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Examining India's New Medical Device Regulation in Light of the United States and the European Union Rules

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Introduction

Medical devices forms an integral part of healthcare sector and with each passing day, it continues to grow in importance, reaching new markets worldwide in this globalised world. The current global market for medical devices is estimated at USD 425.5. billion in 2018 and is expected to reach USD 612.7 billion by 2025 as, according to a report, it will grow at a CAGR of 5.4% from 2018-2025[1]. However, this rapid growth in medical device sector poses some predictable as well as unforeseen risks, which in some circumstances, may lead to immediate life-threatening consequences. In such conditions, regulation in this area of health and safety becomes significant for alleviation of risks not only for individuals but also for the society as a whole. Medical device regulation fits into the category of product safety regulation. For easier understanding, medical devices generally means the specific devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human being or animals and will also include surgical dressings, surgical bandages and surgical staples amongst other things. This definition of "medical device" essentially remains the same across different systems of the world with only a few minor differences.

In India, the first law that was enacted, though not directly relating to the aforementioned specific area, was the Drugs and Cosmetics Act, 1940. The primary goal of the Act is to make certain that the drugs and cosmetics sold in India are safe, effective and conform to the quality

[1] Medical Devices Market Size, Share and Industry Analysis by Type (Orthopaedic Devices, Cardiovascular Devices, Diagnostic Imaging, IVD, MIS, Wound Management, Diabetes Care, Ophthalmic Devices, Dental & Nephrology), End User (Hospitals & Ambulatory Surgical Centers and Clinics) and Regional Forecast, 2019-2025. (2020). *Medical Device/Medical Devices Market*. https://www.fortunebusinessinsights.com/industry-reports/medical-devices-market-100085.

standards as laid down in the Act. It was formulated in 1940 in pursuance of recommendations of Chopra Committee constituted in 1930 by Government of India. The drugs under this Act cover wide varieties of therapeutic substances, diagnosis and medical devices. Since, its enactment, several amendments took place in 1949, 1960, 1962, 1964, 1982, 1995, 2007, 2008 among others and most importantly, in 2008, namely, The Drugs and Cosmetics Amendment Act, 2008 which provides for deterrent penalties for manufacture of adulterated drugs and accordingly, inserted new Sections 17E (adulterated cosmetics) among others and amended Sections 18, 26A, 27, 27A, 28 and others. Along with this, guidelines were also issued for taking action on samples of drugs declared to be adulterated or not of standard quality in the light of the amended Act. Subsequently, a bill, namely, the Drugs and Cosmetics (Amendment) Bill, 2013 proposed to change the name of the Act to 'Drugs, Cosmetics and Medical Devices Act, 1940' and also, proposed changes in regulation of drugs, cosmetics and medical devices in all aspects but was withdrawn from Rajya Sabha on August 10th, 2016 on the ground that certain recently discovered new areas in medical field such as stem cells, medical devices and others could not be effectively regulated under law and further, decided to frame separate rules for regulating medical devices under the existing Act. Earlier, medical devices were covered within the ambit of the definition of drugs but this bill changes it by adding a definition of medical devices amongst other things. In the meanwhile, the Department of Health and Family Welfare proposed to introduce an amendment bill on the same in 2015 in the Budget Session of Parliament which aimed to amend the long title, Preamble, Section 1, among other things to include in its ambit medical devices. Later on, in 2017, another amendment in the Act was introduced Lok Sabha with a view to establish the Drugs and Cosmetics Price (Control, Regulate and Monitoring) Authority and likewise, in 2018 also, a bill was introduced with the intent of providence for establishment of an Accreditation Board, appointment of Registrar for keeping registry of clinical trials among other things.

Several amendments took place in Drugs and Cosmetics Rules, 1945 accordingly. Then, 'Medical Devices Rules, 2017' came into effect from January 1, 2018. It lays down a classification of medical devices along with a list of medical devices along with their risk class. In a notification dated 11th February, 2020, the Ministry of Health and Family Welfare (MoHFW), issued 'The Drugs and Cosmetics (Amendment) Rules, 2020' to amend the Drugs and Cosmetics Rules, 1945 which will be in force from 1st day of March, 2021 and it proposed to insert the definition of 'marketer' and provisions relating to marketing of drugs. Subsequently, 'Medical Devices (Amendment) Rules, 2020 (MDR) via a notification dated

