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MEDICAL DEVICE REGULATIONS AND CURRENT CHALLENGES IN THE GROWTH OF MEDICAL DEVICES IN INDIA: AN OVERVIEW

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ABSTRACT: Medical device, a device or instrument or apparatus or that is used to treat or prevent or diagnose or mitigate or cure the disease or to replace the structure of the body parts mimicking the natural function. The medical device sector started to grow rapidly in the last 8 years. Developed countries like the USA, European Union, and Japan concentrated on this sector to increase their production capability, and regulations were stringent to prevent unlawful happenings. India still lags in the development of the medical device sector. Earlier the rules and regulations for medical devices in India were followed the same as the drugs and cosmetics, which raised various questions regarding the regulatory process of medical devices. Very later the Medical Device Act 2017 was introduced which explained the manufacture, import, export & clinical investigation regulatory process required for a medical device. The Medical Device Act 2017 is framed as competent with the other national authority regulators and internal medical device regulator forums. This paper discusses the Medical Device Act 2017, the crisis which stopped or delayed the medical device sector growth in India and suggests corrective and preventive action to the mentioned crisis.

INTRODUCTION: The healthcare sector is one of the promising growing fields in India, this is because of the increased population, increased life expectancy, decreased infant mortality, increased health expenditure of patients, and government support. The country has various specialty centers, well-qualified doctors & telemedicine which makes India become a major medical tourism country [1]. As of 2020 Indian healthcare industry accounts for $190 billion and is expected to reach $370 billion by 2024-2025, this is possible because of the demand for quality medical care systems [3].

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India possesses a medical device market size of around $ 11 billion, further introduction of the national medical device policy in 2023 make help achieve a market size of $50 billion by 2030 [2]. Approximately 80% of medical devices were imported, which shows that India depends majorly on foreign supplies, especially on cardiac diagnostics, ultrasonic scans, PCR, *etc*. PLI scheme introduced by the central government of India hopefully promotes medical device manufacture within the country highlighting Make in India [2, 3].

The medical device in India is defined as substances used for in vitro diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant and substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides [4].

Medical devices are classified into four categories depending on the risk factor of the medical device [4]. The medical device act 2017 was implemented by the government of India and came to effect on 1 January 2018. Medical device act 2017 was framed with complying with the global harmonization task force (GHTF) and differentiating from pharmaceutical drugs [5]. This article discusses the regulatory process involved in medical device manufacture, import & classification as per the medical act 2017 and the current problem faced in the medical device sector.

History: In India, the development of regulation for drugs and cosmetics were initiated earlier compared to regulation development for Medical device. In 1940, the Drugs and cosmetics act 1940 & drugs and cosmetics rules 1945 were implemented to regulate the manufacture, Import, Distribution, and sale of drugs and cosmetics [6]. Some medical devices were notified by CDSCO which could follow the Drugs and cosmetics act 1940 and Rules 1945 [7].

In 1989, Disposable hypodermic syringes & needles and disposal perfusion sets were notified to regulate under the Drug and cosmetics act 1940 & 1945 rules, In 2002 In vitro Diagnostic Devices for HIV, HBsAg, and HCV were notified as drugs. In 2005 Cardiac Stents, Drug Eluting Stents, Catheters, Intra Ocular Lenses, I.V. Cannulae, Bone Cements, Heart Valves, Scalp Vein Set, Orthopedic Implants, Internal Prosthetic Replacements and 2016 Ablation device were also notified to regulate under Drug and cosmetics act 1940 & 1945 rules [8].

Licensing: Medical device manufacturing license for sale and distribution is given by the state licensing authority or central licensing authority depending on the classification of the medical device. Class A and Class B medical devices manufacturing licenses for sale and distribution application are made to the State licensing authority, whereas Class C and D medical devices licenses are made to the Central licensing authority. The registration application for all classes of medical devices can be found in the online service of the Ministry of Health and family welfare [9]. Class A and Class B manufacture license for sale and distribution is applied through MD-3 & MD-4 application form respectively along with the applicable fee. The applicant must comply with the Quality management system as notified in the fifth schedule. The audit may be conducted before providing the manufacturer license which ultimately depends upon the class of Medical device, generally Class B medical requires a compulsory audit 90 days from the date of application. State licensing authority on examining the documents and audit reports state licensing authority provides the Manufacture license for sale and distribution under MD-5 or MD-6 (if Loan License) for Class A & B.

