical Devices Rules, a watershed move by the Central Government, in tune with the international standards developed by the Global Harmonization Task Force (GHTF) and WHO Model Regulations 2017. Further, in 2019, NITI Aayog proposed a new Medical Devices (Safety, Effectiveness and Innovation) Bill. The Bill proposed an independent regulatory body for medical devices. However, the Bill hasn't come into force. As mentioned earlier, this research paper strives to make a comparative analysis of the WHO Guidelines and Medical Devices Rules, 2017, adopted in India at the first level in the following areas.

**Definition of Medical Devices**

The definition of medical devices differs according to the perspectives of the regulatory authority. WHO, in simple terms, defines a medical device as 'any instrument, apparatus, implement, machine, appliance, implant, and 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 a medical purpose'.[34] Since India lacked a specific legislative framework to regulate medical devices, the definition of the term medical device was vague and ambiguous. The definition of drugs under section 3(b) of the Drugs and Cosmetics Act originally incorporated medical devices as well. It defined drugs to include 'devices which are intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, including that are notified by the Central Government from time to time'.[35] However, the Medical Devices Rules, 2017 introduced a new definition for medical device, which means;

[34] Medical Devices, WHO, *available at:* https://www.who.int/health-topics/medical-devices#tab=tab_1 (last visited on December 29, 2021).

[35] The Drugs and Cosmetics Act, 1940 (Act 23 of 1930), section 3 (b) –
"drug" includes—(i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;

(ii) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of [vermin] or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;

(iii) all substances intended for use as components of a drug including empty gelatin capsules; and

(iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board;

(A) substances used for in vitro diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bags with or without anticoagulant covered under sub-clause (i),

(B) substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified in the Official Gazette under sub-clause (ii),

(C) devices that are notified from time to time under sub-clause (iv), of clause (b) of section 3 of the Drugs and Cosmetics (D&C) Act.[36]

The definition of the medical device is further elaborated and clarified by the latest notification issued in 2020. As per the notification drug under section 3(b) (iv) of the D & C Act include;

'All devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of ―

(i) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;

(ii) diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;

(iii) investigation, replacement or modification or support of the anatomy or of a physiological process;

(iv) supporting or sustaining life;

(v) disinfection of medical devices; and

(vi) control of conception.[37]

[36] The Medical Devices Rules, 2017, r. 3 (zb).

[37] Notification, Ministry of Health and Family Welfare, February 11, 2020, *available at:* https://thehealthmaster.com/wp-content/uploads/2020/02/S.O.-648E-dt-11-02-2020-Medical-Device-Definition-Instruments-apparatus-etc-are-drugs.pdf (last visited on January 15, 2022).

The notification was issued in tune with the definition proposed by GHTF[38] and as per the WHO Model Framework[39], it creates legal uncertainty. Because instead of introducing an amendment in the Medical Devices Rules, 2017, it elaborated the scheme of devices through the notification. Recently, the notification was challenged before the Delhi High Court and the court upheld its validity.[40] Thus, it is suggested that the definition clause of the Medical Devices Rules, 2017 be amended to ensure conformity with the WHO Model Framework.

**Classification of Medical Devices**

As per the records of the WHO, there are an estimated 2 million different kinds of medical devices in the world market, categorised into more than 7000 generic device groups.[41] For regulation, medical devices are classified on the basis of;[42]

a. the risk associated with medical devices,
b. the intended purpose of the medical device,
c. indication for the use of a medical device.

The Medical Device Rules 2017 generally followed the GHTF and the WHO Model Framework for the classification of medical devices. It classified medical devices based on potential harm associated with the use of medical devices. To classify medical devices other than IVDs (*in vitro* medical devices), the following rules shall be considered: whether the medical device;[43]

a. is life-supporting or sustaining;
b. is invasive and if so, to what extent and for how long;
c. incorporates medicinal products;
d. incorporates human or animal tissues or cells;
e. is an active medical device;
f. delivers medicinal products, energy or radiation;
g. could modify blood or other body fluids;
h. is used in combination with another medical device.

[38] Final Document, GHTF, *available at:* https://www.imdrf.org/documents/ghtf-final-documents (last visited on December 29, 2021).
[39] WHO Global Model Regulatory Framework for Medical Devices Including in vitro Diagnostic Medical Devices, 2017, at 8, *available at*: https://www.who.int/publications/i/item/9789241512350 (last visited on February 20, 2024).
[40] *The Surgical Manufactures and Traders Association* v. *Union of India*, 2023 SCC Online Del. 5443.
[41] *Supra* note 3.
[42] *Supra* note 34.
[43] *Supra* note 39 at 9.

For IVDs, the authority classifying medical devices shall consider the intended use, intended user, the importance of information for the diagnosis, screening, monitoring of disease and the impact of the test result on the individual/public health.[44]

In consonance with the WHO Model Framework, the Medical Device Rules, 2017, also in the First Schedule, listed the parameters to be followed by the Central Licensing Authority (Drug Controller General of India[45] ) while classifying the medical devices.[46] It also empowers the Drug Controller General of India to classify medical devices, including in vitro diagnostic medical devices, into four groups.

| Class of medical devices | Medical Devices Other than IVDs | IVDs |
|---|---|---|
| Class A | Low Risk | Low Risk |
| Class B | Low Moderate Risk | Low Moderate Risk |
| Class C | Moderate-High Risk | Moderate-High Risk |
| Class D | High Risk | High Risk |

**Legal Regulations and Quality Management Systems**

Legal regulations and quality management systems are primarily intended to ensure the safety and standards during the entire life span of a medical device. The life cycle of a medical device has seven phases, including conception and development; manufacture; packaging and labeling; advertising; sale; use, and disposal.[47] In all these seven stages of the life cycle of a product, the laws impose regulations in the interest of all stakeholders, such as manufacturers, vendors, and users. The manufacturers shall be bound to adhere to the regulations relating to conception and development, manufacture, packaging and labelling. Restrictions on advertisements and sales are intended to regulate the vendors. Though the users are beneficiaries, they are also bound to follow the essential guidelines relating to the use and disposal of medical devices.[48] The legal regulations mainly focus on pre-market review of the product, on - market and post-market surveillance. The pre-market review includes the first three stages of a product life cycle: conception and development, manufacture, packaging, and

