ejpmr, 2024, 11(10), 488-497

SJIF Impact Factor 7.065

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

Research Article

ISSN 2394-3211

EJPMR

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES IN INDIA AS PER CENTRAL DRUGS STANDARD CONTROL ORGANIZATION COMPARISON WITH SPAIN

[1*]Dr. P. Ashok Kumar, [2]Ashritha, [3]Bhoomika K., [4]Meghna S. R., [5]Rathna N. R. and [6]Trishmita Saha

[1*]Professor, Sree Siddaganga College of Pharmacy, Mahalakshmi Nagar, Batawadi, Tumkur-572103, Karnataka, India.
[2,3,4,5,6]Department of Pharmaceutical Regulatory Science, Sree Siddaganga College of Pharmacy, Mahalakshmi Nagar, Batawadi Tumkur-572103, Karnataka, India.

***Corresponding Author: Dr. P. Ashok Kumar**

Professor, Sree Siddaganga College of Pharmacy, Mahalakshmi Nagar, Batawadi, Tumkur-572103, Karnataka, India.

Article Received on 27/08/2024 **Article Revised on 16/09/2024** **Article Accepted on 06/10/2024**

ABSTRACT

Any Country's Regulations and Processes Pertaining to the medical device industry must be followed in order to get into the country Since ancient times, medical gadgets have been utilized for both diagnosis and treatment of illness. Trephination has been documented in Neolithic times, and Jericho archaeological digs have revealed instruments dating back as 2000 BC. The Central Drug Standard Control Organization (the CDSCO) is the regulatory body in India for medical devices, overseen by the drug controller general of India (DCGI). These guidelines address a number of device-related topics, such as post-marketing procedures, labelling, sales, manufacturing and import, categorization, registration, and labeling.

KEYWORDS: CDSCO, DCGI, DMF, PMF, AEMPS, GHTF.

INTRODUCTION

The definition of medical device follows a schedule. In contrast to medications, medical devices are defined in M III as medical tools "which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means." This distinction between medical device and drugs is made clear.

An instrument, apparatus, implant, in-vitro, reagent, or other like correlated item used for the diagnosis, prevention, or treatment of disease or other disorders is referred to as a medical device (MD). Since ancient times, medical gadgets have been utilized for both diagnosis and treatment of illness.

A medical tool that "does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means" is what is referred to as a medical device, as defined by schedule M-III, which distinguishes medical devices from drugs.

Schedule M-III will not apply to medical products covered by the Drugs and Cosmetics Act (DCA). Medical devices will be categorized under schedule M-III into four classes A, B, C, and D, based on the degree of risk associated with them.

RESEARCH METHODOLOGY

There was no mention of distinct rules for the import, manufacturing sales, and distribution of invitro diagnostic medical equipment in the drugs and cosmetics Act 1940 and Rules 1945.

Medical equipment and drugs are not the same in many ways. Therefore, it is not advised to regulate these under the same set of rules.

Medical Devices approved by government of India

The Ministry of health and family welfare, notified the medical device rules 2017 vide G. S. R. 78 (E) dated 31.01.2017 under the provision of drugs and cosmetics act, 1940. the said rules came into effect from 01.01.2018 to regulate the clinical investigation, manufacture, import, sale, and distribution of the medical devices in the country.

APPLICATION

1. Materials covered by subclause that are used for in vitro diagnostics, surgical dressings, bandages, staples, sutures, ligatures, blood, and blood component collecting bags with or without anticoagulant.
2. Materials such as pesticides, disinfectants, and mechanical contraceptives (condoms, IUDs, tubal rings) reported under subclause.

3. Devices that are periodically informed under subclause (iv), of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940.

CLASSIFICATION

Medical devices are classified as per the risk level and intended uses.

Classification by CDSCO and MDD.

1. Class A – Devices involving low risks levels (Thermometer).
2. Class B – Devices involving low to medium risk (Hypodermic Needle).
3. Class C – Devices involving moderate to high risk (Lung ventilator).
4. Class D – Devices involving high risk (Heart valve, implantable device).

Figure No. 1: Classification of Medical Device.

