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Research Article

Comparative Regulatory Insight for Medical Device in India and EU

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ABSTRACT

Medical Device is an emerging market. The specific areas of application and extent of usage of medical devices is ever increasing throughout the world and becoming more and more sophisticated with every passing year. Regulations of Medical Devices vary from country to country. European Medical Agency (EMA) regulates medical devices in EU while the Central Drug Standard Control Organization (CDSCO) is its counterpart in India. Recently introduced guidelines and various amendments provide adequate guidance for the manufacturers, distributors and competent authorities to manage various activities and regulatory processes in an efficient manner. They perform a gap analysis of various regulatory frameworks of their business interests in order to thoroughly understand the inputs required for regulatory approvals across geographic territories. This research highlights comparative study of current regulations in India and EU, pertaining to applications for medical device registration certificates and medical device manufacturing/importation licenses. The recommendations are to be expected to implemented and regulated properly with effective outcome.

Keywords: Importer; CE marking; Medical device; Documentation

INTRODUCTION

Medical device is any instrument, implement, device, appliance, machine, implant, reagent for in-vitro use, material, software or other similar or related article, intended by the manufacturer to be used in combination or alone, for human beings, wherein the software required by its manufacturer is intended to be used exclusively for therapeutic/diagnostic purpose and vital for its proper application for one or more of the specific medical purpose(s) of:

A) Diagnosis, monitoring, preventing, alleviation or treatment of disease,

B) Examination, modification, support or replacement of the physiology process or anatomy,

C) Life sustaining or supporting or system,

D) Conception control [1].

India

In June 2005, CDSCO in India produced Medical Device guidelines and in Jan 2017, MOH notified through GSR. 78 (E) the separate guideline for "Medical Devices Rules, 2017" which came into force from 1st Jan 2018. Before implementing the Medical Device rules of the Medical Device Rules, 'notified medical devices' were considered as pharmaceutical drugs in India according to the Drug and Cosmetic Act, 1940. Hence, it was necessary to have separate guidelines for pharmaceutical drugs and medical devices [2].

Classification

In line with world rules and regulations, there are new rules which are introduced based on the risk the new rules for classification.

Medical Devices are classified by CDSCO and it will periodically publish the classified medical devices on website. To classify the medical devices the importers and manufactures should follow the below mentioned classification list (Table 1). If the medical device classification is in higher grade especially in GHFT countries here also it will be considered as higher grade medical devices.

Table 1: Complete list of compounds and their origin.

Class	Risk level
Class A	Low
Class B	Low-moderate
Class C	Moderate-high
Class D	High

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European Union

On 25 May 2017 the latest MD Regulation (EU) 2017/745 and IVD Regulation (EU) 2017/746 come into effect [3].This replaces the 3 Directives which is existing beginning from May 2020 (for mds) and from mid-2022 (for ivds). The producers were granted this transitional phase to conform to the current MD/IVD regulations (Table 2). Until the time as nbs have been assigned to certify against both the newly introduced regulations, all the mds must meet the important/essential requirements set out in the directives [4,5].

Table 2: Classification of medical device as per EUMDR.

Classes	Risk description	Example
Class I- sterile	Reusable sterile surgical instruments	Sterile gloves. Dressings, etc.
Class I- measuring	Provided sterile and/ or has a measurement function (low/medium risk);	Volumetric urine bag
Class I- basic	Provided non-sterile or will not have measurement feature (low risk)	Non-sterile gloves
Class IIa	Medium risk	Suction equipment, Surgical Blades.
Class IIb	Medium to high risk	Radiotherapy equipment, orthopedic implants
Class III	High-risk	Drug-eluting cardiac stents, Absorbable Sutures, AIMD

Objectives:

- To review regulatory framework for import registration.
- Potential Impact of Medical Devices Regulation, 2017/745
- To compare the detail regulations of Medical Device in EU and India to address compliance.

METHODOLOGY

The research carried out with the collected data by analyzing the terms of the below parameters:

1. Internet using official web page
2. Overview of Regulatory Guidelines
3. Review and compilation of documents

RESULTS

Medical device registration and import regulations in India

Registration procedure: In India, for the medical devices import, registration and import permits are essential. Therefore, an individual who is likely to import medical devices into India must obtain a certificate of registration and import permit. Both production and import license applications are dealing with thru an online portal, SUGAM– an online licensing program is part of the MoHFW.

SLA shall control the manufacturing authorization for products of Class A and B medical device, and the prerequisite for Class C and D licenses will be referred to the CLA. A Quality Assurance Report (QAR) of Class B, C and D goods must be published in accordance with manufacturing license; By comparison, a QAR for medical devices under Class A has to be issued within 4 months from the authorization date of the license for manufacture. In the event that products were not shipped into the nation before the date of the notification, the import is not authorized. The permission of the competent authority is needed for the importation of medical devices into India. Certain products that are already in use are placed introduced in the market for a certain period of time until the request made is denied or accepted [6].