[44] *Id*. at 10.
[45] *Supra* note 36, s.3(h).
[46] *Id.*, I Schedule, Part I & II.
[47] Medical Device Regulations: Global overview and guiding principles, *WHO*, 2003 at 5 & 6.
[48] *Id.* at p.7.

labelling. On-market regulations relate to advertisements and sales, and post-market rules ensure that medical devices remain safe and effective.[49] For the detailed analysis, the Medical Devices Rules, 2017, has been considered under three levels as mentioned below.

*Pre-market Regulations*

The Medical Device Rules, 2017, embodies specific regulations for licensing and registration of medical devices. As per the Medical Device Rules 2017, only notified medical devices had to be registered with the licensing authority. However, the Medical Devices (Amendment) Rules, 2020, mandatory registration extended to all medical devices.[50] The licensing authorities are functioning at the national (Central Licensing Authority) and state levels (State Licensing Authority). The Central Licensing Authority is empowered to govern matters relating to the manufacture of Class C and Class D medical devices and the import of all classes of medical devices. On the other hand, the State Licensing Authority can govern matters relating to the manufacture for, sale or distribution of Class A and Class B devices and the sale, stock, exhibit or distribution of all classes of medical devices.[51] For obtaining a license, the Rules 2017 mandate standards for ensuring the quality and safety of medical devices(non-sterile and non–measuring devices are excluded).[52]

The first stage for obtaining a license is to categorise the medical devices by the person intended for import, manufacture for sale or distribution, sale, stock, or exhibit in accordance with the guidelines issued by the Ministry of Health and Family Welfare (*hereinafter* referred as 'MoHFW'). The manufacturers always adhere to the essential principles of safety and performance of medical devices as prescribed by the MoHFW. The vital principles of safety and performance adopted on April 19 2018[53], in tune with the WHO Model Framework, provide for three types of standards;

[49] *Id.*, at p. 9.
[50] The Medical Devices (Amendment Rules), 2020, r.19A.
[51] *Supra* note 36, r. 8.
[52] The Medical Devices (Sixth Amendment) Rules, 2022, *available at:* https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTAwMzM= (last visited on February 20, 2024).
[53] Essential Principles for Safety and Performance of Medical Devices, *Ministry of Health and Family Welfare*, (April 2018), *available at:* https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/medical-device/Essentialprinciples.pdf (last visited on January 19, 2022).

a. Basic or Horizontal Standards[54]

b. Group or Semi-Horizontal Standards[55]

c. Product or Vertical Standards[56]

In addition, the medical devices shall conform to the Bureau of Indian Standards (BIS) or the standards prescribed by the MoHFW from time to time. In the absence of such measures for any specific medical device, such devices shall conform to the standards laid down by the International Organisation for Standardisation (ISO), the International Electro-Technical Commission (IEC), or any other pharmacopeial standards.[57] In the absence of all these standards, medical devices shall conform to the validated manufacturer's standards.

To ensure quality standards, the Medical Device Rules, 2017 provides for the accreditation of notified bodies[58], designated Medical Device Testing Officer[59] and Medical Device Officer[60] and the establishment of a Central Medical Device Testing Laboratory.[61] For licensing the manufacture of medical devices, the application shall be accompanied by an undertaking that the requirements of the Quality Management System specified in the fifth schedule have been complied with. For all classes of medical devices except the class A devices, the pre-manufacturing site audit/inspection by the notified body / Central Licensing Authority is required.[62]

For class A medical devices, the audit shall be completed within 120 days of the State Licensing Authority granting the licence.[63] While applying for the grant of a licence, the applicant shall ensure that the manufacturing activity is taking place under the supervision of a qualified staff

[54] Standards indicating fundamental concepts, principles and requirements with regard to the general safety and performance of all kinds of devices.
[55] Standards applicable to families of similar products and/or process.
[56] Safety and performance standards applicable to specific products and /or process.
[57] *Supra* note 36, r.7.
[58] *Id.*, r. 3 (zj) reads: "Notified Body" means a body corporate or other legal entity, registered under rule 13 as a body competent to carry out the audit of manufacturing site, assessment, and verification of specified category of medical devices for establishing conformity with standards.
[59] *Id.*, r. (zf) reads: "Medical Device Testing Officer" means an officer appointed or designated by the Central Government under sub-rule (1) of rule 18.
[60] *Id.*, r. (zd) reads: "Medical Device Officer" means an officer appointed or designated by the Central Government or the State Government, as the case may be, under sub-rule (2) of rule 18.
[61] *Id.*, r. (ze) reads: "medical devices testing laboratory" means any institute, organisation registered under sub-rule (3) of rule 83 for carrying out testing or evaluation of any medical device on behalf of a licensee for manufacture for sale.
See also *Id.*, r. 13, 18 & 19.
[62] *Id.*, r. 20 & 21.
[63] *Ibid.*

possessing the prescribed educational qualification. In addition, the manufacturer is responsible for complying with the duties of the licence holder specified under Rule 26. The licence is valid in perpetuity, and it may be suspended or cancelled by the State or Central Licensing Authority if the licence holder contravenes any of the provisions of the Act or Rules.

An authorised agent with a licence for manufacture for sale or distribution or wholesale licence or distribution shall apply to the Central Licensing Authority to import medical devices. The Central Licensing Authority may grant permission if they have confirmed that the quality of the product is not compromised. The Rules also empower the Central Licensing Authority to oversee manufacturing site inspections.[64] The licence granted will be valid in perpetuity, and the Central Licensing Authority may revoke it on the same grounds for revocation of licence of manufacturers.[65] The licence holder is also duty-bound to comply with the duties and responsibilities prescribed under Rule 38.

