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Research Article

A Study on Evolution of Medical Device Sector in India and Comparison of Registration Process of Medical Devices in India with Countries like China, Australia, USA And Europe

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Abstract
Healthcare sector in India has undergone significant upgrades in the 21st century. Over the years, India has attained a 10% growth rate in this sector and by 2025 it is expected to reach $280 billion. In 2016, percapita spending on healthcare in India was $75 which was negligible in comparison to that of the United States, European Union (EU), China, and the Global average which was $9403, $3613, $420, and $1061, respectively. Today Indian healthcare market size is $128 billion and is expected to grow at 12% for next four years. Indian regulators have made a conscious effort to change their approach to regulating medical devices – from one that is piece meal and need based to one that is systematic and pre-planned. Consequently, an attempt is being made to anticipate developments in this field and to put in place a regulatory framework that is competent enough to test the effectiveness of these developments and can lay down standards to be adopted for their safe deployment. This trend has been welcomed by stakeholders. To further this process, stakeholders need to engage in an effective dialogue with the regulators.
Keywords: Healthcare sector, medical devices, regulatory framework, healthcare market.

Article Info

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1. Introduction

Medical devices have emerged as a key aspect in the healthcare sector of any developing healthcare sensitive nation. These are used for various functions in the field of healthcare, as but not limited to, screening and diagnosis, treatment/care, restoration, and monitoring. The medical device market in India is one of the top 20 medical device markets globally. It is growing at a fast pace of 15% annual growth rate and is expected to touch $50 billion by 2025. The devices distributed in various segments differ in terms of market share in India. Largest segment is of the medical instruments and appliances (34%), followed by diagnostic imaging devices (31%), consumables and implants (19%), and patient aids and others (16%). Approximately 70% of medical devices in India are imported. This gap in import vs. manufacturing provides a big opportunity to medical device manufacturers to fulfill this gap by indigenous manufacture and sales. Currently, the medical device development process is very complex and is time-consuming. Its approval is one of the most structured processes, which is highly regulated and governed by Indian Medical Device Rules (IMDR) 2017 and Medical Devices (Amendment) Rules, 2020. These rules cover various aspects of device-related regulations, including classification, registration, manufacturing and import, labeling, sales, and post-market requirements, etc[1-3].

The new EU Medical Device Regulations (MDR) and *in vitro* Diagnostic Regulation (IVDR), 2017 make notified bodies, competent authorities and the European Commission more responsible than ever before for the safety of medical devices, including *in vitro* Diagnostics. Now all the medical devices need to be reassessed for compliance and certification. In the EU, clinical evaluation is the foremost step for demonstrating and establishing the safety of medical devices. It is also an important instrument for long term safety evaluation and continuous safety monitoring of the devices. The European Parliament and the Council of the EU recently (April 23, 2020) adopted a proposal to extend the transitional period of the MDR by 1 year (26 May 2021) while there is no delay in the IVDR implementation (applicable from 26 May 2022). The updated guidelines have many commonalties with the USFDA guidelines which are stringent with respect to approval process. While clinical evaluation requirements in India as per IMDR are limited to the development phase of only certain medical devices; though post-market requirements are there, they have their own limitations. ASEAN, an economic grouping of 10 countries in Southeast Asia has set up a committee responsible for MD regulatory harmonization - The Medical Device Product Working Group (MDPWG). The MDPWG is in the process of finalization a unified set of rules for MDs, which would be called “ASEAN Medical Device Directive (AMDD)” Currently, out of the 10 ASEAN countries, 6 have laws or “administrative guidelines” that govern MDs. Though AMDD will not be a law in ASEAN countries, but all member countries will be required to pass laws with the same provisions. Product registration will be the major focus area of the AMDD.[8] In Singapore, (a key country within ASEAN), before a device dossier or product registration application is submitted, the Health Sciences Authority (HSA) initially verifies that the product qualifies as a MD under the Health Products Act. Only upon confirmation, the application process actually begins. Registered MDs are listed on the Singapore Medical Device Register (SMDR). Dossier for product registration is based on ASEAN common submission dossier template (CSDT) format. From 1st of May 2010, supply of unregistered Class B, C and D devices will be prohibited.