Chapter 5 of the MDR 2017 deals with the import of medical devices for marketing and distributing in the Indian market. International manufacturers may select a competent Indian agent to carry out PMS operations and medical device delivery by holding the license. Any authorized agent who already had a license for manufacturing the medical devices for the purpose of distribution or sale may request for an import license shall be presented to the CLA for all classes of medical devices. Indeed, any wholesaler planning to produce medical devices for import must request for an import license. The mechanism for licensing is governed through MoHFW under central government. The ministry has an electronic database, from which the demand for an import license will be rendered. Use Form MD-14, the submission is submitted with the regional licensing authority (Table 3).

Table 3: List of document to be submitted with form MD 14.

SL. No.	Documents	SL. No.	Documents
1.	Covering letter	2.	Power of attorney
3.	Wholesale license	4.	Free Sale Cert.
5.	Audit report for past 3 years	6.	ISO 13485 Cert.
7.	Full quality assurance	8.	CE Design Certificate
9.	510K cert	10.	Decl. of Conformity
11.	Plant master file General information Personnel Premises and facilities Equipment Sanitation Production Quality assurance Storage Documentation Medical device complaints and field safety corrective action Internal audit Contract activities	12.	DMF-Executive Summary

13.	Subsequent equivalence	14.	Labels and IFU
15.	Device design and manufacturing process flow chart	16.	Essential Principles Checklist
17.	Risk analysis and control summary	18.	Design Verification and Validation
19.	Bio-compatibility	20.	Medicinal Substances Data
21.	Biological safety (TSE/BSE)	22.	Sterilization Validation Data
23.	Software validation/verification	24.	Animal Studies Preclinical Data
25.	Stability validation data	26.	Clinical Evidence
27.	Post marketing surveillance	28.	Batch Release Certificate
29.	Notarized copy of overseas manufacturing site or establishment or plant registrations in country of origin issued by competent authority	30.	Constitution Details of Authorized Indian Agent

As well, the individual is required to present several other documentation together with the verification form. First of all, the submission must have a cover letter in an appropriate template, and the application must have the correct details. In addition, the applicant may apply for a valid Indian medical device distributor wholesale/manufacturer permit. This is an essential condition for submitting a request. The purchaser always needs to present the submission with FSC. A certificate signifies the manufactured medical devices are openly available into the selling country's open market and are allowed for sale and trade globalization is said to be Free Sale Certification.

The supporting documentation often include standard certificates from international manufacturers guaranteeing good quality of the product being imported. A DMF that describes the importing medical device technological, health, and safety-related information and test data. The application should also include a PMF which describes specifics of the medical device's manufacturing process.

In India, there are many items requiring registration including spinal pins, heart valves, syringes, annuloplasty tubes, and needles, cardiac stents, cochlear implants, catheters, etc. Any business company that wants to license or import medical devices lawfully into India must abide by the rules laid down in the New Medical Device Regulation 2017 of CDSCO. In case, in India, there is no registered office of the organization, then the organization will need to appoint an "authorized agent" to manage the registration processes and other functions (Figure 1). An "authorized agent" is the one who have a very important role in the registration process and is also authorize for the follow-up actions [7,8].

1. Business activity

2. PMS

3. Pre-certification.

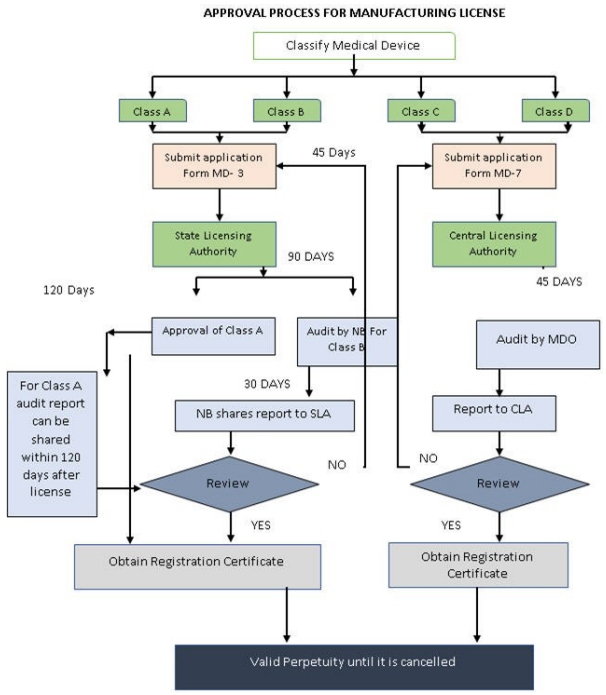

Figure 1: Process of obtaining registration.

Medical devices import procedure in India

A list of documentation is required for importation of medical devices to be submitted with Form MD 14 (Figure 2).

Figure 2: Application for import license *via* SUGAM portal.

Registration certificates

The 2017 Rules also eliminated the need for a certificate of approval to recognize an international manufacturer its location and the goods. Presently we have to make two separate applications to import and marketing products in India (registration and import

license) (Table 4). The international distributor shall designate an authorized agent in India after the start of the Rules 2017 and is applied to get import license to get imported and marketed devices into the nation. After 9 months the claimant will be issued an import permit (Table 5).

Table 4: Timeline to obtain manufacturing/import license for medical device.

Class/Timeline	Class A	Class B	Class C	Class D
Manufacturing license	45 days	140 days	150 days	150 days
Import license	Within 9 months			

Table 5: Potential impact of medical devices regulation, 2017/745.

Parameter	Change	Potential impact
Scope of devices regulated	In new regulation include the some cosmetic devices and the devices using non-viable human tissues	Mainly impacted on the industrial regulators and increased training and the consultancy work increases for newly included devices
Validation of notified bodies	Mainly on the selection of notified body (NBs) with detailed criteria and the monitoring to notified body about requirements.	Shortage of the resourced validated notified bodies and strict requirements for present NBs and increased biocompatibility assessments and the higher costs and longer time periods for approval to manufacturer's
Device testing and inspection	Providing the more health safety and efficiency information details of high-risk devices and the supporting clinical investigation data and increased work for NBs for the providing data for EU reference laboratories which is validated for testing. The second look by the NBs for the biocompatibility for high risk devices, and authorization to conduct the confirmatory testing, NBs analysis of relevant laboratory results, and the unannounced inspection of premises by NBs of the high risk MD premises (e.g. Annually for class III devices)	The more importance on the test laboratory selection and increased release testing and must should be compliance to current standards and More need in biocompatibility /performance test training. Increased interpretation of requirements and standards and less tolerance for gaps in biocompatibility and enhance monitoring of controls on change.
Surveillance	Robust requirements and improved PMS, increased coordination in vigilance case analysis and reactions	Potential for higher expense for manufacturers and supplier Lawsuits.
Manufacturer staffing	The organization of a well-qualified person who will be responsible for regulatory compliance and increased manufacturer's Responsibility	Increased in demand of qualified personnel and increase the resource needed and costs increases

In India, renewal process for certificates is far less rigorous when compared to other countries (Supplementary Table 1). For retaining certificate's permanent validity, the applicant should incur an annual renewal, maintenance charge of Rupees 20,000 (about $310) every 5 from years from the issuance date [9-15].

DISCUSSION AND CONCLUSION

The changes made by Medical Devices Rules 2017 are anticipated to allow more multinational companies (MNC) to build manufacturing facilities for medical devices in

1. From this research project it is inferred that no such strict regulations and rules for the import, production, and selling of medical devices existed till 2017.

2. The approved medical devices need to carry unique device identifiers by 2020. Medical devices licensed for manufacture, selling or delivery in India shall carry two different types of unique identifiers, beginning on January 1st, 2022 to ensure safety and effectiveness, the government is setting up research labs in the country to address shortcomings in medical device goods.

3. Nonetheless, some analysts do believe that the strict regulations will contribute to delays in securing the approval of CE mark and leads to a significant decline in the number of ground breaking CE marked MDs. The EU MDR is projected to dramatically alter MD manufacturers ' activities and even affect the structure of both their current and prospective portfolios.

REFERENCES

1. Medical devices full definition according to WHO in Medical device section 2018.
2. Harish R. Medical devices regulatory priorities in India. Med Device Online 2018.
3. George B. Overview of current regulations governing medical devices. Int J Drug Regul. Aff.2019;7(2):62-6.
4. European Union country Profile 2018.
5. George B. Registration of medical devices. Perspectives in Clinical Research. 2010 Jul; 1(3):90.
6. Nasim F. Manufacture of Class C, D medical devices: CDSCO Makes Centre The Licensing Authority.2019.
7. Budhwaar V, Rohilla Y, Choudhary M, Kumar P. Regulations of registration and import of medical device in India. Int J Drug Regul Aff. 2018;6(1):8-12.
8. Ratna JV, Parimalambica M, Murthy KV. Requirements for introducing Medical devices in India and US market-A comparative study of regulations. Int J Drug Regul Aff. 2018;6(4):9-20.

9. Medical device registration in india. Clini Experts.

10. A guidance document for medical devices draft version 2018 Indian Pharmacopoeia Commission CDSCO.

11. Approval process for Application received Online Sugam Portal with respect to Medical Devices.

12. Medcitynewscom MedCity News.

13. Table of Contents for the EU MDR 2017/745 of 2018.

14. Regulation (eu) 2017/745 of the european parliament and of the council. Official Journal of the European Union. 2017.

15. Radhadevi N, Balamuralidhara V, Kumar TM, Ravi V. Regulatory guidelines for medical devices in India: An overview. Asian J Pharm. (AJP). 2012;6(1).