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Aspects of Indian Medical Device Regulation

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Abstract

The current study's goal is to provide some information or a comparative analysis of medical device regulations in India. Numerous medical devices created by numerous users are vital to the healthcare industry, and it is important to properly identify, categorize, and code their usage. Many people other than physicians use, produce, and evaluate medical gadgets on a regular basis. Vaccines, medications, and medical devices are the three main pillars of the modern healthcare sector nowadays. A medical device is crucial to the screening, monitoring, diagnosis, and treatment of patients as well as the provision of high-quality healthcare at every stage of the process. Furthermore, India's medical device market is among the fastest-growing in the world when seen through the lens of market growth. By October 1, 2023, medical device importers and manufacturers in India were required to obtain licenses for their high-risk category items. Since 1940, medical devices have been governed by the Drug and Cosmetic Act of 1940 and the Rules of 1945. Only a small number of medical devices were regulated by CDSCO (Central Drug Standard Control Organization) through gazette notifications; these devices are known as notified devices. With over 7000 generic device categories, there are an estimated 2 million distinct types of medical devices available on the global market today. This article compares and contrasts the recently announced and established guidelines and modifications concerning the regulation, manufacturing, import, and administration of medical device quality systems into India.

Keywords: Healthcare, Conventional Gadgets, Medical Devices.

1. Introduction

First of all, Any tool, machine, appliance, software, or material intended for single or combined use in diagnostic and therapy in order to prevent and treat disease is considered a

medical device. Medical devices vary based on their intended usage and indications. The term “medical devices” refers to a broad category of products that ranges from highly modified computerized medical technologies and diagnostic medical devices to therapeutic devices with medical applications like wound healing or clogged arteries.

Medical devices support an individual’s life and assist with the anatomy or replacement of any kind of process. They also control the creation and disinfection of medical devices in hospitals and other locations. Information about sample kits, reagents, chemicals used for cleaning, calibrators, and software data is provided by means of in vitro examination of specific specimens derived from the human body, which does not achieve its intended action through pharmacological, metabolic, or immunological means but which may be used in such ways. Medical devices include a wide range of products, including bandages, medical gloves, contact lenses, disinfectants, X-ray equipment, pacemakers, dialysis equipment, incubators, and heart valves.

Medical devices is a worldwide industry that produces and develops apparatus for healthcare, ranging from basic items like thermometers and stethoscopes to more sophisticated items like pacemakers, ultrasounds, and surgical robots. As of 2016, the medical device market was valued at over 5.5 billion. Currently, the medical device industry is mostly governed by large, multinational corporations; it can be started that imported medical equipment account for 75% of total sales. The import of medical equipment under the direction of federal and state governments. The primary duties of the Drug Controller General of India (DCGI)- led Central Drug Standard Control Organization (CDSCO) include overseeing the actions of state drug licensing bodies, regulations, and the consistent application of the act across the country.

The purpose of the legislation and its regulations is to control the import, production, sale, and distribution of medical equipment. The state and federal governments view informed medical device regulation. There are not many additional legal criteria for importing medical devices into India. The provisions of the import and export policy regulate the import of medical devices into India. In India, almost 70% of medical devices are imported. The US (29%), Germany (20%), other EU nations (17%), China (8%), Japan (7%), and other countries (19%) are the countries from which medical devices are imported.

