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Review Article

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A Review of Registration and Approval Process of Medical Device in India and Japan

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Abstract

Today, millions of people rely on medical device-based treatment to manage and diagnose a variety of disorders. The regulatory requirements determine the device's quality and safety. Because of the enormous population and the potential severity of the consequences of introducing inferior and dangerous materials to the market, medical device production in India should be regarded seriously. As a result, a legislation including suitable guidelines for rules and regulations is required to monitor the introduction of such devices into public health use. Currently, the regulatory body CDSCO governs device regulation in India, and amendments to the law will give public health safety ensure over time. In Japan, pharmaceutical regulatory affairs are overseen by the Ministry of Health, Labor, and Welfare (MHLW or Koseirodosho in Japanese). Formal authorization and licenses obtained from the MHLW are required for drug marketing in Japan. The regulatory plans are one of the most difficult components of launching a medical device because every medical device is unique. Every significant market, such as India and Japan, has its own specific set of legal requirements. Understanding the critical need for national standardization in order to reduce regulatory burdens, ease commerce, and provide access to innovative technology requires more research.

Keywords: Medical device, Drug and Cosmetic Act 1940 and Rules 1945, CDSCO, MHLW, PMDA, QMS, MAH, Registration process for medical device.

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1. Introduction

The amount of study into medical devices has multiplied with the growth of technology and greater scientific inquiry. Increasing the output of these devices is the goal. for brand-new, improvised rules on them to ensure consistency in quality and avoid injecting unsuitable products into a marketplace. Each nation has its own governing body for implementing this purpose. Regulatory organizations have developed specific regulations for the manufacture, dissemination and sale of these gadgets. majority of the Asian nations, such as South Korea, Malaysia, In Thailand, Indonesia, Vietnam, the Philippines, and Singapore, medical devices and pharmaceuticals are governed by different regulatory systems. Though, In India, medical devices are subject to regulation. the same medications & Cosmetics Act applies to medications 1940. The Indian government is currently keen on separating pharmaceuticals from medical devices to promote manufacturing, R&D, and imports made into the nation. This article addresses the protocol for using medical devices that is India. (1)

Overview of CDSCO's Medical Device Registration Process in India

Due to massive imports, India is currently one of the major worldwide markets for medical devices. In the past, Indian manufacturers of medical equipment had the freedom to sell their products wherever. Since 2006, all medical devices in India must adhere to the CDSCO's Indian Medical Device Regulations. There is currently a formal process in place in India for the registration of particular types of medical devices that fall under the purview of the Medical Device Rules.

Medical equipment and IVD (In-Vitro Diagnostics) sold in India are governed by the CDSCO (Central Drug Standard Control Organization). The Drug Controller General of India (DCGI) is in charge of the CDSCO, while the SLA (State Licensing Authority) and CLA (Central Licensing Authority) each have a portion of the approval jurisdiction. In India, the Drugs and Cosmetics Act 1940 and Rules 1945 govern the production, import, sale, and distribution of medical equipment. Therefore, in

India, CDSCO Medical Device Registration is required. (2)

Before, there were no rules governing how these devices were made in India. Manufacturers are able to produce any type of medical equipment without a court order. But in 2006, it was made mandatory for the Indian Medical Device Regulations must be followed when importing medical devices into India. Rules established by the CDSCO. Throughout the past. The Indian medical regulatory framework has only recently has grown extremely complex. There are around 30 "families" of devices that describe the medical devices that require registration. (3)

Legal Definition of Medical Device

The new definition as per the notification dated February 11, 2020 states, All devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of -

(i) Diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;
(ii) Diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;
(iii) Investigation, replacement or modification or support of the anatomy or of a physiological process;
(iv) Supporting or sustaining life;
(v) Disinfection of medical devices; and
(vi) Control of conception. (4)

Applicable Laws

- Section 3(b)(iv) of the DCA- Provides for definition of drugs vis-à-vis medical devices.
- MDR (notified on 31 January 2017) provides for rules & regulations regarding manufacturing, sale, import and labelling of medical devices.
- MoHFW vide the second notification (No. S.O 648[E]) dated February 11, 2020 in pursuance of Section 3(b)(iv) notified new medical devices to be considered as drugs as per Section 3(b) of DCA.
- In accordance with the Medical Devices (Amendment) Rules, 2020 (Notification No. GSR 102 [E]), newly notified medical devices must be registered.
- A provisional registration number can be generated under the Medical Devices (Amendment) Rules, 2022 (Notification No. GSR 19 [E]). (4)

Eligibility to Apply for the Medical Device Registration

- Domestic Manufacturer
- IAA (Indian Authorised Agent) of the Manufacturer
- Any foreign enterprise holding Indian Subsidiary
- Importer (4)

1.2 Classification of Medical Devices (5)

Table 1. M.D Classification in India

Class A	Class B
Low Risk	Low Moderate Risk
eg. Absorbent cotton wools, Alcohol swabs	eg. Thermometer, BP Monitoring Device
Class C	**Class D**
Moderate High Risk	High Risk
eg. Implants, Haemodialysis Catheter	eg. Angiographic Guide Wire, Heart Valve

Information on classes of medical devices

- **Class A and B**
- Manufacturer must submit an application through a designated Ministry online portal with the required paperwork as per the Fourth Schedule and the fees listed in the Second Schedule.
- No class A device audit is required before a license is granted.
- Within 120 days after the license's issuance date, the audit may be completed.
- Prior to issuing a manufacturing licence, a Class B device audit must be completed, and it must be completed within 90 days of the application date.
- The notified body has 30 days to submit its report to SLA.
- **Class C and D**
- The application must be submitted to CLA via the central government's online portal with the necessary paperwork and costs.
- Within 60 days of the application date, CLA may conduct an inspection with the assistance of any expert and notified body.
- If a facility is already licenced to produce medical devices, there is no need to inspect it in order to award a loan licence.
- When the inspection is over, the inspection team must send the report.
via the internet link to CLA. (6)