February 11, 2020 came into force from April 1, 2020 which aimed at ensuring that medical devices meet certain standards of quality and efficacy and also included medical equipments used on humans or animals as "drugs" under Section 3 of the Act on the recommendation of the Drugs Technical Advisory Board (DTAB). Further, Chapter IIIA was introduced in it which expresses the requirement of mandatory registration of medical devices with the central licensing authority through an identified online portal established by the Central Drugs Standard Control Organisation (CDSCO) for this purpose. This chapter is applicable to all devices notified under clause (b) of Section 3 of the Act except the medical devices specified in the Annexure of Eighth Schedule of these rules i.e., it exempts 37 categories of medical devices which will remain unaffected by this amendment if they were regulated or notified before the date of this amendment i.e., February 11, 2020 and therefore, will not require registration. Although, exemption does not mean exemption from MDR itself. Rather, these devices and the entire supply chain will have to observe the compliances stipulated under MDR at all times. The work will present a detailed analysis of these new rules and their likely impact on various spheres like healthcare, economy, safety and others.

Besides India, there are several diverse international classification systems for medical device regulation. Even World Health Organisation has been working towards achieving harmonization in medical device regulation nomenclature. Likewise, United States and European Union have different systems for medical devices regulations. Their strengths and weaknesses of pre-approval and post-approval surveillance systems for medical devices have been hotly debated in the wake of safety concerns. The current work will use these settings to evaluate the regulations prevalent within these two regulatory frameworks. In addition to this, it will also analyse the flaws/shortcomings in their respective systems. Finally, the paper in toto, will attempt to present a comparative analysis against the backdrop of India.

Comparative Overview of Medical Device Regulatory Framework

Since medical devices are serving an increasingly pivotal role in clinical practice, improving the health of patients and quality of life. Thus, the regulation of medical devices becomes sine qua non for every country's scheme of management of risk and for ensuring safety, efficacy and effectiveness of medical devices.

- **United States**

Background:

Before World War II, there was no federal regulation to provide any assurance of the safety, efficacy, or quality of medical devices in US. The Pure Food and Drugs Act (also called the Federal Food and Drugs Act) did not include medical devices. But it established the precursor to the present-modern day "Food and Drug Administration (FDA)". In 1938, the Federal Food, Drug and Cosmetic Act (FD&C Act) became the primary statute that included medical devices and authorised FDA's regulation of the same[2]. However, it only required manufacturers of medical devices to notify FDA about placement of a product in the market and FDA was only able to assess a product's safety and effectiveness after it had been placed in the market. As a consequence, this statute proved to be ineffective. The same was true with drugs as well which led to the Drugs Amendments in 1962. As an outcome of these changes, drugs were not allowed into the market before approval from the FDA but it did not include medical devices.

Significantly, in 1970, President Nixon established the 'Cooper Committee' which was chaired by Theodore Cooper, M.D. (then Director of the National Heart and Lung Institute) to study the requirement of medical device legislation. It recommended a separate legislation that would specifically be targeted to medical devices as it poses different issues than drugs. Further, it also introduced the concept of risk-based classifications for medical devices. There was a growing public desire for more oversight over medical devices in 1960s and 1970s and consequently, Congress responded to it. Finally, in 1976, Medical Device Amendments (MDA) to the FD&C Act came into being. It intended to provide reasonable assurance of the safety and effectiveness of medical devices and created a three-class, risk-based classification system for all medical devices.[3] It also established the regulatory pathways for new medical devices, for example, devices that were not on the market prior to May 28, 1976, or had been significantly modified to get to market: Pre-market approval (PMA) and premarket notification (510(k)).[4] Most prominently, it also established several key post-market requirements: registration of establishments and listing of devices with the FDA, Good Manufacturing Practices (GMPs), and reporting of adverse events involving medical devices. It also

[2] Meritz, & White. (2008). Achieving medical device safety in an era of globalization. *Food and Drug Law Journal*, *63*(3), 647–655. https://doi.org/https://www.researchgate.net/publication/23495544_Achieving_medical_device_safety_in_an_era_of_globalization

[3] *A History of Medical Device Regulation and Oversight in the US*. (2019, June 24). A History of Medical Device Regulation & Oversight in the United States | FDA. Retrieved December 1, 2022, from https://www.fda.gov/medical-devices/overview-device-regulation/history-medical-device-regulation-oversight-united-states

[4] *A History of Medical Device Regulation and Oversight in the US*. (2019, June 24). A History of Medical Device Regulation & Oversight in the United States | FDA. Retrieved December 1, 2022, from https://www.fda.gov/medical-devices/overview-device-regulation/history-medical-device-regulation-oversight-united-states

empowered FDA to ban devices too. In 1977, the Bureau of Medical Devices and Diagnostic Products was renamed as the Bureau of Medical Devices.