Labelling of medical devices is another essential part of pre-market regulations. As per the Medical Device Rules, 2017, from January 1, 2022, a medical device approved for manufacture for, sale, distribution, or import shall have a unique identification number consisting of a device identifier and production identifier.[66] In addition to this, on the outer cover of each medical device, the following details shall be printed in indelible ink;[67]

i. Name and other details necessary to identify the device and its use.
ii. Name and address of the manufacturer and manufacturing premise and the manufacturing licence number;
iii. Correct statement about the net quantity, measure, volume, number of units etc.
iv. Manufacturing month and years and date of expiry,
v. Indicate whether the device contains medicinal or biological substances,
vi. Distinctive batch number or lot number shall be provided,
vii. Indicate proper way of storing and handling conditions,

[64] *Id.,* r. 35.
[65] *Id.,* r. 37.
[66] *Id.*, r. 46. (i) reads: "device identifier" means a global trade item number.
(ii) "production identifier" means a serial number, lot or batch number, software as a medical device version, manufacturing and or expiration date.
[67] *Id.,* r. 44.

viii. Indicate if the device is supplied as a sterile product, its sterile state and the sterilisation method;

ix. Give warnings or precautions to draw the attention of the user of the medical device;

x. label the device appropriately if the device is intended for single use;

xi. Print specifically 'Physician's Sample—Not to be sold', if a medical device is intended for distribution to the medical professional as a free sample;

xii. In the case of imported devices, the import licence number, name and address of the importer, address of the actual manufacturing premises and the date of manufacture;

In comparison with the WHO Model Framework, it can be seen that the Medical Device Rules, 2017, are in parity with the standards prescribed under the WHO Model Framework for ensuring the quality standards of medical devices in the pre-market regulatory phase.

*On Market Regulations*

The on-market regulations generally focus on advertisements and the sale of medical devices. The WHO Model Framework specifically provides that in addition to labelling regulations, national laws should have provisions to prohibit advertisements and promotions of medical devices.[68] Such regulatory measures should ensure that medical device promotion;

i. does not target inappropriate audiences;

ii. makes only claims that are supported by evidence;

iii. covers only medical devices that have been authorised for marketing;

iv. is consistent with indications for use and other information in the product labelling;

v. does not make false or misleading claims.

On a basic comparison with the WHO Model Framework, provisions for regulating promotions and advertisements of medical devices are absent in the Medical Device Rules, 2017. In relation to the sale of medical devices, there is a separate chapter under the Medical Device Rules, 2017. Instead of adopting separate rules for the sale of medical devices, it provides that Part VI of the Drugs and Cosmetics Rules 1945 will also apply to the sale of medical devices

[68] *Supra* note 39 at 27.

(a separate scheme has been introduced to grant registration for sellers who are not covered under the Drugs and Cosmetic Rules).[69] As per the Drugs and Cosmetics Rules, medical shops must obtain a licence from the State Licensing Authority, which will be valid for five years.[70] This is not in tune with the perpetual validity of the licence provided under the Medical Device Rules, 2017. In addition to that, drugs can be dispensed under the supervision of a qualified pharmacist[71]. No separate qualification is prescribed for selling medical devices under the Medical Device Rules 2017. Hence, it may be assumed that pharmacists are qualified to sell even medical devices, which is against the spirit of the Medical Device Rules 2017. Also, it is essential to note that for devices included in class C and D groups, no specific conditions are laid down for sale in the Rules as in the case of drugs.[72]

*Post-Market Surveillance or Vigilance*

The safety and performance of medical devices in use are the objectives of post-market surveillance. The Pre-Market regulations may not effectively identify failures or incidents of device misuse.[73] Hence, post-market studies and surveillance are mandatory to prove the efficiency and performance of the medical device. Post-market surveillance is a broad term that essentially includes post-market surveillance studies and adverse events reporting.[74] The policies or regulations on post-market vigilance shall ensure the following;

i. implant registration: facilitates notifying the patient of pertinent post-implant information;

ii. distribution record: for complete and rapid removal of devices in case of problems;

iii. recall procedures: in case of device recall, the procedures are in place and can be implemented;

iv. mandatory reporting: reporting of any adverse events of devices in use

v. complaint handling: procedures and records of reported problems relating to safety or performance.

[69] The Medical Devices (Amendment) Rules, 2020, *available at:* cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTI2OA== (Last visited February 20, 2024).
[70] The Drugs and Cosmetics Rules, 1945, r. 59 and 63.
[71] *Id.*, r. 65.
[72] *Ibid.*
[73] *Supra* note 39 at 13.
[74] *Ibid.*

The Medical Device Rules, 2017 provides for product recall, and it directs the manufacturers or authorised agents to mandatorily report adverse events to the competent authority in all cases the manufacturer or the authorised agent considers or has reason to believe that the medical device may cause a threat to the health of the patients. In such cases, they must adopt measures to recall such devices, associate with competent authorities, and take steps to prevent any risk to the patients due to the failure of medical devices.[75] It also directs the manufacturers to adopt a quality policy, auditing, corrective or preventive actions and management review to ensure the continued suitability and effectiveness of the medical devices.[76]

The manufacturers shall also maintain the records of all consumer complaint investigations, notify adverse events and take appropriate actions to eliminate the causes of nonconformities to prevent or correct recurrence.[77] On approval of investigational medical devices, Periodic Safety Update Reports (PSUPs) shall be submitted every six months for two years and then be presented annually.[78] In contrast to the WHO Model Framework, the Medical Device Rules 2017 have no provision to enable patients and users to report adverse events to the competent authorities. Also, it lacks a proper system for handling complaints regarding failures or adverse incidents of any medical device.