Registration Process for Medical Device

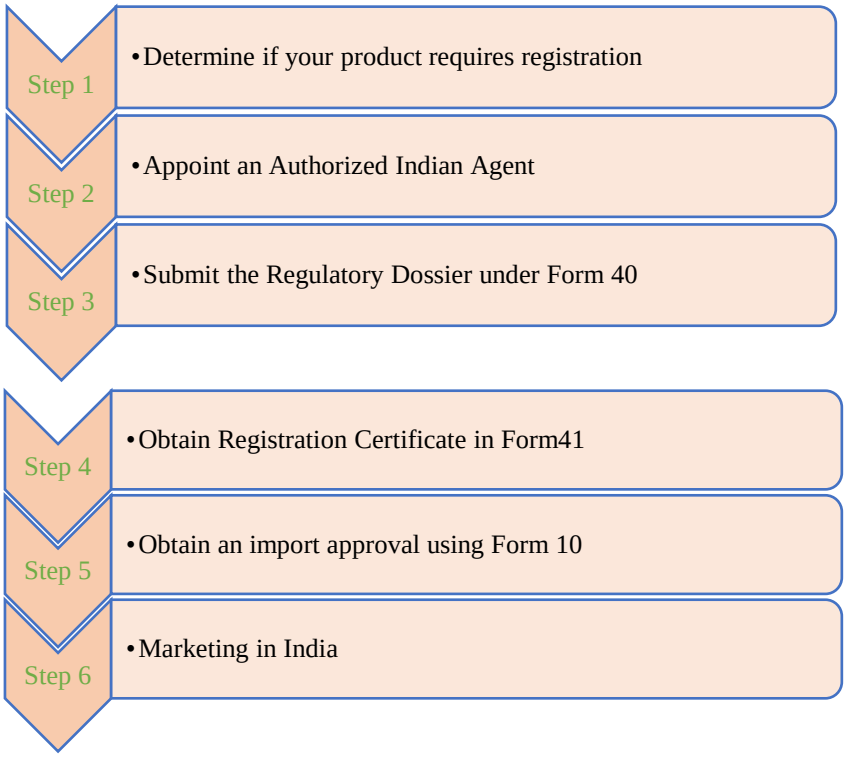

Figure 1. M.D Registration Process in India

2. Information on Registration Process of Medical Device

Step 1: Determine if your product requires registration

Under the Drugs and Cosmetics Act, 1940 and Rules, 1945, the import, manufacturing, sale, and distribution of medical equipment are all regulated in India. Currently, the aforementioned Act regulates 22 Notified Medical Devices. Spinal needles, cochlear implants, annuloplasty rings, trachestomy tubes, syringes and needles, surgical sealants, heart valves, cardiac stents, orthopaedic implants, endotracheal tubes, and catheters are just a few examples of medical equipment that must be registered in India. The CDSCO (Documents required to register your medical device in India) should be contacted to register these devices.

Step 2: Appoint an Authorized Indian Agent

An authorised Indian agent can be appointed by a manufacturer to register on their behalf with the CDSCO. This agent will serve as a liaison between you and the CDSCO's Medical Devices Division. A wholesale medicine licence in categories 20B and 21B should be held by the designated Indian agent. The maker will hold the registration certificate and be able to choose numerous distributors throughout the nation.

Step 3: Submit the Regulatory Dossier under Form 40

To begin the registration process, a dossier with the necessary list of documents must be completed. An outline of the necessary documents is provided below.

- Form 40
- TR6 Challan
- Power of Attorney
- Schedule D (1)
- ISO 13485 Certificate
- Full Quality Assurance Certificate

- CE Design Certificate
- Declaration of Conformity
- Free Sale Certificate
- Certificate of Marketibility from GHTF countries
- Other Regulatory Approvals
- PMS report
- Plant Master File
- Device Master File
- The CDSCO charges US $1500 for registering a single production site and US $1000 for a single product family. The duration of the registration process could range from 6 to 9 months. The procedure time will increase and a special committee will be formed to assess the products' safety and efficacy for the Indian market if they lack a predicate in India.

Step 4: Obtain Registration Certificate in Form 41

After the document submission the CDSCO will get back to the Indian Agent with first query letter in about 3 Months' time Upon receiving the answers for the query the CDSCO will either issue a subsequent query letter or grant license. The registration certificate is valid for 36 Months.

Step 5: Obtain an import approval using Form 10

Distributor must submit the Form 10 directly to CDSCO. A Form 8 application must be submitted with a Form 9 that includes the registration certificate number: 4 to 12 weeks are required for this process.

Step 6: Marketing in India

Once the registration certificate and the import license are issued the product can enter the Indian market Any changes, negative experiences, recalls in other countries, etc. should be immediately reported to the CDSCO by the authorized Indian agent. (7)

Role of the Central Drugs Standard Control Organization (CDSCO) in PMS (Post Marketing Surveillance)

To maintain compliance with PMS requirements, India's regulatory body Central Drugs Standard Control Organization (CDSCO) is essential. They make sure that producers of medical devices carry out post-market surveillance investigations and submit routine PMS reports outlining the findings of their surveillance operations. The Materiovigilance Programme of India (MvPI) was authorized by the Ministry of Health and Family Welfare (MoHFW), Government of India (GoI), and launched in the nation in 2015 with the sole purpose of ensuring the safety and caliber of medical devices used in the nation. Manufacturers, importers, distributors, healthcare professionals, and others can use the adverse event reporting form that MvPI has made available as well as the monitoring centers it has set up. If PMS rules are not followed, there may be consequences such as fines, penalties, or even product recalls.

Future of PMS in India for Medical Devices

The future of post-marketing surveillance (PMS) for medical devices in India is anticipated to be influenced by a wide range of factors, including developing technology, shifting regulatory frameworks, and growing collaboration between regulatory authorities and medical device manufacturers. One significant development that is projected to have an impact on PMS in India is the growing use of digital technology and artificial intelligence (AI) in medical devices. By providing real-time data on device performance and patient outcomes and by making it simpler to identify patterns and trends in adverse events, these technologies expand the potential of PMS. Manufacturers and regulatory agencies can immediately detect and address any safety issues or product faults by reviewing this data.

In order to retain patient trust and confidence in medical devices, producers must abide by the regulatory regulations. PMS plays a crucial role in guaranteeing the safety and efficacy of medical devices in India. Adopting an efficient PMS is not without its challenges. To find out more about PMS in India, get in touch with our regulatory specialist right away. (8)

3. Japan

Introduction

The healthcare market in Japan, which has the largest and most advanced healthcare system in the area, presents many difficulties for international manufacturers of medical devices. With success in the Japanese market, medical device makers can expand their business to new heights thanks to predicted growth of about 7% and a $29.3 billion market value. Japan is a market that needs to be taken into account for all medical device manufacturers aiming for significant growth in Asia due to its aging population, high per capita income, and enormous demand for high tech products. Self-care, preventative care, at-home care, health IT devices, and enhanced diagnostics that leverage AI to support assessment and treatment options are other high potential specialist areas.

Despite this, several device sectors, such as those for home therapeutic equipment, diagnostic imaging equipment, dialyzers, endoscopes, and surgical equipment, will face problems on the highly developed Japanese market. The Ministry of Health, Labour and Welfare (MHLW) oversees the medical device market in Japan, and like other markets, they have put in place systems to assist keep costs down, particularly given their increasingly aging population. One of these techniques is the adoption of a strong reimbursement system that is applicable to both private and public insurance policies.

They have also created a Cost-Effectiveness Assessment (CEA) system and recently enacted the 2018 Basic Policy on Economic and Fiscal Management and Reform, colloquially known as "honebuto," to monitor welfare spending and give suggestions for enhancing the reimbursement system. Foreign manufacturers of medical devices are strongly advised to investigate how their products will be valued and priced at the initial phases of market strategy development. (9)

Japan MHLW and PMDA Medical Device and Pharmaceutical Regulation

The organization in charge of enforcing laws governing food and medications in Japan, the Ministry of Health, Labor, and Welfare (MHLW), also develops and enforces safety standards for pharmaceuticals and medical equipment. The Pharmaceutical and Medical Device Agency (PMDA), a separate organization that works with the MHLW, is in charge of examining applications for drugs and medical devices. The PMDA works with the MHLW to assess the safety of new products, develop comprehensive regulations, and monitor post-market safety.

The Pharmaceutical Medical Device Act (PMD Act)

The Pharmaceuticals and Medical Devices Act (PMD Act), also referred to as the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics, outlines the current PMDA rules in Japan. All facets of the Japanese medical product registration process, including as in-country representation, certification procedures, licencing, and quality assurance systems, are impacted by the PMD Act. On November 25, 2014, the Pharmaceutical Affairs Law (PAL) was replaced with the PMD Act. The regulations main components are as follows:

- Certain Class III medical devices can go through independent certification.
- Programmes for creating medical software are independently governed.
- Manufacturers must register rather than obtain a licence.
- Systems for quality management (QMS) have been streamlined. The Japanese Marketing Authorization Holder is the subject of a QMS inspection, which is carried out per product family rather than per item. (10)

Classification of Medical Device

Table 2. M.D Classification in Japan

Class I General medical Device eg. X-ray film, steel surgical instruments	**Class II** Controlled /Designated controlled medical device eg. MRI units, dental alloys
Class III Specially controlled medical device eg. Artificial bones, Dialyzer	**Class IV** Specially controlled medical device eg. Pacemaker, Artificial heart valves

Information on Classes of Medical Devices

Class I

Other than particularly controlled medical devices and controlled medical devices, general medical devices (Class I) are those that MHLW deems to represent a practically negligible risk to human life and health in the case of malfunction or adverse effects. Although they do not need approval, communication to PMDA is necessary, and the conditions listed below must be satisfied.

After completing a registration procedure called as notification, Class I medical devices can be marketed. Applications for notice should include information about the equipment, such as its appearance, characteristics, materials, and manufacturing method. Notification is a self-certification process that does not include evaluation.

No QMS Audit is required.

- A third-grade Marketing Authorization Holder (MAH) license is required of the application.
- The manufacturing facility needs to be licensed to produce medical devices.

Class II

Other than specially controlled medical devices, controlled medical devices/designated controlled medical devices (Class II) are those that MHLW deems to need management due to the relatively low risk they may in the case of a malfunction or side effects, represent a risk to human life and health.

The majority of Class II medical devices need to be certified, which entails inspection by an Registered Certification Body (RCB). RCBs carry out reviews in accordance with the relevant certification standards and put QMS audits into practice.

Class II medical devices that fall short of certification standards must go through the approval process. See the descriptions for Classes III and IV below for more information.

Class II medical equipment are subject to the following additional regulations:

1. Medical devices that do not meet appropriate certification standards fall under the category of regulated medical devices and require PMDA approval review.
2. Medical devices classified as restricted medical devices must have their certification requirements assessed by a Registered Certification Body (RCB) in order to be certified.
3. Typical specifications for class II medical devices.
    - The candidate must hold an MAH license for the second grade.
    - The producer needs to be licensed to make medical devices.
    - The MHLW regulation 169's requirements for quality management systems (QMS) must be followed by the manufacturer.

Class III & IV

Class III and Class IV medical devices are those that MHLW has determined need special care due to the relatively significant or potentially deadly risk to human life and health they pose in the event of malfunction or adverse consequences. These gadgets fall under the Class III or Class IV categories.

Applications for Class III and Class IV medical device approval must be submitted, and PMDA (the Pharmaceuticals and Medical Devices Agency) will review them. There are various application categories as stated in the table below since Class III and Class IV encompass a wide range of medical equipment. The application categories affect the requirements, review period, and price. (11)

Medical Device Clinical Trials in Japan

As medical gadgets get more complicated, clinical trials for new ones are popping up more frequently. Clinical data proving the usefulness and safety of devices are required due to the increased complexity. Now, American businesses are attempting to enter Japan's expanding medical equipment sector. The creation of clinical trial strategies would be impacted by the recently updated Japanese Pharmaceutical Affairs Law (PAL), according to clinical and regulatory affairs managers.

The Japanese government is updating its regulatory framework for medical devices to keep up with developments in science and the global medical device industry. The Ministry of Health, Labor, and Welfare (MHLW) started the first stage of its extensive modernisation effort in April 2004. The Organization for Pharmaceutical Safety and Research (OPSR), the Japan Association for the Advancement of Medical Equipment (JAAME), and the Pharmaceuticals and Medical Devices Evaluation Center (PMDEC) were all combined into the new Pharmaceuticals and Medical Devices Agency (PMDA). Previously, the three pillars of Japan's device and pharmaceutical regulation system were PMDEC, JAAME, and OPSR.

The government of Japan has made significant modifications to clinical trial regulation in an effort to enhance patient safety and the standard of clinical research. Additionally, the ministry's clinical trial evaluation procedures will be streamlined by the government. This article concentrates on the new PAL rules pertaining to the design and execution of clinical studies.

Clinical Trial Notification

As a result of the PAL modification, clinical investigation sponsors are now required to file a clinical trial notification (CTN) 30 days before to the start of a new device study. The amendment also mandates that adverse events that happen during a clinical trial be reported to MHLW. Additionally, it has clauses protecting patient privacy. Similar to a U.S. IDE application, the CTN includes a device description, preclinical data, a clinical trial protocol, and an analytic plan. (12)

Market Authorization Holder (MAH) (13)

Japanese DMAH Agent To commercialize devices in Japan, foreign manufacturers are required to appoint a commercialize Authorization Holder (MAH) or Japan DMAH agency. The Designated Market Authorization Holder (D-MAH) can be appointed, according to the PMDA. In the first situation, MAH is in charge of and owns the product's registration, certification, and approval. In the second instance, a foreign manufacturer owns and is in charge of the product's registration, certificate, and certification, with D-MAH serving as their agent in Japan. Because it is simpler to replace a D-MAH than an MAH, it is preferable to appoint one.

Foreign Manufacturer Registration (FMR)

The Ministry of Health, Labor and Welfare (MHLW) requires all foreign manufacturers who want to sell their products to Japan to register. Foreign Manufacturer Registration (FMR) is the new name for the registration process that was formerly known as "Foreign Manufacturer Accreditation (FMA)" or "Accreditation of Foreign Manufacturers (AFM)".

Pre-market Submission

Manufacturers may submit a pre-market submission to the PMDA for general medical devices (Class I). There will be no review or evaluation by the PMDA of this notification.

Pre-market Certification

It applies to Class II (and a few Class III) devices that must undergo pre-market certification and have an associated certification standard (JIS). Similar to the European CE Marking procedure, reviews are contracted out to a Notified Body or other outside organization.

Registration Process for Medical Device (13)

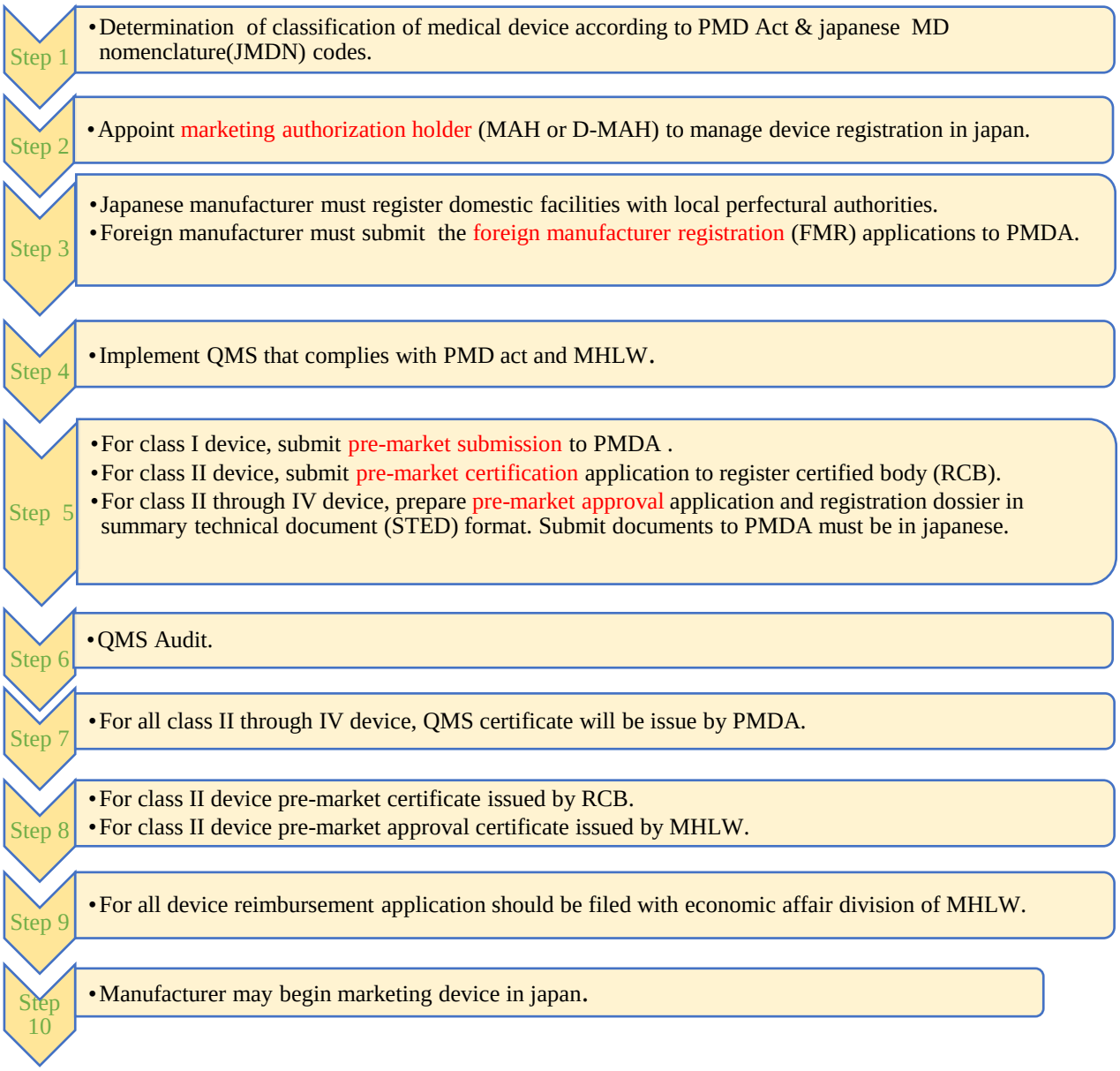

Figure 2. M.D Registration Process in Japan

Pre-market Approval

All Class IV devices and some Class II and III devices without a specified certification standard are subject to the pre-market approval procedure, often known as Shonin. The MHLW must ultimately approve this proposal after it is presented to the PMDA. (14)

Post Marketing Surveillance

Manufacturing/Marketing Authorization Holders (MAH) selling medicines or medical devices in Japan are obligated to conduct post-market surveillance. A product recall and/or loss of market access could result from failure to comply with reporting obligations. In Japan, post-market surveillance entails documenting and disclosing negative incidents, or fuguai, as well as taking appropriate corrective action when necessary.

The Ministry of Health, Labor, and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) are both in charge of post-market surveillance. Together, the organizations list package inserts, product recalls, patient drug information, other urgent safety alerts, reports on adverse drug reactions, and adverse events of medical devices that have been submitted to the PMDA in order to gather information on adverse events and promote the safe use of medical and pharmaceutical devices. (15)

4. Comparative Chart of Medical Device in India and Japan

5. Conclusion

India has become a "World Pharmaceutical Hub," yet its regulatory body is still having trouble keeping up with the expansion of the global economy. The Indian medical equipment market has advanced considerably. Prior until this, India's regulations governing medical devices lacked clarity. As a result, the Indian Ministry of Health and Family Welfare published new "Medical Device Rules" to provide a strong regulatory framework for the country's

growing medical device industry. In recent years, Japan's system for approving drugs and medical devices has undergone significant reform and modernization. Although the government has set ambitious targets and the PMDA and MHLW have significantly improved, approval times still lag behind those of other developed nations. In this article I conclude that registration and approval process of medical device in India and Japan needs to be more stringent to ensure the safety and efficacy of medical devices.

Table 3. Comparative chart of M.D in India and Japan

Sr. No.	Contents of comparison	India (16)	Japan
1.	Regulatory Authority	DCGI under CDSCO	Pharmaceutical and Medical Devices Agency (PMDA) (17)
2.	Regulation	Medical Device Rules, 2017	Japanese pharmaceutical affairs law and new pharmaceutical and medical device act (18)
3.	Class of medical device	Four Class: Class A Class B Class C Class D	General – CLASS I (low risk) Controlled – CLASS II (medium risk) Specified Controlled – CLASS II (medium risk) Highly Controlled – CLASS IIIa (high risk) Specified Highly Controlled – CLASS IIIb (high risk) Highly Controlled – CLASS IV (high risk) (19)
4.	QMS requirement	ISO 13485:2016	ISO 13485:2003 (20)
5.	Submission format	Paper / Electronic	Electronic common technical document (eCTD) regulations in the review process (21)
6.	Language	English	According to the Pharmaceutical Affairs Law of Japan, all marketing application forms must be presented in Japanese (22)
7.	Clinical evidence report	Mandatory for class C and D devices	Mandatory for Class III and IV medical device is authorized in Japan, manufacturer needs to provide evidence of the clinical performance and safety, and clinical benefits of medical device in a clinical evaluation (23)
8.	In country clinical test	Not strictly required	Required (By Sakigake pathway) (24)
9.	Registration expiry	3 Years	The QMS certificates must be renewed by the sponsor every five years even though the medical device registration is perpetual (25)
10.	Time requires for approval	6-12 months for the notified device	Depending on the device's classification, take between one and three years (26)
11.	On site audit	Applicable (Notified Bodies)	The main law outlining the specific requirements for QMS is Ministerial Ordinance 169. Some Class III and most Class IV medical devices require physical on-site audits for QMS compliance (27)

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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