In 1990, the Safe Medical Devices Act (SDMA) gave more power to FDA to actively control medical devices on the market. It also improved post market surveillance of devices, extended reporting requirements for medical device manufacturers, authorized the FDA to order device recalls and to impose civil penalties for violations of FD&C Act. Then, in 1997, Food and Drug Administration Modernization Act (FDAMA) came into being which created the less vexatious provisions for premarket review and especially, it generated the option of accredited third parties to conduct initial premarket reviews for certain devices. The Medical Device Amendments of 1992 and the Food and Drug Administration Modernization Act of 1997 were the legislature's answers to increasing criticism by manufacturers, but also Congress committees, mainly aimed at the length of review times for market access of medical devices and the administrative burdens placed on businesses.[5]

The key development took place in 2002 with the Medical Device User Fee and Modernization Act (MDUFMA) which updated the 1976 Medical Device Amendments. The 2002 Act granted FDA the authority to collect user fees for specific medical devices premarket submissions and also, created set performance goals for premarket submissions. It also authorised e-registration of medical device firms. In 2007, Food and Drug Administration Amendments Act (FDAAA) called for all registration and listing to be performed digitally/electronically and also, entailed the FDA to set up a unique device identification (UDI) system for medical devices to mandate device labels to bear a unique identifier.

In 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA) made certain improvements to premarket review and also, permitted FDA to work with foreign governments to balance regulatory requirements. Finally, in 2017, Food and Drug Administration Reauthorization Act (FDARA) reauthorized medical device user fee program and further, improved premarket review times. Furthermore, it essentially approved risk-based inspection for device establishments and made it de rigueur for the FDA to conduct a project to explore the other countries in order to improve its post market surveillance.

<u>Risk based Medical Device Classification System:</u>

[5] SORENSON, C., & DRUMMOND, M. (2014, March 6). *Improving Medical Device Regulation: The United States and Europe in Perspective*. PubMed Central (PMC). Retrieved December 1, 2022, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3955380/

The regulatory regime for medical devices in US entails a risk based classification system that identifies the level of regulatory control which is vital to ensure the safety and effectiveness of medical devices. There are three risk classes with the level of associated risk:

1. Class I for low-risk devices (General Control): Devices falling under this category are exempted from 510(k) premarket notification submission. They are subject to the least regulatory control. Although, some general controls apply like device registration and listing, labelling regulations.
2. Class II for medium-risk devices (Special Control): most of the devices falling under this category are submitted for premarket notification and are required to clear it. Several devices under this category need to go through premarket approval (PMA) which is rather a tough requirement as the PMA application of the applicant needs to get approved before the applicant begins any marketing activities. There are two scenarios where PMA is mandatory for a c Class II device:
    a) a manufacturer thinks that their device is not substantially equivalent and cannot find suitable predicate; and
    b) Manufacturer applies for 510(k) submission with the predicate, but it gets rejected by FDA stating that the device is not substantially equivalent.[6]

It usually takes 180 days according to the regulations, to approve or reject a PMA application but, in reality, it takes longer than this, approximately about 6 to 12 months. When FDA determines the submission, it notifies the applicant whether its application is approved or rejected and when the PMA process is successful, a private license is granted to the applicant as a permission to market the device.

3. Class III for high risk devices: Devices falling under this category usually support or sustain human life and are of substantial importance in preventing impairment of human health or unreasonable risk of illness or injury to the patient. Such devices need to go through the premarket approval application (PMA) and other Class III devices which are exempted from PMA, have to submit a 510(k) notification to FDA. It may take more than twelve months in its approval.