2. Methodology

Global statistics on MD manufacturers reveal that the US, Japan and EU countries manufacture approximately 85% of the MDs in the world. Implementing a full regulatory programme can be very demanding on resources, especially for a developing nation. A good approach to setting a clear direction for all stakeholders is to establish a comprehensive national policy or guideline on MD. The government can subsequently bring in

legislation and enforcement to suit the country's conditions and needs. The GHTF, a voluntary group of international regulatory affairs experts from United States, the European Union, Canada, Australia and Japan for MDs is working towards harmonizing the regulation of MDs internationally. By following recommendations from the GHTF, countries can ensure that their regulatory controls are not in significant conflict with global harmonization recommendations. GHTF also provides a risk-based device classification system (Ref GHTF document SG1-N015R14).[1] The World Health Organization (WHO), with its partners, is also working towards achieving harmonization, which will have a significant impact on patient safety. The WHO guidelines emphasize the need for establishment license or registration which requires that the vendor either obtains a license or is registered before they are allowed to sell MDs. As per WHO guidance document, a "Vendor" is any person who sells medical devices. This person could be a manufacturer, an importer, a distributor, a wholesaler, or a retailer and a "Manufacturer" is any person who produces MDs. Advantages with registration is many folds. It ensures that the government can i) have a record/listing of the vendor; ii) lay emphasis on after-sale obligations; iii) enforce orders on defaulters like suspension of licenses iv) have a renewal system in place for registration thereby maintaining updated information[4-7].

3. Results and Discussion

Clusters of medical devices in India:

Karnataka: Mainly focuses on the manufacture of Insulin Pens, Cardiac Stents and implants, Medical IT, PCR machines and these products are developed by manufacturers such as Biocon, GE Medical, Skanray, Bigtec Labs etc.

Haryana: Focuses on the manufacture of consumables and dental equipment's and the companies working are BD, Hollister and Poly Medicure.

Delhi: Medtech Innovators such as Standford-India Bio design program.

Gujarat: Manufacturing of stents is supported by Envision Scientific, Invent Bio-Med.

Tamil Nadu: This is a large hub for production of diagnostics, critical life support systems, and Ophthalmology products. Companies manufacturing these are Trivitron Healthcare, Opto Circuits.

Regulatory authorities for medical devices in India:

The Government of India has introduced Medical Device Regulation which has the task to regulate manufacturing and marketing of medical devices and the authorities governing it are:

1. Central Drug Standards Control Organization: Main regulatory body for pharmaceuticals and medical devices
2. The Drug Controller General in India is the crucial official under CDSCO
3. Drugs & Cosmetic Act and Rules govern the manufacture, import, sales and distribution of medical devices.

Medical devices in China

The development of medical device sector in China has attracted much attention from around the world due to the nation's huge market and rising research and development (R&D) capabilities.[1,2] The sales of medical devices in China totaled no more than CNY 14.5 billion in 2000, but increased to CNY 308 billion in 2015. Since 2013, China has been ranked as the second-largest medical device market in the world after the United States.[3,4] The global consumption proportion of medicine to medical devices was 1:0.7 in 2014, while for developed countries, it had reached 1:1.02. However, it was only 1:0.19 for that of China, which indicates its vast market potential for medical devices.

Medical device registration in Australia

To eventually supply a medical device, sponsors need to submit a market authorization application to the Therapeutic Goods Administration (TGA) to include their medical device in the Australian Register of Therapeutic Goods (ARTG).

This guidance provides:

- A summary of the medical device life-cycle
- An overview of what to consider during the design and development phase
- An overview of the pre-market (application preparation) phase
- A guide to compiling your clinical evidence

Medical device registration process in EU

Medical devices cannot be placed on the European market without conforming to the strict safety requirements of the European Union; one of these requirements is the affixation of the CE conformity mark. This article is an overview of the CE marking process only; it is not a document that should be referred to on its own. All manufacturers wishing to gain a CE mark should refer to the official documents.

Medical Device Registration in USA

In order to be marketed in the United States, all Medical Devices must be registered with the FDA. Manufacturing facilities are subjected to FDA inspections to ensure compliance with the American GMP requirements[8-9]. In addition, each establishment where production, distribution, import and marketing of Medical Devices are performed in the U.S.A. must be disclosed and registered

at the FDA, through Establishment Registration, in accordance with 21 CFR 807.

4. Conclusion

Indian regulators have made a conscious effort to change their approach to regulating medical devices – from one that is piece meal and need based to one that is systematic and pre-planned. Consequently, an attempt is being made to anticipate developments in this field and to put in place a regulatory framework that is competent enough to test the effectiveness of these developments and can lay down standards to be adopted for their safe deployment. This trend has been welcomed by stakeholders[10]. To further this process, stakeholders need to engage in an effective dialogue with the regulators. The aim for such dialogue being – to help develop a framework regulatory framework that would make medical devices developed and approved in India, reliable and trustworthy globally. It is imperative for regulatory agencies to work towards achieving harmonized regulatory systems to raise the quality of MDs in their respective country to meet international standards.

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