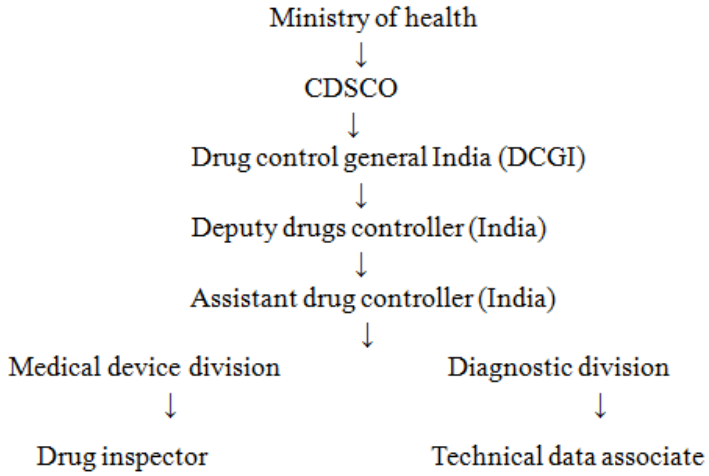
Classification by EUMDR

Medical devices in Spain are classified according to their risk level, intended use, and duration of contact with the body. The classification system is similar to the one used throughout the EU

- Class I: Devices with the lowest risk. Examples include bandages, manual wheelchairs, and some dental instruments. Class I devices are further categorized into
  - Class I: Non –Sterile: Devices that do not need to be sterile.
  - Class I: Sterile: Devices that need to be sterile.
  - Class I: with Measuring Function: Devices with measuring functions, such as thermometers.
- Class II a: Devices with a moderate risk. Examples include infusion pumps and hearing aids. This class is further divided into.
  - Class II a: Devices with lower risk within the moderate range.
  - Class II b: Devices with higher risk within the moderate range.
- Class III: Devices with the highest risk. Examples include implantable devices, such as pacemakers and prosthetic joints.

Regulatory Authorities for Medical Devices

Organizational structure



Device Class / Activity	Class A	Class B	Class C	Class D
IMPORT	CLA	CLA	CLA	CLA
MANUFACTURE	SLA	SLA	CLA	CLA
Permission to conduct CI	Permission from CLA			
SALE	SLA			
QMS Verification by	*Notified Body	*Notified Body	CLA	CLA

*Note: Notified Bodies shall be registered with Central Licencing Authority. Prior inspection shall not be required before the grant of manufacturing of Class A devices.

Figure No. 2: Regulatory Authority of Medical Device.

Regulation in India

In India, the Ministry of health and family welfares directorate general of health services under the auspices of CDSCO (central Drug Standard Organization). India's medical device regulation structure; Ministry of health and welfare Drug controller general of India. Central drugs standard control organization (CDSCO) - medical devices division.

Manufacture of Medical Devices

1. Application for the grant of license for manufacture of these notified sterile devices in the country shall be made in form 27 to the state licensing authority, accompanied by the requisite fee in the form and manner as prescribed in the said rules along with a copy to the office of DCG (I).

2. A period of 60 days would be provided for making the application for manufacture from the date of publication of this guideline.

3. In case of devices belonging to above said categories which have not been manufactured in the country before the date of notification, no manufacture would be permitted hence fourth without the approval of the competent authority as per norms prescribed.

4. The applicant shall provide the following information along with the application for consideration of the licensing authority.

Permission to Manufacture New Medical Device (M D 26, 27)

In accordance with the 2017 Medical Devices Regulations, medical devices that are to be imported or manufactured in India and do not have a corresponding medical device must file an application using from MD-14.

FORM MD -14: A request for authorization to produce or bring in new medical equipment that does not already have a counterpart in India.

FORM MD -15: This form is used to obtain approval to import or manufacture medical equipment that are not already manufactured in India.

How to Apply

Product evaluation to determine whether MDR 2017 registration is necessary. Classification evaluation according to product risk category document preparation following the MD 14 checklist.

Designate an authorized agency in the event that the product is imported. The application is generated online. The authorized agent or manufacturer must approve or confirm the draft application before it can be submitted. Follow-up with SEC and the regulatory body regarding the clinical investigation waiver.

If the clinical investigation waiver is granted, the application in Form MD-27 is approved.

Fee Involved in Obtaining Licencing

The required payment to obtain authorization to produce or import or import medical equipment without a corresponding device is INR 50,000.

Important Documents to Be Submitted to the Cental Licensing Athority to Get a License

> Wholesale license.
> A copy of a foreign manufacturing plant or registration of establishment. This copy must be notarized.
> Free sale certificate from GHTF.
> Data for design analysis.
> Biocompatibility tests data.
> Risk management data.
> Animal performance data.
> Safety and performance data.
> Pharmacovigilance data.
> A copy of letter which shows approval status in countries like United Kingdom. United states of America. Australia, Canada, Japan, EU. The approval letter must contain the number and date.