[6] Borad, A. (2018, February 22). *An Overview of FDA Regulations for Medical Devices*. An Overview of FDA Regulations for Medical Devices. Retrieved December 1, 2022, from https://www.einfochips.com/blog/an-overview-of-fda-regulations-for-medical-devices/

Essentially, the classification of a device will identify the process for placing the product on the market- either pre-market notification [510(k)] or pre-market approval (PMA)- that manufacturer must complete in order to obtain FDA clearance/ approval for marketing of the devices. The 510(k) pre-market notification is a much less burdensome procedure of market access for the devices, as applicants/manufacturers base their submissions on evidence which shows substantial equivalence of their device to a pre-existing other device already on the market.[7] The PMA process applies to those devices for which this is not the case, and especially to all high risk medical devices (Class III). MDA empowers FDA to even reclassify a medical device after its initial clearance for sale. For this, FDA has to satisfy three procedural conditions to reclassify a device:

a) publish a proposed reclassification order in the Federal Register;
b) convene a "device classification panel" to study the proposal;
c) receive and consider public comments.[8]

FDA can even voluntarily initiate this process either of its own accord or in response to a request for change in classification based upon new information.

Apart from this, FDA also performs post-market surveillance wherein reports of adverse events are collected on a worldwide basis and analysed for trends which may trigger alerts to potential quality problems with individual devices. In case of emergence of such problems, the FDA has a number of measures at its disposal which includes warning letters, seizure of products, import detentions and recall actions.

Flaws:

The premarket medical device review process has widely attracted substantial criticism. This system is widely perceived as slow, inefficient and substantively unpredictable. Few of them are as follows:

- FDA's 510(k) decision-making has attracted significant criticism wherein commentators and agencies have argued that the ubiquity and relative ease of premarket

[7] SORENSON, C., & DRUMMOND, M. (2014, March 6). *Improving Medical Device Regulation: The United States and Europe in Perspective*. PubMed Central (PMC). Retrieved December 1, 2022, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3955380/
[8] POWELL. (2018). Changing Our Minds: Reforming the FDA Medical Device Reclassification Process. *FOOD AND DRUG LAW JOURNAL*. https://doi.org/https://www.fdli.org/wp-content/uploads/2018/02/Powell-Final.pdf

notification diminishes the likelihood that new devices are reasonably safe and efficient.[9]

- The regulations for reclassification does not attempts to establish an independent evidentiary standard for reclassification decisions, i.e., a standard distinct from FDA's general guidelines for classifying devices in the first instance.
- Commentators have also argued that in order to reduce the lag time in bringing new medical devices in the market, FDA should shift some or whole of its premarket review to the post market period. This is advised so as to make the American device regulatory system less cumbersome in comparison to the faster European Union model which will be discussed later in this paper.
- It is also stated that the American Regulatory System for medical devices should be reformed in such a way to make it clear, fair, predictable, straightforward and consistent so as to encourage creative innovators of medical device technology from timely entering the medical devices market.
- Many commentators also state that the FDA's decision-making is pretty lethargic especially in context of reclassification of medical devices.
- It is also alleged that the whole medical device classification system is too expensive and too unpredictable which deters public confidence in it.
- Evidences regarding weak use of FDA's authority have been purported in order to support that FDA does not require clinical trials for modified PMA applications and even when it requires clinical trials for PMA applications, its scientific standards are much lower than for evaluating pharmaceutical drugs.[10]

American Medical Device market produces almost half of the world's medical devices. Thus, reforms are required in this system to protect consumers from defective devices and ensure safety and effectiveness of these devices. These reforms will also make it at par with the benefits accredited to the European Model of medical device regulations. Hence, attention needs to be paid towards the FDA's classification decisions, excessive pre market review time

[9] POWELL. (2018). Changing Our Minds: Reforming the FDA Medical Device Reclassification Process. *FOOD AND DRUG LAW JOURNAL*. https://doi.org/https://www.fdli.org/wp-content/uploads/2018/02/Powell-Final.pdf
[10] FOX, D. M., & ZUCKERMAN, D. M. (2014, March 6). *Regulatory Reticence and Medical Devices*. PubMed Central (PMC). Retrieved December 1, 2022, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3955381/

and post market reclassification regulations amongst several others. The paper will further cover the comparative analysis between the regulatory frameworks as against Indian system.