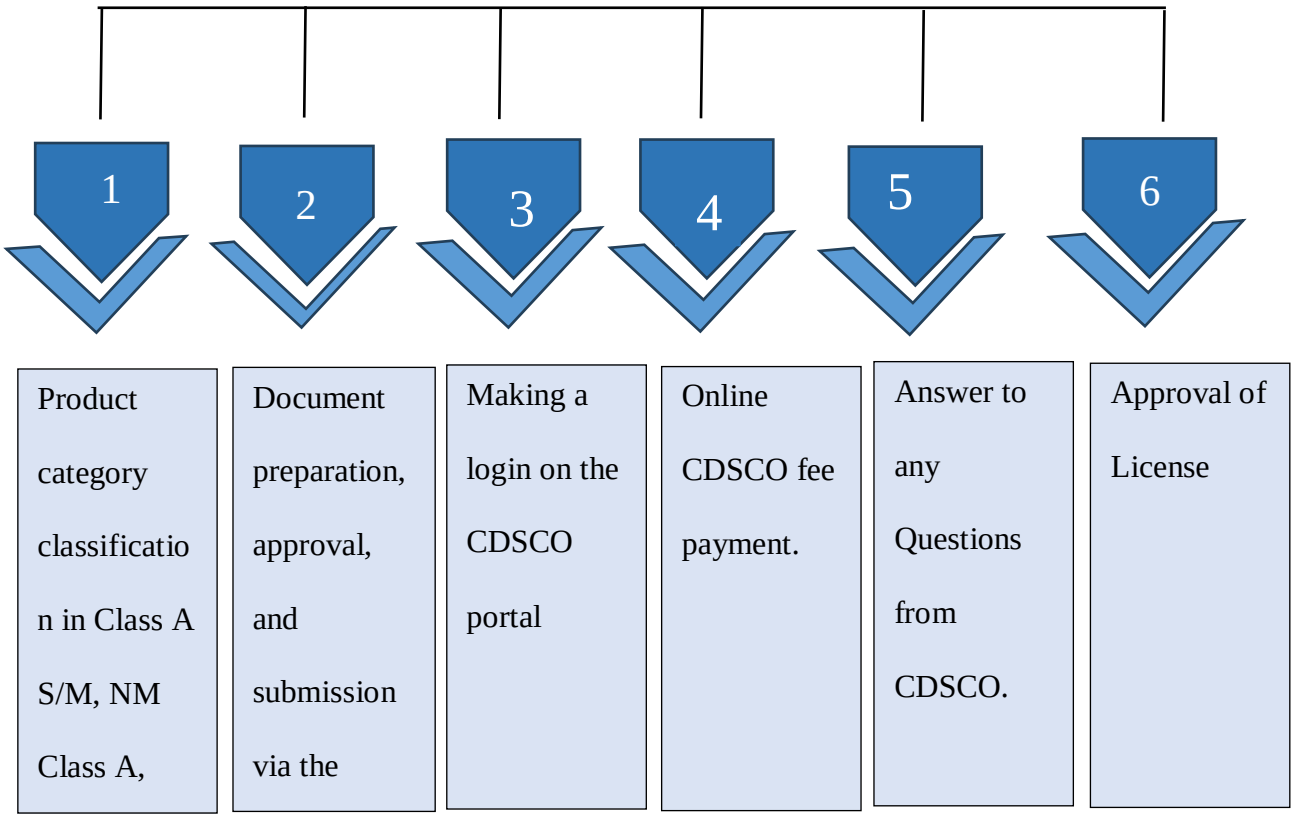

Figure.1. CDSCO Medical Device Registration Process

2. Medical Device Classifications Based on Risk

Medical devices are classified according to their manufacture point, technological model, or intended medical application. However, the regulatory bodies have categorized medical devices based on their effectiveness, safety, and quality requirements that are globally established. Medical equipment are categorized differently in each nation.

CLASS-A: Known as low risk devices, these medical equipment are governed by broad rules. Class 1 is governed by regulations. This category is mostly includes prohibited equipment as well as good manufacturing practices, replacement, refund, repair, and notification. Devices classified as class 1 are not intended to prevent any harm to human health. Most of these are not subject to premarket notification.

Examples include an examining glove, a toothbrush, surgical instruments, and elastic bandages.

CLASS-B: Both general and particular controls are mostly included in this class. Compared to class 1, it needs additional regulatory oversight. We call these devices low- medium risk gadgets. The notified body must certify them. They are carried out as directed without endangering the user or the patient. These include of post-marketing surveillance and unique criteria. For instance, sterile supplies, surgical gloves, tracheal tubes, stomach tubes, urine catheters, and needles.

CLASS-C: Also known as medium-high risk devices, these devices require certification from the authority that is notified in order to be designed and manufactured as medical equipment. They adhere to the system of quality management. Examples include anesthesia machines, non-absorbable sutures, blood bags, condoms, and contact lens care supplies.

CLASS-D: Premarket approval is required for both general and specific controls. We call these medical equipment “high risk”. Premarket approval was necessary for these gadgets in order to guarantee their safety and efficacy. Usually, these gadgets allow people to survive. It is helpful in lowering the risk of harm or impairment to human health. Heart valves, implanted defibrillators, angioplasty catheters, pacemakers, and vascular grafts are a few examples.

3. 2017 rules for medical devices Control over medical equipment

1) Except for in vitro diagnostic medical devices, other medical devices must be categorized according to the guidelines in part 1 of the First schedule into the following classes:

(Class A); low risk

(Class B); low moderate risk

(Class C); moderate high risk

(Class D); and high risk

2) In vitro diagnostic medical devices are to be categorized into the following classes:

(Class A); low risk

(Class B); low moderate risk

(Class C); moderate high risk

(Class D); and high risk

3) The Central Licensing Authority will categorize the medical devices mentioned in rule 2 according to their intended use as well as other guidelines outlined in the first schedule.

4) A class-by-class list of medical devices will be posted on the Central Drugs Standards Control Organization website, based on the categorization mentioned in sub rule (3): With the caveat that the Central Licensing Authority is free to change the class of any medical device or add or remove items from this list at any time.

5) Medical device grouping: Any anyone wishing to apply for a medical device license for the following purposes

(a) Import

(b) Produce goods to be distributed or sold; and

(c) Offering for sale, stock, display, or sale may combine any and all medical devices in accordance with the policies that the Central Government's Ministry of Health and Family Welfare will occasionally issue, taking into account advancements in technology and the field of in vitro diagnostic medical devices.

6) Fundamentals of medical device manufacturing-

Medical device manufactures must adhere to the fundamentals of safety and functionality as outlined in the guidelines periodically released by the Central Government's Ministry of Health and Family Welfare, taking into account the most recent advancements in science and technology. As long as the parameters that are to be stated comply with both these rules and the Act's stipulations.

7) Product standards for medical devices-

a) The medical device must meet the standards set by the Bureau of Indian Standards, which was founded in accordance with section 3 of the Bureau of Indian Standards Act, 1985 (63 of 1985), or as may be periodically notified by the Central Government's Ministry of Health and Family Welfare.

b) In the event that sub rule (1) does not specify a relevant Standard for any given medical device, the device must comply with any other pharmacopoeial standards or the standards established by the International Electro Technical Commission (IEC) or the International Organization for Standardization (ISO).

c) The device shall comply with the validated manufacturer's requirements in the event that the standards have not been specified under sub-rules (1) and (2).

4. Production of Medical Equipment for Retail or Wholesale Application for manufacture of a Class A or Class B medical device for sale or distribution

a) To manufacture a Class A or Class B medical device, an applicant must apply to the state licensing authority for a license or loan license to manufacture the device for sale or distribution

b) The application under sub rule (1) must be submitted via the Ministry of Health an Family Welfare's designated online portal in the Central Government using Form MD-3 for a license or Form MD-4 for a loan license, along with the appropriate documentation as listed in part 2 of the Fourth Schedule

c) Among other things, the application submitted in accordance with sub rule (1) must be supported by an undertaking attesting to the fulfillment of the Fifth Schedule's requirements for the Quality Management System.

d) Within 45 days of the date the application is made under sub-rule (1), the State Licensing Authority shall, following review of the documents and upon being satisfied that the requirements of these rules have been met, grant a license to manufacture Class A medical devices in Form MD-5 or, if applicable, grant a loan license in Form MD-6. If the authority is not satisfied, it shall reject the application for reasons to be recorded in writing. Assuming that (1) A license or loan license to manufacture, sell, or distribute Class A medical devices shall not be granted without first requiring an audit of the manufacturing site; and Within one hundred and twenty days of the State Licensing Authority granting the license, the body must be completed in the manner outlined in the Third Schedule.

e) Before a license is granted, the applicant's manufacturing site for Class B devices must comply with the standards outlined in the Fifth Schedule of the Quality Management System and any applicable standards as specified by these rules.

This compliance must be confirmed by an audit conducted by a Notified Body, as required by Rule 13.

f) If an application is made for a license or loan license to produce Class B medical devices for sale or distribution, the registered Notified Body must:

1) Audit the manufacturing site in accordance with the Third Schedule's guidelines within ninety days of the application date;
2) After the audit is finished, the Notified Body has thirty days to submit its findings to the state Licensing Authority;
3) Within twenty days of receiving the audit report from the Notified Body, the State Licensing Authority must either approve the application for a license to manufacture Class B medical devices in Form MD-5 or, if necessary, a loan license in form MD-6, or , if disapproving the application for reasons to be documented in writing, grant a license to manufacture Class B medical devices in Form MD-5 after reviewing the relevant documents.

g) If the application for a license or loan license to manufacture goods for sale or distribution is denied under sub-rules (4) or (6), the aggrieved party may file an appeal with the State Government within 45 days of the rejection date. Following an investigation and an opportunity for the appellant to be heard, the appeal may be resolved with in 60 days.

h) The State licensing authority, in the case of a Class A or Class B medical device, or the Central licensing authority, in the case of any Class of medical device, may order a team of officers referred to in rule 23 to cause an inspection of a licensed manufacturing site if they have reason to believe, or if it has been alleged or suspected, that the medical device does not conform to the standards of quality, or if the provisions of the Fifth Schedule are not being followed.

5. Application for producing gadgets that fall under Class C or Class D.

1) To manufacture a Class C or Class D medical device in Form MD-7 or Form MD-8, respectively, an application must be made to the Central Licensing Authority via a designated online portal of the Central Government for a license or loan license.
2) The application in Form MD-7 or Form MD-8, as mentioned in sub-rule (1), pertaining to a Class C or Class D medical device, as applicable, must be submitted with the documentation listed in clause(2) of Part 2 of the Fourth Schedule and a fee as stipulated I the Second Schedule.
3) For the purpose of reviewing applications and other technical documentation, the Central Licensing Authority may, when necessary, engage the assistance of any expert in the relevant field in the case of Class C or Class D medical devices.
4) The Central Licensing Authority must finish the examination mentioned in sub-rule (3) within 45 days of the application's online filling date.
5) Should the documentation be determined to be accurate and full, the Central Licensing Authority will arrange for a rule 23 examination of the manufacturing site, conducted by a term of officers and any specialists deemed appropriate.
6) When necessary, the Central Licensing Authority may use the services of a Notified body as specified in sub-rule 13 (4) regarding the inspection of Class C and Class D medical device production facilities.
7) If the Central Licensing Authority determines that the documents submitted with the application, as mentioned in sub-rule (1), are not complete and in order, it will reject the application, and send the applicant an electronic notice

explaining why. With the caveat that the period mentioned in sub-rule (4) will begin on the day that any flaws that can be fixed are identified by the Central Licensing Authority within the allotted time.

6. Test license to manufacture for testing, assessment, clinical research, etc.

1) The Central Licensing Authority will send a show-cause notice to any license under rule 31 that violates any of these regulations, requesting the license holder to explain why the license should not be revoked.
2) The Central Licensing Authority shall issue an order for cancellation or otherwise and record the reasons there of in the said order after providing the license a chance to defend itself in writing.
3) A license holder who has had their license revoked has 45 days from the date of ruling to file an appeal with the Central Government.