## VI. Regulatory regime of Medical Devices: A Comparative Analysis of USA and European Union Regulations

Countries across the globe have adopted regulatory standards for ensuring the quality, performance, and patient safety of the medical device. However, diverging standards exist for classification, licensing, quality management, market vigilance, etc. Due to the relentless efforts made by GHTF and the present IMDRF, countries are attempting to codify their regulations following the WHO Guidelines and IMDRF Recommendations. Hence, this research paper aims to analyse regulatory perspectives in the US and EU to examine the effectiveness of Rules 2017 and to suggest progressive regulatory measures to be introduced in India.

[75] *Supra* note 36, r. 89.
[76] *Id.*, Schedule V.
[77] *Ibid.*
[78] *Id.*, Schedule VII.

**United States**

The Food and Drug Administration (FDA), established in 1906, was the oldest consumer protection agency in the United States to protect and promote the development of drugs, biological products, medical devices, food and cosmetics.[79] In 1982, the Centre of Devices and Radiological Health (CDRH) was constituted to regulate medical devices and radiation-emitting devices.[80] A committee chaired by Theodore Cooper (Cooper Committee) in 1970 recommended new legislation specifically to regulate medical devices and classify medical devices on the basis of risk.[81]

To maintain the regulatory environment of medical devices, including *in-vitro* diagnostic medical devices, various legislations have been adopted since 1976, such as the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, 1976, the Safe Medical Devices Act, 1990, the Mammography Quality Standards Act, 1992, Food and Drugs Modernization Act, 1997, the Medical Device User Fee and Modernization Act, 2002, the Food and Drug Administration Amendments Act, 2007, the Food and Drug Administration Safety and Innovation Act, 2012, the 21st Century Cures Act, 2016 and the Food and Drug Administration Reauthorization Act, 2017.

In the United States, the regulations on medical devices are enforced by FDA and CDRH. As per the FD & C Act, 1938 amended in 1976, medical devices means 'an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or is intended to affect the structure or any function of the body of man or other animals'.[82] The FDA has classified 1700 different generic medical devices into 16 specialities, commonly called panels.[83] For regulatory purposes, all such devices are brought under three broad classes on the basis of the risk involved. The spectrum of device classification is as follows.[84];

[79] A History of Medical Device Regulation & Oversight in the United States, *available at:* https://www. fda.gov /medical-devices/overview-device-regulation/history-medical-device-regulation-oversight-united-states (last visited on January 10, 2022).
[80] *Ibid.*
[81] *Ibid.*
[82] The Food Drug and Cosmetics Act, 1938, s.201 (h).
[83] Classify Your Medical Device, *available at:* https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device (last visited on January 10, 2022).
[84] The Medical Device Amendment Act, 1976, s. 513.

a. Class I – Low to moderate risk device,
b. Class II – Moderate to high-risk devices,
c. Class III – High-risk devices.

FDA follows regulations at two levels to ensure the safety and quality of medical devices. It provides for the establishment of a registration and approval system for medical devices. FDA regulations mandate annual registration of all establishments, including foreign establishments engaged in manufacturing, producing, importing, reprocessing, and relabeling medical devices. They shall register with the Secretary annually.[85] Such establishments shall also list the medical devices manufactured there or other activities performed over such devices.[86] This is known as the listing of medical devices.

In addition to this, the producers of medical devices shall adhere to the quality control measures adopted by the FDA. For the Class I medical devices, the general control is applicable.[87] This includes regulations for adulterated, misbranded or banned medical devices, remedies in cases of product failures, unique identification numbers, product tracing, adverse event reporting, Good Manufacturing Practices, etc.[88] Similarly, general and special controls will be applicable for Class II devices. Special controls are device-specific and include standards for performance, post-market surveillance, patient registries, special labelling requirements, etc.[89] For Class III medical devices, Pre-market Approval (PMA) is essential. PMA ensures the safety of the product on the basis of scientific evidence.[90]

To ensure quality and performance, the 21 Code of Federal Regulations (CFR) Part 820 lays down device quality system regulations in fifteen sub-parts, including quality system requirement, design control, document control, purchasing control, identification and traceability, production and process control, labelling and packing control, handling, storage,

[85] The Food and Drug Administration Amendments Act, 2007, s.222.
[86] Device Registration and Listing, *available at:* https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing (last visited on January 10, 2022).
[87] Regulatory Controls, *available at:* https://www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls#gen (last visited on January 10, 2022).
[88] *Ibid*.
[89] *Ibid.*
[90] PMA Approvals, *available at:* https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals (last visited on January 10, 2022).

distribution, installation etc.[91] The quality requirements under CFR are similar to that of ISO 13485.[92] Medical devices that do not comply with the CFR will be considered adulterated. Also, the regulations empower the FDA to ban unsafe medical devices that have substantial deception or risk of illness or injury.[93]

Regulations also provide adequate measures for Post – Market Vigilance. The manufacturers, importers and distributors shall maintain records and prepare reports to prove that the device is not adulterated or misbranded and to ensure the safety and effectiveness of such medical devices. They are also responsible for providing this information to the Secretary as and when required.[94] The Code of Federal Regulations (CFR) also mandates reporting adverse events of medical devices. As per CFR, the manufacturers, importers and device user facilities can report deaths and serious injuries caused by devices they manufactured or imported.