- **European Union (EU)**

Background:

Before 1990, each member state of European Union had its own approach to regulate medical devices. Thereafter, the EU regulatory framework on medical devices was created under the so-called "New-Approach Directives" which were introduced by the European Council that defined the "Essential Requirements" to ensure devices' safety and performance and they apply to all countries. This was done so as to regulate a diverse and complex market and promote the "international market" in Europe. There are in toto three directives under this "New Approach", namely: 1) Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) (1990), (2) Council Directive 93/42/EEC on Medical Devices (MDD) (1993) and (3) Council Directive 98/79/EC on in vitro Diagnostic Medical Devices (IVDMD) (1998). Under these directives, devices are categorised into four classes according to the degree of risk associated with their intended use. The EU regulatory framework has been complemented by several guidance documents that are legally non-binding and reflect the consensus of major stakeholders regarding the interpretation of the Directives.[11] Since the adoption of New Approach, the three directives have been supplemented by amending and implementing legislation.[12]

Recent Changes:

The latest is the adoption of two new regulations on medical devices and in vitro diagnostic medical devices which will repeal the current Council Directives on Medical Device (93/42/EEC) and Active Implantable Medical Devices (90/385/EEC) and in vitro Diagnostic Medical Devices (98/79/EC). The two new regulations i.e., Medical Device Regulation and In

[11] Contardi, M. (n.d.). *Changes in the Medical Device's Regulatory Framework and Its Impact on the Medical Device's Industry: From the Medical Device Directives to the Medical Device Regulations · Erasmus Law Review · Eleven Journals*. Changes in the Medical Device's Regulatory Framework and Its Impact on the Medical Device's Industry: From the Medical Device Directives to the Medical Device Regulations &Middot; Erasmus Law Review &Middot; Eleven Journals. Retrieved December 1, 2022, from https://www.elevenjournals.com/tijdschrift/ELR/2019/2/ELR-D-19-00012

[12] Contardi, M. (n.d.). *Changes in the Medical Device's Regulatory Framework and Its Impact on the Medical Device's Industry: From the Medical Device Directives to the Medical Device Regulations · Erasmus Law Review · Eleven Journals*. Changes in the Medical Device's Regulatory Framework and Its Impact on the Medical Device's Industry: From the Medical Device Directives to the Medical Device Regulations &Middot; Erasmus Law Review &Middot; Eleven Journals. Retrieved December 1, 2022, from https://www.elevenjournals.com/tijdschrift/ELR/2019/2/ELR-D-19-00012

Vitro Diagnostic Medical Devices Regulation entered into force on May, 25th 2017 and will be fully applicable from May 26th, 2021 and May 26th, 2022 respectively.[13] It was stated that, 'since the EU's rules on the safety and performance of medical devices were laid down in the late 1990s, however, there have been discrepancies in their interpretation across Europe'.[14] Therefore, in order to fully demonstrate the progress over the last twenty years, the EU has revised its regulatory framework as adopted by the Council of Ministers and European Parliament, of these two new regulations. It has been asserted by the European Commission (EC) that the adoption of these two regulations will establish a modernised and more robust EU legislative framework to ensure better protection of public health and patient safety which in turn, will uplift the confidence in the medical devices industry of the EU. It is necessary to comprehend the current council directives and the two new regulations in brief in order to analyse the remodelling of the system.

Current Council Directives:

The medical device Directives aimed at balancing the two major goals of EU action in this field: ensuring the free movement of medical devices as goods in the internal market, and guaranteeing of high level protection of public health and patient safety.[15] The legal structure of medical device regulation in the EU is established by the directives, which describe procedures and standards and are binding on member states.[16] EU "guidance documents" provide definitions, recommendations for testing, information on specific topics such as integration of software into medical devices, and details on classifications for combination products and other complex devices.[17] Guidance documents aid the member states in ensuring that they are meeting the directives. Together, directives and guidance documents outline the

[13] *Press corner*. (n.d.). European Commission - European Commission. Retrieved December 1, 2022, from https://ec.europa.eu/commission/presscorner/home/en

[14] *Press corner*. (n.d.). European Commission - European Commission. Retrieved December 1, 2022, from https://ec.europa.eu/commission/presscorner/home/en

[15] Contardi, M. (n.d.). *Changes in the Medical Device's Regulatory Framework and Its Impact on the Medical Device's Industry: From the Medical Device Directives to the Medical Device Regulations · Erasmus Law Review · Eleven Journals*. Changes in the Medical Device's Regulatory Framework and Its Impact on the Medical Device's Industry: From the Medical Device Directives to the Medical Device Regulations &Middot; Erasmus Law Review &Middot; Eleven Journals. Retrieved December 1, 2022, from https://www.elevenjournals.com/tijdschrift/ELR/2019/2/ELR-D-19-00012

[16] *Ensuring medical device effectiveness and safety: a cross--national comparison of approaches to regulation - PubMed*. (2014, January 1). PubMed. Retrieved December 1, 2022, from https://pubmed.ncbi.nlm.nih.gov/24772683/

[17] SORENSON, & DRUMMOND. (2014, March). Improving Medical Device Regulation: The United States and Europe in Perspective. *The Milbank Quarterly*, *92*(1), 114–150. https://doi.org/https://www.jstor.org/stable/24369824#metadata_info_tab_contents

mechanics of pre- and post-approval regulation of medical devices in the EU.[18] However, Guidance Documents remains non-binding and each country has flexibility in meeting the essential requirements.[19] Any medical device can be legally marketed in the EU after it receives a 'Conformite Europeenne' (CE) mark from Notified Body (NB) which is a private, for profit organisation based in a member state which specializes in evaluating the medical devices. A CE mark points out that the device conforms to the directives. Moreover, approval from more than seventy NBs in the EU will permit the marketing in all member states of EU. Each member state in the EU also has a governmental Competent Authority (CA) which oversees the NBs and has primary responsibility for post-approval surveillance.[20] The aspects of such CAs vary amongst member states.

Basically, EU incorporates a four-tiered classification system which is based on the degree of risk associated with the medical device. Similar to those of US, the evidence of essential requirements for market authorisation increases with the degree of risk associated with the device. Following is the four-tier classification of medical devices:

- Class I: It poses low risks associated with their use.

Pre-market requirement only entails that the manufacturers of these medical devices only have to self-declare conformity with the essential requirements to a national CA without a need to involve a NB in this declaration. Under this category, approval is not required.

Post market Requirements primarily entail that the manufacturer are required to implement a post market study and/or vigilance program according to the national requirements, which includes reporting serious incidents to the relevant Competent Authority.[21]

- Class IIa: Devices under this category pose relatively low risk to the human body.

For the marketing of the Class IIa devices, besides declaring conformity with the provisions of the Directives and essential requirements, there is an additional requirement concerning

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[18] *8 Key Changes To Understand In The New European MDR And IVDR*. (n.d.). 8 Key Changes to Understand in the New European MDR and IVDR. Retrieved December 1, 2022, from https://www.meddeviceonline.com/doc/key-changes-to-understand-in-the-new-european-mdr-and-ivdr-0001

[19] *Ensuring medical device effectiveness and safety: a cross--national comparison of approaches to regulation - PubMed*. (2014, January 1). PubMed. Retrieved December 1, 2022, from https://pubmed.ncbi.nlm.nih.gov/24772683/

[20] *8 Key Changes To Understand In The New European MDR And IVDR*. (n.d.). 8 Key Changes to Understand in the New European MDR and IVDR. Retrieved December 1, 2022, from https://www.meddeviceonline.com/doc/key-changes-to-understand-in-the-new-european-mdr-and-ivdr-0001

[21] SORENSON, & DRUMMOND. (2014, March). Improving Medical Device Regulation: The United States and Europe in Perspective. *The Milbank Quarterly*, *92*(1), 114–150. https://doi.org/https://www.jstor.org/stable/24369824#metadata_info_tab_contents

verification of conformity by a NB which reviews performance and reliability testing appropriate to the risks of the device's intended use.[22] NBs commonly approve devices based on a "performance" standard, or demonstration that a device performs in the manner intended with expected benefits that outweigh expected risks.[23] It may take a general time of one to three months for approval.

- Class IIb: They pose medium risk to high risk to the human body. For marketing, the assessment by the NB of the technical documentation for full quality assurance will be required.
- Class III: The medical devices falling under this category possess high risks and require permanent monitoring during their lifetime. They have to pass a conformity assessment procedure wherein the manufacturer must prove that the devices for which it seeks approval, satisfies the essential requirements and NB verification. Devices under Class III also have to undergo clinical investigations/ studies. Just like in case of Class II medical devices, conformity assessment will also include an audit or assessment of the technical documentation. Also, the manufacturer has to submit the design dossier to the NB for approval under audit of the full quality assurance system.

After the completion of the aforementioned procedures, the manufacturers receive a Declaration of Conformity and apply for a CE marking and notified body number. Following this, the medical device enters the market.

New Regulation on Medical Devices (2017):

The new regulation on medical device is a response to technical and scientific developments that have occurred over the years and required attention in order to keep the regulatory framework for medical devices in pace with time. The objective of these new regulations is to ensure that the medical devices entering the market are safe and effective as well as can be freely traded throughout the EU market. The recent high-profile incidents/cases acted as catalysts for reform and highlighted the requirement for strengthening the regulatory

[22] *DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL*. (2011, June). Official Journal of the European Union. Retrieved December 1, 2022, from https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:174:0088:0110:en:PDF

[23] *Ensuring medical device effectiveness and safety: a cross--national comparison of approaches to regulation - PubMed*. (2014, January 1). PubMed. Retrieved December 1, 2022, from https://pubmed.ncbi.nlm.nih.gov/24772683/

framework and called for attention for improvement in standards and procedures. The most significant changes in the new regulation concerning medical devices include:

1. Expansion of scope of definition: The definition of medical devices and active implantable medical devices under the Medical Device Regulation (MDR) has been expanded to include devices that do not possess medically intended purpose.
2. Qualified Person: Manufacturers of medical devices will be required to identify at least one person within their organisation who is ultimately responsible for all aspects of compliance with the requirements of the new regulation.[24] Some special reliefs have been provided to the micro and small enterprises.
3. Unique Device Identification (UDI) [Articles 27, 87, 18 & 19]- The MDR mandates the use of UDI mechanism in order to in enhance the ability of manufacturers and concerned authorities to trace specific devices through supply chain and also, to facilitate recall of medical devices that have been found to present a safety risk. This UDI shall also be referenced in Vigilance Reports and will be used for reporting serious incidents and also, field safety corrective actions.
4. Vigilance and Post-Market Surveillance (PMS) [Articles 84, 85, 86, 87, 88, 93/ EUDAMED Database Article- 33]: MDR increases the PMS, affecting the responsibility of economic operators and national bodies, via establishment of EU database on Medical Devices which will record data pertaining to registration of devices, Periodic Safety Update Report (PSUR), Safety and Clinical Performance Reports (SSCP), UDI and others. In addition to this, unannounced audits, along with product sample checks and device testing will strengthen EU's enforcement regime[25] and will also assist in reducing risks arising from unsafe devices.
5. Conformity Procedures: The transition from current Directives to the new regulations will make the conformity procedure more rigorous and stringent. Further, the currently approved medical devices will not be exempted from the requirements of the new regulation and will have to undergo re-evaluation and re-approval.
6. Economic Operators [Articles 10, 11, 13, 14, and 30]: Economic Operators include manufacturers, distributors, importers, suppliers, subcontractors, assemblers, EU

[24] *medical device market*. (n.d.). Medical Device Regulation. Retrieved December 1, 2022, from https://www.tuvsud.com/en-in/industries/healthcare-and-medical-devices/medical-devices-and-ivd/medical-device-market-approval-and-certification/medical-device-regulation

[25] *medical device market*. (n.d.). Medical Device Regulation. Retrieved December 1, 2022, from https://www.tuvsud.com/en-in/industries/healthcare-and-medical-devices/medical-devices-and-ivd/medical-device-market-approval-and-certification/medical-device-regulation

Authorised Representatives who carry responsibility for conformity to the regulations. The Medical Device Directive did not include requirements for importers and distributors. But the new regulation illustrates an increase in the responsibilities of all the stakeholders.

7. Safety and Performance Requirements [Annex I]: These requirements will replace the Directive's Essential Requirements. Under the Safety and Performance Requirements, manufacturers will have to showcase/demonstrate compliance through risk management, technical studies, testing and via other means.
8. Change in supervision of NBs: The NBs will face a considerable change which will start from the requirement that they have to apply for a new designation. In this process, some notified bodies may be re-notified, or may not be re-notified, or many won't be notified with the same scope. Additionally, NBs will be required to even consult the EC on its adequacy of clinical evaluation and port market clinical follow-up plans prior to the granting of certificates for Class III implantable and Class IIb devices.
9. Classification of Products [Articles 1, 2, 22, 23, 51, 52 & Annex VIII, IX, X, XVI]: Though, the classification system remains unchanged but the rules have been tightened and significantly changed for some devices which might result in some devices being classified in a higher level of class. In addition to this, devices that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body will be given a different classification depending on varying factors.[26]

Besides these significant changes, there are several provisions that remain as it is i.e., these provisions have been retained in similar form to the current Medical Device Directives. For example: the four tier-classification system, classification rules (which remain essentially the same but with additions), technical documentation (new requirements added and have been made clearer), registration requirements (remain the same but additionally, more information regarding the device has to be provided by the manufacturer) amongst others.