The manufacturing license for the sale and distribution of class C & D medical devices is made through MD-7 & MD-8 applications with prescribed fees. The central licensing authority examines documents along with relevant field experts, inspects the manufacturing site, and on satisfying central licensing authority requirements, they shall provide a license under MD-9 or MD-10 (if loan license) for class C and D. The validity of the License could be for 5 years, further prescribed retention fee paid before completion of five years [4].

Import: The agent who possesses the license to manufacture for sale or distribution or wholesale license for sale or distribution shall proceed application to grant approval of import for medical device in MD-14 with the applicable fee. The application service can be assessed through the online portal of the Ministry of Health and family welfare of India. The manufacturing site shall be inspected following the submission of the application. On verifying the documents and inspection reports, the license for import of medical devices in MD-15 form.

Class C and Class D medical devices require to ensure safety through clinical investigation but issuance of free sale certificates for specified medical devices by national regulatory bodies or other authorities like Australia, Canada, Japan, EU, or USA shall apply without carrying out the clinical investigation. Class A and B medical devices can be submitted with published clinical investigation studies. Import of medical for the purpose test, clinical investigation, or evaluation permission by central licensing authority can be applied through MD-16 and granted the license in MD-17 [4].

Classification: According to the medical device act 2017, the central licensing authority classifies medical devices and IVD into four categories, namely.

TABLE 1: CLASSIFICATION OF MEDICAL DEVICE

Category	Level of Risk
Class – A	Low risk
Class – B	low Moderate risk
Class – C	-Moderate high risk
Class – D	High risk

Part I of the first schedule medical device act 2017 explains the parameter and principles for classifying medical devices. The following basic principle considered for the classification of medical devices,

- The classification depends on the intended purpose of the device.
- Accessory or combinational medical device has to be individually classified.
- Software used in the device has to be classified in the same classification as its device.
- A device that can be intended for multi-specified use requires to be classified depending on the most critical use.
- When several rules apply to the device, the strictest rules resulting in higher classification have to be applied [10].

The following parameter should be considered for the classification of medical devices:

- Non-invasive medical which could contact with injured skin.
- Non-invasive medical device for channeling or storing substances.
- Non-invasive medical device for modifying compositions of substance.
- Other Non-invasive medical devices.
- Invasive medical device for transient use.
- Invasive medical devices for short-term use.
- Invasive medical device for long-term use.
- Invasive medical device for connection to the active medical device.
- Surgically Invasive medical device for transient use.
- Surgically Invasive medical device for short-term use.
- Implantable medical devices and Surgically Invasive medical devices for long-term use.
- Active therapeutic medical device for administering or exchanging energy.
- Active diagnostic medical devices.
- Other active medical devices.
- Medicinal devices incorporating medicinal products.
- Medical devices incorporating animal or human cells, tissues, or derivatives.
- Medical devices for sterilization or disinfection.
- Medical devices for contraceptive use [4].

Authorities: The central licensing authorities are responsible for carrying out the rules relating to the import, clinical investigation, and approval of investigational medical devices, manufacture of class C and D medical devices, clinical performance evaluation, and approval of IVD and coordination with state authorities. State license authority regulates the manufacture of class A & B, and sells, stock, distribution, or sale to all classes of medical devices [4].

Essential Principle of Safety and Performance of the Medical Device: Medical device manufacturers should follow the essential principle of safety and performance of medical device guidelines issued by the Ministry of Health and family welfare.

The Medical device manufactured should deliver its intended purpose for the user without compromising the safety of the user and clinical condition. The risk of the medical device should be outweighed by the potential benefits of the device and the harmful risk should be cleared as much as

possible to ensure the safety of the patient [4]. A medical device must withstand its quality while in transport and storage. Appropriate clinical studies are to be done to demonstrate its potential benefits and intended use of medical devices. Chemical, physical and biological properties of the medical device should be studied to avoid incompatibility, stability issues, and material character deterioration. The appropriate material has to be chosen to make a device to avoid carcinogenicity, toxicity, and incompatibility with the medicine or drug that is in contact. The microbiological contamination of medical device has to be avoided and require sterile packing. In the case of non-sterile packing, the cleanness of the packing process and appropriate environmental condition is to be ensured.