They must also maintain the adverse events files.[95] The user facility may also report unexpected side effects, adverse events, quality issues, etc., through the MedWatch online portal.[96] MedWatch online reporting system is a voluntary online reporting facility available for medical professionals, consumers, and patients. Another major initiative is the Voluntary Malfunction Summary Reporting (VMSR) program, which was established in 2018 as per S. 227 of the Food and Drug Administration Amendments Act of 2007 to permit manufacturers to report specific device malfunctioning.[97]

Medical Device Recall is another mechanism to ensure the safety and efficiency of medical devices. The recall is a method to correct or remove medical devices that violate laws and cause a risk to the health of people.[98] Manufacturers or importers can voluntarily recall their medical

[91] 21 Code of Federal Regulation, Part 820, *available at*: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820 (last visited on January 10, 2022).
[92] Quality System (QS) Regulation/Medical Device Good Manufacturing Practices, *available at:* https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-system-qs-regulationmedical-device-good-manufacturing-practices (last visited on January 10, 2022).
[93] *Supra* note 84, s.516
[94] *Id.*, s. 519.
[95] *Id.*, Part 803.1
[96] Med Watch Online Voluntary Reporting Form, *available at*: https://www.accessdata.fda.gov/scripts/medwatch/ (last visited on January 11, 2022).
[97] Medical Device Reporting (MDR): How to Report Medical Device Problems, *available at*: https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems (last visited on January 11, 2022).
[98] Recalls, Corrections and Removals (Devices), *available at:* https://www.fda.gov/medical-devices/postmarket-requirements-devices/recalls-corrections-and-removals-devices (last visited on January 12, 2022).

devices.[99] In cases where the importers or manufacturers fail to recall their medical devices, the FDA may issue a recall order to the manufacturer. The CFR directs the manufacturers and importers to report to the FDA that any device correction or removal is initiated to reduce the risk to health. Reporting shall be made within ten days of initiating such correction or removal.[100] Also, in cases where devices are introduced for commercial distribution and present an unreasonable risk of substantial harm to the public, the Secretary may issue an order to the manufacturers, importers or distributors to submit an action plan for the repair or replace medical devices or refund the purchase price of the device.[101]

**European Union**

The EU Medical Device Directive – MDD - (Directive 93/42/EEC) was adopted in 1993 to harmonise the laws and standards relating to medical devices and ensure safety standards and security. The In Vitro Diagnostic Medical Device Directive -IVDD-(98/79/EC) regulated the access and use of in-vitro medical devices. The MDD was reviewed in 2007, and compliance with the new Directive became mandatory in 2010.[102] Nevertheless, two new regulations were adopted, the Medical Device Regulation (MDR) 2017/745 and In Vitro Diagnostic Medical Device Regulation (IVDR) 2017/746, on May 25, 2017, to replace the Directives for medical devices and in-vitro medical devices. Due to the unexpected situation that arose inconsequent to the COVID-19 pandemic, the period for adopting the MDR was extended to May 26, 2021.[103] Similarly, the IVDR is to come into force from 2022. The Medical Device Regulation, 2017 will only be analysed for this study.

Medical Device Regulation is to be implemented at the state level, and the European Medicines Agency (EMA) is the central agency involved in the regulatory process to oversee conformity with the Regulations of the EU.[104] The new EU-MDR is intended to provide an all-inclusive legislative framework to supervise the manufacturers, authorised representatives, distributors

[99] *Supra* note 92, Part 7.
[100] *Id.*, CFR 806.
[101] *Supra* note 85, s.518(b).
[102] Kristina Zvonar Brkic, Infographic: EU MDR vs. MDD – What has changed?, *available at:* https://advisera.com/13485academy/blog/2020/11/24/infographic-eu-mdr-vs-mdd-what-has-changed/#:~:text=The%20Medical%20Device%20Directive%20%28MDD%29%20was%20first%20published,been%20continuously%20updated%20during%20this%20almost%2030%20years (last visited on January 12, 2022).
[103] Regulation (EU) 2020/561 amending Regulation (EU) 2017/745, *available at:* https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2020.130.01.0018.01.ENG (last visited on January 12, 2022).
[104] Medical Devices, *available at:* https://www.ema.europa.eu/en/human-regulatory/overview/medical-devices (last visited on January 12, 2022).

or importers of medical devices and ensure the quality, safety and performance of medical devices. EU-MDR gives a broad definition for medical devices to include some of the non-medical products and is identical to the definition put forward by the GHTF. As per EU-MDR, medical device means[105] 'any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

> a. diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;
>
> b. diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability;
>
> c. investigation, replacement or modification of the anatomy or of a physiological or pathological process or state;
>
> d. providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations;
>
> e. devices for the control or support of conception;
>
> f. products specifically intended for the cleaning, disinfection or sterilisation of devices'.

For the effective regulation of medical devices, EU-MDR provides a four-level classification similar to India and the WHO Model Framework. It includes Class I, Class IIa, Class IIb, and Class III.[106] The Rules adopted under Annex VIII provide a detailed explanation for the classification of medical devices into four groups based on the nature of the product, the risk involved and intended use.[107] All medical devices that fall under any of these four classes shall comply with the general safety and performance requirements.[108] Devices that conform with the requirements provided under the EU-MDR shall always bear the 'CE' marking of conformity.[109]

To ensure the quality and performance of medical devices, the EU-MDR envisages the registration of establishments and medical devices similar to those in the US. Manufacturers, authorised representatives and importers are duty-bound to register their establishments and

[105] Medical Device Regulation, 2017, art. 2.
[106] *Id.*, art. 51.
[107] *Id.*, annex VIII, chapter III, rules 1-22.
[108] *Id.*, art. 5.
[109] *Id.*, art.20.

adopt the conformity assessment. The competent authority will assign a Single Registration Number (*hereinafter* referred as 'SRN') upon completing the conformity assessment. For registration of medical devices, the manufacturers assign a Unique Device Identification (*hereinafter* referred as 'UDI') number at the first stage. UDI is primarily to identify and facilitate traceability of devices and to report adverse events.[110] After assigning the UDI, the manufacturer shall apply to the notified body for conformity assessment and provide all core data relating to the medical device as enlisted in Annex VI of the EU-MDR to the UDI database.[111] Then, they shall apply for a CE mark. The procedure mentioned above applies to all devices except Class I. A self-declaration of conformity, as prescribed in Annex II and III, is only required for Class I devices.[112]

The EU–MDR explicitly provides duties and responsibilities of manufacturers, authorised agents, importers, and distributors. As part of the quality assurance of medical devices, EU-MDR mandates that all manufacturing institutions shall have at least one person responsible for regulatory compliance possessing the required qualification mentioned in the EU-MDR.[113] Such officials will be responsible for ensuring that the products are manufactured in compliance with the quality management requirements, preparing technical documentation and EU declaration of conformity and post-market surveillance, etc.[114]

To enforce the quality requirement of medical devices, the notified bodies are empowered to conduct quality assessments. Such notified bodies will be monitored and supervised by authorities responsible for notified bodies. The conformity assessment procedure differs according to the nature and class of the medical devices, and the manufacturer shall follow the appropriate conformity assessment procedure provided in Annexes IX to XI of EU-MDR.[115]

EU-MDR lays down robust Post-Market Surveillance and Adverse Event Reporting. As part of the post-market surveillance, the manufacturer is responsible for preparing a plan for establishing, documenting, maintaining, and updating a post-market surveillance system.[116] It also directs the manufacturers of Class I devices to prepare a Post–Market Surveillance Report

[110] *Id.*, art. 27.
[111] *Id.*, Annex VI.
[112] *Id.*, art. 52.
[113] *Id.*, art. 15.
[114] *Ibid.*
[115] *Ibid*.
[116] *Id.*, art. 83 & 84.

and make it available to the competent authority on request.[117] The manufacturers are bound to prepare a Periodic Safety Update Report (*hereinafter* referred as 'PSUR'), summarising the results and conclusions of the analyses of the post-market surveillance data collected. Along with PSUR, the manufacturers shall also submit the preventive and corrective actions taken.[118] The manufacturers shall report any incidents of a serious nature to the competent authority within 15 days after the connection between the incident and the device is established. They shall report the field safety corrective action taken along with the report.

Though there is no specific provision enabling healthcare establishments and patients to report an adverse event, EU-MDR directs the member states to adopt appropriate measures to organise information campaigns, and encourage and help healthcare professionals, patients and users to report suspected severe incidents to the manufacturer without any delay.[119] In case reports of serious incidents are communicated to the manufacturers, they are duty-bound to initiate an investigation and must cooperate with the competent authority in this regard. The competent authority can intervene in the investigation if they find it necessary.[120]

Trend Reporting is another important feature. Trend Reporting is a mechanism to study and adopt corrective measures for statistically significant incidents that are not serious in nature. The manufacturer shall prepare the Trend Report along with specific actions to be adopted to manage such incidents.[121] EU-MDR directs the member states to develop an electronic system for collating and processing various aspects of post-market surveillance, including reporting of serious incidents, summary reports of manufacturers, trend reports, etc.[122] It also endorses market surveillance by competent authorities and directs member states to develop cooperation and sharing of information and harmonise the market surveillance system.[123] The market surveillance empowers the competent authorities to analyse the impact and implementation of quality management systems and to prepare and report their finding of inspections and compliance proceedings annually.[124]

[117] *Id.*, art. 85.
[118] *Id.*, art. 86.
[119] *Ibid.*
[120] *Id.*, art. 89.
[121] *Id.*, art. 88.
[122] *Id.*, art. 92.
[123] *Id.*, art. 93.
[124] *Ibid.*

The EU-MDR also adopted a specific procedure for dealing with devices causing risk to the health of patients or users. In cases where the competent authority finds that any medical device presents an unacceptable risk to the health and safety of patients or users, they may carry out an evaluation of devices with respect to all quality requirements.[125] They may take corrective action following the evaluation procedure, including withdrawing or recalling medical devices.[126] Another essential feature is the introduction of implant cards and patients' right to get information about the implanted device. The implant card will help the patient identify the device, device name, lot number, UDI, expected lifetime, safe use of the device, etc. In addition to quality management measures, EU-MDR gives importance to confidentiality and data protection of confidential information, details of inspections, investigations and audits.[127] It also directs the member states to devise a proper penalty regime that is proportional and effective.[128]

## VII. Understanding the missing links under the medical devices rules, 2017, in comparison with regulations in the USA and EU

The adoption of Medical Device Rules in 2017 in India was a laudable step taken by the Ministry of Health and Family Welfare by assimilating the necessary principles of medical device regulations enshrined under the WHO Model Framework and the recommendations of GHTF. Nevertheless, Medical Device Rules, 2017 lacks provisions to implement quality management systems effectively and adopt corrective measures for the safety of patients and users. Also, it failed to adopt a harmonised approach in tune with international standards. Following are the significant findings of the study.

### Definition of Medical Device and Nomenclature

In India, medical devices are treated as drugs, and it has been defined as part of drugs under the Drugs and Cosmetics Act, 1940. The Medical Devices Rules, 2017, further expanded the definition to include *in vitro* diagnostic medical devices, mechanical contraceptives, surgical dressings, disinfectants, notified medical devices etc. Later in the MoHW, the recent notification expanded the term medical devices given under section 3(b) of the D & C Act. The

[125] *Id.*, art. 95.
[126] *Ibid.*
[127] *Id.*, art. 109 & 110.
[128] *Id.*, art. 113.

definition provided in the notification is akin to the GHTF and WHO Model Framework. However, a definition given under a notification has no legal relevance and does not affect the statutory definition. Thus, in a legal context, though the definition provided in the notification is a universally accepted one, the new definition will remain only in the paper. Additionally, India being a global player and importer of medical devices, it is the need of the hour to adopt uniform nomenclature of medical devices that is globally applicable to reduce convolutions in applying quality standards and corrective measures. Hence, it suggested to incorporate the new definition by way of an amendment in the Rules, 2017 and adopting a globally relevant nomenclature.

**Registration of Medical Devices and Establishments**

For effective implementation of regulations on medical devices, it is imperative to require registration for both establishments and medical devices. The two-way registration procedure is envisaged under the WHO Model Framework and in the US and EU Regulations. Indian licensing schemes for establishments and devices are analogous to the two-way registration process in other countries. However, it is crucial to note that Medical Device Rules, 2017 introduced a perpetual licensing system for medical devices except for sale. The US has an annual registration process for establishments, and medical listing is adopted to register medical devices. The same procedure is adopted under EU-MDR. Though it will reduce the administrative burden, the perpetual medical device registration will dilute the quality management measures. Thus, adopting an appropriate registration method with a mandate for periodic renewal is essential.

**Medical Device Officers and Medical Device Testing Officers**

Medical Device Officers, Medical Device Testing Officers, and the Licensing Authority play a pivotal role in regulating medical devices in India. Nevertheless, a fundamental error slithered into the appointment of the Medical Device Officers and Medical Device Testing Officers. The Government Analyst and Inspector appointed under section 20 and 21 of the Drugs and Cosmetics Act, 1940 are designated as Medical Device Testing Officer and Medical Device Officer, respectively. Under Medical Device Rules, 2017, their duties include inspection of manufacturing units and testing the safety and performance of medical devices. Everyone knows that the qualifications and expertise required for drug and medical device testing are different. Additionally, the Medical Device Rules, 2018 does not provide any direction for

giving training to the officials. In this context, it is highly imperative to have Medical Device Officers and Medical Device Testing Officers of appropriate qualifications appointed exclusively to enforce medical device regulations to ensure medical device standards and performance requirements and the quality of establishments manufacturing medical devices.

**Unique Device Identification (UDI) and Right to Know of Patients and Users**

Nation-states across the globe are looking for harmonisation of standards for the regulation of medical devices and adopting UDI numbers that can be used at the global level. The Rules, 2017 also provides for adopting the UDI number, which is expected to be implemented from January 1, 2022. In contrast to the EU-MDR, there is nothing provided in the Rules, 2017 for implementing the UDI number system. The procedure for obtaining UDI is not delineated in the Rules. Thus, it shall be amended appropriately to include the implementation of the UDI numbering system and the process to be followed by the manufacturers of medical devices to obtain the UDI number. It is also important to note that the Rules, 2017 contains no provision to safeguard the right to know of patients or users of medical devices, especially implanted medical devices. Like EU-MDR, implant cards shall be made available to the patients, and their right to know about medical devices shall be specifically mentioned in the Rules, 2017.

**Wrong and Misleading Advertisements and Banning Unsafe Medical Devices**

Like Drugs, it is essential to prohibit misleading advertisements of medical devices in the market. However, there is no provision in the Medical Device Rules, 2017, to restrict and regulate advertisements of medical devices. Similarly, the Medical Device Rules, 2017 lacks provisions that empower the Licensing Authority to ban unsafe medical devices and present any risk to patients or users. As per the WHO Model Framework and in the US and EU, regulations specifically regulate advertisements and ban unsafe medical devices available in the market. Since regulations for medical devices have been introduced in India recently, there shall be a mechanism to assess the quality of medical devices available in the market and eliminate unsafe ones.

**Post Market Surveillance and Product Recall**

In the US and EU, the regulatory regime gives particular emphasis to post-market surveillance and product recall. Whereas, in India, the market surveillance measures are confined to reporting adverse events and adopting corrective actions by the manufacturers in the case of nonconformities or consumer complaints. The existing regulations are superficial, leading to

gross safety and performance standards violations and seriously affecting patients' health. Even after experiencing the difficulties of a product recall in connection with the DePuy hip implant in India, the policymakers gave the least importance to post-market surveillance and product recall measures.. Another major drawback of the existing system is that no enabling provision permits the patients or users to report adverse events to the competent authorities. Additionally, there is no clarity regarding the corrective steps to be taken by manufacturers, importers, and distributors. As per Schedule V to the Medical Device Rules, 2017, manufacturers must adopt various remedial measures.

However, as no specific corrective measures are listed in the Rules, thus there will not be a uniform implementation of these directions. The corrective actions, including provision for repair, replacement or reimbursement, are not even mentioned in the Medical Device Rules, 2017.Most importantly, under Medical Device Rules, 2017, no penalty is specified against violations. Also, it is essential to note that the Trend Reporting and Market Surveillance Studies provided under the EU-MDR are absent under Medical Device Rules, 2017. At this juncture, it is crucial to take note of the materiovigilance programme launched by the MoHW in 2015.[129] However, no efforts have been made to incorporate and coordinate the materiovigilance programme under the Medical Device Rules, 2017. In light of the high rate of medical device import, it is high time to adopt a proper post-market surveillance system and an efficient strategy for enforcing corrective measures in tune with international standards.

**Single-use and Refurbished Medical Devices**

Single-Use Medical Devices (*hereinafter* referred as 'SUMDs') are intended only for single use. Hence, they do not come with appropriate instructions for cleaning, disinfecting or sterilisation procedures. In exceptional situations, such SUMDs may be reprocessed and used repeatedly.[130] This may pose various health risks to the patients. In contrast to SUMDs, some medical devices will have a long life span. Such medical devices may be refurbished by an organisation other than the original manufacturer to extend their service life.[131] Refurbishing is a process to restore the safety and performance of devices comparable to their condition

[129] Launch of Materiovigilance Programme of India, *available at:* https://ipc.gov.in/mandates/pvpi/materiovigilance-programme-of-india-mvpi/8-category-en/432-launch-of-materiovigilance-programme-of-indiamvpi.html#:~:text=Materiovigilance%20Programme%20of%20India%20%28MvPI%29%20to%20monitor%20the,July%202015%20at%20IPC%2C%20Ghaziabad%20by%20DCG%20%28I%29 (last visited on January 20, 2022).
[130] *Supra* note 39, at 44.
[131] *Id.*, at 45.