Thus, this analysis between the current Directive and the new Regulation displays that the latter is stricter in terms of various things like devices being placed in Class III and an increase in regulation of NBs amongst others. This reflects that this new regulation intends to enhance patient safety and to revamp device traceability throughout its lifetime. Though, the new Regulation is not fully applicable and a transition period has been provided but commentators

[26] *8 Key Changes To Understand In The New European MDR And IVDR*. (n.d.). 8 Key Changes to Understand in the New European MDR and IVDR. Retrieved December 1, 2022, from https://www.meddeviceonline.com/doc/key-changes-to-understand-in-the-new-european-mdr-and-ivdr-0001

expect the new Regulation to result in an increase in safety and post market surveillance. Some commentators even state that if the implementation is not efficient enough, then the whole procedure has the tendency to become vexatious and cumbersome and thus, end up being troublesome to manufacturers. Although, the actual results are still awaited.

Conclusion:

In light of the aforementioned analysis, it can be stated that there exist some of the basic fundamental differences between the regulatory framework of US and EU like, in terms of missions and standard for product market authorisations. Though, one of the main goals that both these frameworks recognise is "device safety" but the procedure for achieving it, is different. EU uses NBs for conducting test and evaluating medical devices whereas in the US, primarily through FDA, all of it is regulated. Another contrast that can be pointed out that under the EU framework, NBs commonly approve devices based on a "performance" standard, or demonstration that a device performs in the manner intended with expected benefits that outweigh expected risks[27] whereas the FDA standard in US is considered to be more lenient as it does not require proof of improvement in clinical end points for Class III devices. Another key difference is that in US, FDA oversees the regulation of devices and maintains the final authority whereas in case of EU, it confers significant authority on a collection of Competent Authorities (CAs) and NBs to oversee device evaluation, market approval and post market surveillance. The approach for regulatory framework of medical devices as adopted by US, theoretically allows the system to have better coordination and ease of enforcing regulatory requirements, although, some commentators believe that 'greater centralisation results in rigidity and lengthy and costly regulatory process'[28], on the other hand, the approach adopted by EU, makes it more flexible and grants faster market access to certain devices under the current Directives. But even EU's system of regulation is not without problems as there are evidences which suggests that there exists difference in standards of NBs which makes it easy for the manufacturers to get a CE mark from the less rigorous body. But the changes brought

[27] *Ensuring medical device effectiveness and safety: a cross--national comparison of approaches to regulation - PubMed*. (2014, January 1). PubMed. Retrieved December 1, 2022, from https://pubmed.ncbi.nlm.nih.gov/24772683/

[28] *8 Key Changes To Understand In The New European MDR And IVDR*. (n.d.). 8 Key Changes to Understand in the New European MDR and IVDR. Retrieved December 1, 2022, from https://www.meddeviceonline.com/doc/key-changes-to-understand-in-the-new-european-mdr-and-ivdr-0001

in by the new Regulation on Medical Devices depicts that there has been attempt to ameliorate the shortcomings and loopholes in regulation of medical devices under the current Directives. It would be worthy to observe the changes after the implementation of the new regulation on Medical Devices.

Coming to India, as already discussed in the preceding sub-topics, the new regulatory process on medical devices under Medical Device (Amendment) Rules, 2020 is expected to give the outcome of a more robust system on regulation of medical devices which ensures patient and device safety and public health in toto. In a bid to achieve these outcomes, the new rules have also introduced the four-tier risk based classification system, just like EU, and has set product standards for medical devices. Prominently, besides other significant changes, it has theoretically strengthened the registration, evaluation and licensing system concerning medical devices. It has also introduced the concept of clinical trial/investigation. This reflects that India has attempted to not only ensure safety and efficacy of the devices but also tried to reach international standards to create a strong market for India outside its territory. It is worthy to mention that the results as a consequence of these significant changes are still awaited but it is expected to yield a setup of good device standard. But it is also expected that among other shortcomings or flaws, the manufacturers may face difficulties in comprehending and strictly following the procedures in the initial years and it is also apprehended that such a procedure might lead to vexation and unnecessary delay. Still, it has yet, to be analysed thoroughly with the passage of some time. Thus, it can be said that in a world with constantly changing social, economical and technological climates, future revisions in the current medical device regulations are anticipated.