Import Of Medical Devices

The Country's import of medical devices has increased over the last three years due to initiatives by the federal

and state governments to support domestic medical equipment manufacture. India increased its imports of medical gadgets from $5.84 billion in 2019-20 and $5.7 billion in 2018-19 to $6.24 billion in 2020 - 21.

Application for Grant of Import License

- An authorized agent who possesses a license to manufacture medical devices for sale or distribution, or a wholesale license for the same, must apply for a medical device import license to the central licensing Authority using Form MD -14. This application must be submitted through a designated online portal of the Ministry of the Health and Family Welfare in the Central government.

- The application under sub-rule shall be accompanied with the fee as specified in the second schedule along with respective documents as specified in the fourth schedule.

- Provided that any change in the documents submitted at the time of application and prior to grant of license shall be informed, in writing, to the central licensing authority.

- The same authorized agent may provide a license for a second medical device produced at the same manufacturing facility, provided that the license is accompanied by the fees listed in the second schedule and the appropriate paperwork listed in the Fourth schedule.

Recent Advertisement

- Healthcare companies must keep ahead of the curve when it comes to medical device trends because the medical device sector is always charging. 2023 is not an anomaly. A business can get a competitive advantage by staying up to date with the newest medical device trends, as new technology and inventive breakthrough emerge.

- The most innovative developments in medical technology for 2023 are examined in this article, which cover everything from 3D - printed implants to 5G telecommunication. Each trend's underlying technology will be examined, along with potential future effects on healthcare organization.

New Invention in Medical Devices

- Technology and medicine have gone hand and hand for many years. Consistent advances in pharmaceuticals and the medical field have saved millions of lives and improved many others. As the years pass by and technology in healthcare continues to improve, there is no telling what medical advances will come next. Here we have rounded up the top new medical technologies, they are.
  - 3D Printing.
  - Medical robots.
  - Wearable's (bio patches, smart eyewear, tracking stress level and sleep apnea, diabetes management.
  - Immersive technologies.
  - Smart bandages.
  - Bluetooth enabled pacemaker devices.

Clinical Investigation of Medical Devices and Clinical Performance Evaluation of New in Vitro Diagnostic Medical Device

Conduct of Clinical Investigation

- No sponsor or individual may carry out a clinical study with an experimental medical device on human subjects unless they comply with these guidelines and the central licensing authority s authorization.

Application for Grant of Permission to Conduct Clinical Investigation

- A Sponsor must submit an application in Form MD - 22 to the central licensing authority in order to request permission to conduct clinical research for an experimental medical device. The application must include the formation listed in the seventh Schedule.
- Application for approval to conduct a pilot clinical trial on an investigational medical device, as mentioned in the second schedule and the seventh schedules list of fees.

CLINICAL TRIALS

- Clinical trials and clinical assessment of medical devices in India follow the guidelines outlined by the global Harmonization Task Force (GHTF), Which are also adopted by the USA, Australia, Japan, Canada, and European union. The GHTF Study Group 5 recommendations on clinical evaluation and investigation have urged the industry to be followed by (GOI). Good clinical practices for more conversation and potential acceptance. The purpose of the document is to offer suggestions that are not mandatory for carrying out clinical trials of medical devices in India.

- Medical device trails ought to take in to account all of the main principles of clinical trials that are outlined for medication trials. When it comes to medicated devices, pre-market certification should be based on a safety assessment, pre-market efficacy of the devices for one to three years, and data on adverse responses. The relevant authorities may determine, on case-by-case basis, the length of the trial and the scope of use.
- Detection, diagnosis, prevention, monitoring.
- Treatment or alleviation of any physiological condition or state of health. Or illness.
- Replacement or modification or support of the anatomy or congenital deformity.
- Supporting or sustaining life.
- Disinfection of medical devices.
- Control of conception.

However, the following important factors that are unique to medical devices should be taken into consideration while evaluating the related research projects.
1. It is important to gather safety information about the medical equipment in animals and to take into account any possible dangers.

2. Un like medication trials, medical device clinical trials cannot be carried out on volunteers who are in good health. therefore, trials on medicated devices do not require phase I trials.

3. Compared to those used on or outside the body, medical equipment utilize inside the body, such as orthopedic pins vs. crutches, may have a higher risk of injury.

4. The risk potential of medical device that are not used frequently is lower than that of those that are, such as contact lenses versus intraocular lenses.

5. Research design for intra-body devices, such as implants, can be extremely difficult and needs sufficient safety precautions. The research ought to be extensive.

Documents required for clinical trail application of notified medical device in India.
1. Covering letter.
2. Duly filled application in form 44: Application for grant of permission to import or manufacture a new drug or to undertake clinical trial.

i) Particular of Subject Device
- