THE COMPARATIVE STUDY OF MEDICAL DEVICE REGULATION OF INDIA AND FOREIGN COUNTRIES: A REVIEW

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Medical devices are used vastly used in the healthcare pharmaceutical industry throughout the world. It has become the integral part of modern medical industry. The dependency on the medical device has increased handsomely in treatment of any diseases. This dependency has led to quality issues in medical care. By using medical devices for the treatment of diseases has improved the patient's health, but sometimes they also complicate the condition of the patients, as the body does not accept them and consider them as a foreign body. Therefore, for the manufacturing of medical devices, safety and quality are given prime importance in its regulation. The regulations are different in different countries at present. The medical device regulation of the US, European region, China, Japan, is more stringent and advanced. In India, the Government has come out with medical device regulation in 2017 for manufacturing companies. These are regularly updated based on the western world. But still, Indian regulation is not stringent as some of the medical devices are still notified as drugs to cap price regulation. This paper studies the current scenario in India with other foreign countries regarding the regulations of medical devices. It concludes that we cannot accept any medical device as it is accepted elsewhere. The acceptance must be from the Indian Government; trials must be conducted in India and must be notified and made public for any damages, recalled action. This will help our local manufacturers compete other manufacturers worldwide, create more jobs and economic growth based on the Make in India concept.

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INTRODUCTION

The pharmaceutical and medical device industry from 1950 to 1960 saw an incredible technological advance. In present context, these industries are worth billions of dollars. Medical devices have boosted healthcare by diagnosis, prevention, and treatment of various diseases and serious health conditions, and made it easier and affordable.1-3

The medical devices industry, as mentioned previously, is a multi-billion dollar industry. In 2015 the global market for medical devices was estimated at over $220 billion, and the USA had about 45% market share and a dominant player, followed by European countries having a market share of 30%, Japan having a share of 10%, and other countries having the share of 15% respectively as shown in Figure 1.2-6

India is one of the world's major medical device market having a value of $5.6 billion in Asia. It is proposed that the medical device industry is expected to reach $10.1 billion in 2020 with a projected annual growth rate of 15%.3-4 India's major segments are equipment and instruments, consumables, disposables, implants, and patient aids. India's medical device market depends on 70% imported devices and around 30% of the devices are manufactured in India.3-4 The export of Indian medical devices is very low. The major medical device cluster in India is shown in Figure 2.

Some of India's top medical devices include Johnson & Johnson, General Electric Co., Medtronic Inc., Siemens A, and Baxter International Inc.
Medical Devices

Medical devices are defined as equipment with various healthcare industry applications, ranging from products like catheters, lenses, bone cement, drug-eluting stents, etc. Hence, in 2003 World Health Organization (WHO) set a framework for defining the term medical device rather leaving it to the manufacturer determine whether it is a device or a drug. This framework was developed to distinguish between pharmaceuticals and medical devices. Therefore, each country has developed their own guidelines for regulation of medical devices. Certain countries like the USA, Canada, European countries formed a consortium to regulate medical devices in their countries. Other countries had their own regulatory mechanisms, and India is one of them. WHO initiated the harmonization process to have common regulatory practices, ensuring safety, good performance, and standard quality of medical devices.1-8

The gap of synchronization around the world has also created an issue for recognizing a different class of medical device based on design complexity, its application, and features safety concern if misused.

It is defined in different categories around the world, but they have typically grouped in 3 classes: class I, II, and III (or A, B, C, D). The classification of medical devices is based on the risk related to health from low risk to high risk as shown in Table 1.

Table 1. Medical devices classification

<table>
<thead>
<tr>
<th>Country</th>
<th>Classification</th>
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<tbody>
<tr>
<td>USA</td>
<td>I II III</td>
</tr>
<tr>
<td>European Union</td>
<td>I Ia Ib III</td>
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<td>China</td>
<td>I II III IV</td>
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<td>Korea</td>
<td>I II III IV</td>
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<tr>
<td>Japan</td>
<td>I II III IV</td>
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<tr>
<td>India</td>
<td>A B C D</td>
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In India, the medical devices are classified as Class A – low risk, Class B – low to moderate risk, Class C – moderate to high risk, and Class D – high-risk medical devices.

Medical Device Regulations

USA

The Federal Food Drug and Cosmetic Act regulate the medical device in the United States. Initially, the application is to be filed with the Food and Drug Administration (FDA), and approval must be received before marketing the medical device in the United States. Primary accountability is of the Center for Devices and Radiological Health (CDRH) within the FDA for pre- and post-market supervision of medical devices in the United States.

The US classification is a risk-based classification according to the risk associated with the use of the device. Devices are classified into a 3-level system (Class I-lowest risk; Class II-intermediate risk; Class III-highest risk). Class I devices: They are low-risk devices and do not lead to a likely serious threat of patient ailment or injury. Class, I devices are regulated with general controls, which are well-accepted norms related to labelling, manufacturing, post-market surveillance, and reporting. For Class I devises, no formal scrutiny is needed for their market launch. Class II devices: Devices are those higher-risk devices and require to establish safety and effectiveness because these devices pose a greater risk. Hence they are bound to the regulation of special controls, which are confirmed by FDA. Class II devices needs FDA clearance of a premarket notification 510 (k) process before the device is launched. In the 510 (k) process, the manufacturer has to submit data compared to existing marketed devices. And sometimes, clinical data has to be submitted. Class III devices: These devices are either life-sustaining/supporting for human health. As they have the highest/potent risk of illness or injury, they require premarket approval (PMA) from the FDA to establish safety and effectiveness before the launch.9,10

European Union (EU)

The EU follows the Medical Device Directive (MDD) to regulate the safety and marketing of medical devices in Europe. The European Union (EU) has four-class. Devices are classified into class I (including Is and Im), Ila, Iib, and III. Class III is ranked as the highest and the higher the classification, the greater the level of scrutiny. To market medical devices in the EU, they have to adhere to stringent regulations, and one of them is affixation Conformite “Europe” (CE) marking. CE marking is to be affixed on all the medical devices to ensure their safety and efficacy for use before marketing. The CE marking is given by private organizations known as notified bodies (NBs). The notified body will check the devices, class, and various documents before giving permission for marketing.5,6

Japan

The Pharmaceuticals Medical Devices Agency (PMDA) regulates medical devices in Japan. It analyses, assesses, and suggests decisions to the Ministry of Health, Labour, and Welfare (MHLW); MHLW is a powerful central ministry amalgamating political authorization and accountability for the whole medical device regulation. In 2005, a new law was introduced, which was harmonized with international regulations. The law is known as the New Pharmaceutical Affairs Law (PAL). In this law, a manufacturer is only accountable for production, and the Ministry is accountable for the launch of the product to the market.

Medical devices are classified into General Medical devices (Class I), Controlled Medical Devices (Class II), and Specially Controlled Medical Devices (Class III and IV). A manufacturer has to notify the device, device certification, or device approval based on the class. Medical devices in class I need device notification, in class II need a device certificate, and medical devices class III and IV need a device approval. Clinical trials are not required for class I and not necessary for class II, in very few cases for class III and mandatory for class IV.5-6

India

The Central Drug Standards Control Organization (CDSCO), part of the Ministry of Health and Family Welfare, currently regulates India's medical devices. The
rules were drafted to differentiate medical devices from drugs for better regulation. This regulation came into effect in January 2018. The important feature of the rules is that only those products will be covered, which are defined as medical devices in the medical device regulation 2017.

The medical devices must have the conformity of BIS (Bureau of Indian Standard) or ISO 9001 as quality standards. For obtaining licenses, definite timelines have been developed. For example, a license to manufacture Class C or Class D medical device, the scrutiny has to be completed and submitted in 45 days from the date of the application.

The inspection of the manufacturing site is to be completed in 60 days from the application date, and the report of the inspection has to be forwarded to the applicant. The decision to grant the license has to be communicated within 45 days from the date of receipt of inspection report. Hence, the total period is of 105 days, i.e., approximately around 4 months from the application date.

In case the authorities are not able to take the decisions then such application will be deemed as granted. The license is granted for a period of 5 years and has to be renewed before expiry. If not renewed within the time frame, it will get cancelled and fresh application has to be submitted for license. The decision-making authorities have to decide the clinical trials requirement with respect to the rules and consultation with the state/central licensing authorities. The State Licensing Authority (SLA) is a competent authority for enforcement of the rules relating to the manufacture of Class A or Class B medical devices and the sales, stocking, and exhibition of medical devices and other related functions. In the case of Class C and D Central Licensing Authority (CLA) regulates the high-risk devices, which investigates the clinical investigation and performance of devices and other functions. For manufacturing predicate medical devices the manufacturers need approval from CLA first before applying to SLA. 5-6,11-22 The comparison of the silent features of medical device regulation of various countries is shown in Table 2.

### CONCLUSION

The regulations of medical devices around the world are very different. Hence, it is necessary to have a harmonized regulation for medical device industry. If all the issues are addressed to have a harmonized regulation it will lead to better quality products, reduce safety concerns, and recall products. The issue identified for harmonization are as follows. First is a universal classification of devices to reduce the risk of the wrong classification, substantial data to assess the safety and efficacy of the medical devices, Transparency and streamlining of the regulatory process for review and post-marketing studies and if we address the above issues, the regulation can be strengthened throughout the world and help improve the medical device industry's better growth.

In India’s case, we have to strengthen our regulation and must not have the policy to accept in India if accepted abroad. A clinical trial needs to be carried out in India on imported medical devices, and we need to strengthen our standards BIS, ISO, so they are accepted worldwide. Our
dependency on imported medical devices will reduce, increasing more job opportunities within India, boosting economy under Make in India concept.

ABBREVIATIONS

WHO  World Health Organization  
FDA  Food and Drug Administration  
CDRH  Center for Devices and Radiological Health  
MDD  Medical Device Directive  
PMDA  Pharmaceuticals Medical Devices Agency  
EU  European Union  
CE  Conformite “Europe”  
MHLW  Ministry of Health, Labor and Welfare  
CDSCO  Central Drug Standards Control Organization  
CLA  Central Licensing Authority  
SLA  State Licensing Authority

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