when it was new.[132] The WHO Model Framework states explicitly that in both the above-mentioned situations, the state regulations shall ensure two things such as the label must convey that the device is reprocessed and refurbished or is a SUMD, and the entity responsible for refurbishing shall meet the same safety and performance requirements as in the case of original medical devices. Considering the Medical Device Rules, 2017, in the light of the WHO Model Framework, it can be seen that no provision exists to regulate such SUMDs or refurbished medical devices in India. Hence, it is imperative to incorporate rules to control such medical devices.[133]

**Substandard and Falsified Medical Devices**

Genuine manufacturing errors or deliberate falsification may lead to the availability of substandard or falsified medical devices in the market. To oversee the availability of such substandard medical devices in the market, the WHO Model Regulation suggest adopting an appropriate post-market vigilance mechanism and encouraging and enabling all users to report suspicious medical devices.[134] Unfortunately, the policymakers ignored the issues of substandard medical devices available in the Indian market, and no provision in Medical Device Rules, 2017 looks into this aspect. Thus, it is suggested that the rules be amended and proper mechanisms laid out to identify and eliminate substandard medical devices from the Indian market.

**Disposal Medical Devices**

Disposal of medical devices is equally essential as manufacturing medical devices. As in the case of the manufacture of medical devices, different standards need to be adopted for the disposal of medical devices. Thus, the regulations shall envisage a proper system for replacing, decommissioning or disposing of medical devices. With regard to the disposal of medical devices, the Biomedical Waste Management Rules, 2016 have only minimal application. It does not envisage the decommissioning of big medical devices. Also, India introduced the E-Waste (Management) Rules, 2022 to regulate the recycling and disposal of electronic and electrical equipment. However, considering the particular nature of medical devices, it is necessary to take appropriate steps to adopt a regulatory framework for the disposal of all types of medical devices.

[132] *Ibid.*
[133] *Ibid.*
[134] *Ibid.*

**Software as Medical Devices and Digital Medical Devices**

Medical device markets are flooded with technology-supported digital devices, including mobile health, connected devices, imaging devices, sensors, and wearable devices. For such devices, the IMDRF developed a definition for Software as Medical Devices (SaMD)[135] and a separate quality management system.[136] In India, though the notification issued by the MoHFW had included software in the definition of medical devices, a similar provision is lacking in the Drugs and Cosmetics Act and the Rules, 2017. Thus, it is high time to amend the definition of medical devices to include SaMD and digital devices. There shall also be a separate quality management system for digital devices.

## VIII. The Future Perspectives of Medical Devices Rules, 2017

Though the study pointed out some of the drawbacks of the Rules, 2017, it has the potential to provide a comprehensive approach to regulating the standards of medical devices. Also, Rules 2017 was a much-awaited piece of legislation for the following reasons.

a. It provides regulatory norms in conformity with international standards for various matters,
b. Adoption led to the launching of a single window clearance portal for medical devices,[137]
c. It imposes stringent measures, which helps to eliminate the substandard products from the market.
d. It also encourages the manufacturers to adopt technologies suitable for the Indian healthcare system.
e. Manufacturing standards comparable with international regulations facilitate the import and export of medical devices.

[135] Software as Medical Device (SaMD): Key Definitions, Final Document, IMDRF, 2013, *available at:* https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf (Last visited on January 16, 2022).
[136] Software as a Medical Device (SaMD): Application of Quality Management System, Final Document, IMDRF, 2015, *available at:* https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-151002-samd-qms.pdf (Last visited on January 16, 2016).
[137] National Single Window System, *available at*: https://www.nsws.gov.in/ (Last visited on February 21, 2024).

f. It will also help the indigenous market to develop affordable medical devices as envisaged in the National Medical Devices Policy, 2023.[138]
g. A robust regulatory framework will attract investors and, ultimately the growth of the Indian economy.

If the policymakers address the developments in medical device technologies and international regulations through timely amendments, the Medical Devices Rules, 2017 can go successfully for a long way in ensuring the availability of affordable and quality medical devices for the Indian healthcare system and can be a leading exporter of medical devices.

## IX. Conclusion

India is an emerging medical device market at the global level. Though India is an import-dependent country, the Government has taken various steps to encourage and facilitate manufacturers to produce indigenous products. This will help to reduce the dependence on imports and develop and design medical devices that are user-friendly as well. The indigenous production of high-end medical devices will also increase medical device exports and economic growth. To achieve this primary objective; it is imperative to have a proper regulatory system that is responsible, transparent, and sustainable to ensure the quality, efficiency, performance, and safety of the medical device. On this point, the Medical Devices Rules, 2017 is highly appreciated as India adopted a separate regulation exclusively for medical devices.

However, the study has identified various shortcomings that will undermine the essence of introducing the regulations for medical devices. The most important of them is adopting a proper definition of medical devices in light of the emerging digital medical devices. Apart from that, the proper strategy must be adopted to register medical devices and identify and track medical devices. For the effective implementation and enforcement of the Medical Device Rules, 2017, it is essential to have qualified Medical Device Officers and Medical Device Testing Officers appointed to conduct proper inspections and evaluations of standards to be followed. It is also quintessential to envisage robust post-market vigilance and reporting of adverse events. Additionally, the Licensing Authority shall be empowered to ban falsified

[138] The National Medical Devices Policy, 2023, adopted on May 2, 2023, *available at*: https://pharmaceuticals.gov.in/sites/default/files/Gazette%20Notification%20%20National%20Medical%20Devices%20Policy%202023.pdf (Last visited on February 21, 2024).

and substandard medical devices and to punish the manufacturers and distributors of such medical devices. Similarly, Medical Device Rules, 2017 must also incorporate regulations to ensure the safety and performance of single-use or refurbished medical devices. Along with it, the use of digital medical devices and SaMD are in vogue. Regulations governing SaMD are lacking under the new regulatory regime. Hence, in the backdrop of the findings of the study, it is highly recommended to revisit the Medical Device Rules, 2017 to ensure a proper regulatory regime for medical devices in India that is in tune with international standards.