7. The value of medical equipment

An essential part of India's healthcare system in medical gadgets. By assisting with numerous medical disorder's diagnosis, treatment, and monitoring, they enhance patient care. Every gadget, from basic ones like thermometers to sophisticated ones like MRI machines, improves the quality of healthcare. Medical personnel are assisted by medical gadgets in providing precise and prompt interventions.

8. Obstacles

The accessibility and affordability of these devices is a significant issue, particularly in rural areas. Expensive medical equipment is just beyond of reach for many people, and even for those who can, local healthcare facilities may not carry them. Making sure these devices are safe and of high quality is another difficulty. To guarantee that the gadgets being used are dependable and efficient, it's critical to have the right laws and standards in place. These are

only a few of the difficulties, but I think that if we keep working hard and make progress, we can get over them and guarantee that everyone has access to better healthcare.

9. Exist any programs aimed at enhancing rural resident's access to medical devices?

India's rural communities now have better access to medical gadgets thanks to a number of efforts. The Pradhan Mantri Janaushadhi Pariyojana (PMBJP) is one such program that seeks to supply reasonably priced generic medications and medical equipment through Jan Aushadhi Kendras all throughout the nation, including rural areas. People in need can now more easily access a variety of high-quality medical gadgets thanks to these Kendra's much reduced rates. Furthermore, telemedicine initiatives and mobile health units are available to provide medical services, including equipment, to isolated regions. These programs are having a beneficial effects and assisting in closing the access gap to healthcare.

10. Aid in Development of Medical Devices

We can take a few actions to support the expansion of the medical device industry. Supporting and encouraging research and development in this area is one strategy. The creation of more sophisticated and reasonably priced medical devices can result from promoting innovation and investment in cutting-edge technologies. It can also have an impact to support laws that give medical equipment affordability and accessibility first priority. Educating people on the value of medical devices and how they affect healthcare is also crucial. We can contribute to the development of an atmosphere that is conducive to the expansion of the medical device sector by enlightening people and exchanging information. We can all help to improve healthcare if we work together.

11. Medical device efficacy and safety

Strong regulatory framework must be in place to guarantee the efficacy and safety of medical devices. This covers appropriate procedures for quality control, certification, and testing. Prior to being utilized in healthcare settings, medical devices must be evaluated and approved by regulatory bodies. Furthermore, healthcare organizations and professionals should remain current on recommended procedures and maintenance schedules for their devices. For ongoing assessment and development, it's also critical to report any unfavorable outcomes or problems pertaining to medical equipment. We can contribute to ensuring the efficacy and safety of medical devices by upholding a strict regulatory framework and raising awareness among medical professionals. Always put safety first!

12. Illustrations of cutting-edge medical equipment Numerous cutting-edge medical gadgets are revolutionizing the healthcare industry

The portable ultrasound gadget is one such. Even in remote locations, healthcare providers may do ultrasound scans at the point of treatment with this small, portable equipment. An additional illustration would be the smart insulin pen, which tracks dosages and sends out reminders to assist diabetics better control their insulin levels. Smart watches and other wearable health monitors are becoming more and more common. They track indicators of the virus, such as heart rate, sleep habits, and level of activity, and they give useful information to patients and medical professionals.

13. Summary

Regulations necessary for the approval of innovative medical devices must protect patient safety while simultaneously offering inventors efficient channels of entry. The Medical Devices Rules, 2017 and the Central Drugs Standards Control Organization (CDSCO) are in

charge of medical device regulations in India. According to these laws, medical devices are categorized into various risk groups according to their intended use and potential for patient damage. Prior to being marketed and sold in India, medical devices must first pass safety, quality, and performance criteria inspections by the CDSCO. In order to adhere to these rules, manufacturers are required to get the requisite licenses and registrations. To further improve the country's medical device regulations, the government is also trying to adopt the Medical Devices (Amendment) Rules, 2020, a separate regulatory framework. To safeguard patient's health and wellbeing, it is crucial that these laws are in place. Our first concern is safety!

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