The drug defined as per the Drugs and cosmetics act 1945 incorporated with the medical device must ensure the Quality and safety efficacy of the drug as well the quality, safety, and performance of the device. The biological material incorporated with the device must not produce any infection, their origin has to be established and viral or any other transmissible agent used should be inactivated. Devices with diagnostic characteristics must produce accurate and precise results using established scientific and technical methods. Numerical data results are much appreciable with commonly used standard units easily understood by the user of the device.

The medical device is built to withstand unintentional radiation and intentional radiation. Radiation produced by the medical device is reduced to prevent harmfulness to the user and outweighs its benefits to the risk. A device with software or standalone software must produce accurate, reliable, repeatable results and requires software validation. The energy supplies to the medical device are designed and manufactured to minimize all possible risks.

The multiple-parameter monitoring device can be fitted with an alarm system to alert the user to avoid serious events. The label of the medical device helps the user to identify the device, understand its function, and any other caution or warning instruction given. The intended purpose of the device is to be demonstrated through literature reviews & reports, clinical evaluation reports, and clinical experience [11].

Labeling: The medical devices are labeled following the medical device act 2017, which enables users to identify the device and trace the supply chain pathway. The label should include the name of the device & other information to identify the device, the name and address of the manufacturer, a statement about its quantity (Content, weight, volume, units, and measures), Month & year of expiration, and any other safety instruction & certification. The information present in the labeling should be based on clinical evaluation and studies. UDI (Unique device identification) should be provided in the label to identify the device and production. Medical devices which are to be exported may adopt the regulation followed in receiving country [4].

Current Issues:

Case 1: India's medical device was mainly dependent on foreign supplies, 80% of medical devices were marketed from foreign countries [2].

Root cause: The root cause for this issue is the less production or manufacturing present in the country. Many foreign companies in India acting as distributors rather than manufacturers.

CAPA: The manufacturing and production capabilities can be introduced into India. The government policy favoring the companies to encourage the manufacture the medical device is to be increased. Following this government has introduced a new medical device policy in 2023 which is expected to reduce the 30% of importing medical devices and promoting high-end medical device production within the country [12].

Case 2: WHO says that in 2004 major diagnostic devices were not distributed to all the areas of India [13].

Root cause: This occurs lack of facilities to operate in rural areas. Most multi-specialty Hospitals and diagnostics in India are located in the urban region and metropolitan cities.

CAPA: The multi-specialty hospitals and diagnostics centers should be increased as much as possible in all the areas of country. This is possible

only with the coordination of both government and private sector. Providing sufficient knowledge is also to be considered. Improper training and knowledge regarding the handling of medical devices is one of the serious concerns which may lead to serious effects on patients. The government sector recruits qualified & well-knowledge individuals but the private sector fails to appoint the proper individuals to operate the medical device. The government Health ministry should monitors and stringent the rules & regulations to provide better knowledge and training about the medical device [13].

Case 3: Price control and fixation are other setbacks for the development of medical devices [14].

Root cause: The Price fixation in India is controlled and monitored by the government of India, this not allow the manufacturer to decide a price higher than the prescribed price.

CAPA: Availability, affordability, and accessibility are the main factors to promote the growth of healthcare and medical devices. Price fixation is monitored by the government, it can be supportive to the user-patient but in the means of business promoters, it is considered as a drawback. The system has to be updated to satisfy both the user and the manufacturer [14].

Besides all these factors, the government of India making efforts to promote medical device, One of those effort is the introduction of the Medical Device Act 2017 which act as a harmonized standard for India. Hopefully, it will facilitate a proper pathway regulatory process involved in the medical device sector.

CONCLUSION: Medical devices are one of the promisingly growing sectors in the healthcare system. India is a better service provider in the healthcare system, developing the medical device system. The government has made efforts to improve the medical device sector, and further development plans have been established by the government to increase the manufacturing capacity of medical devices within the country and therefore cut down the dependence on foreign manufacturers. The Medical Device Act 2017 implemented by the CDSCO defines the required procedure for manufacture, import, and export-related guidelines. All this combined action may hopefully increase the growth of the medical device sector in India.

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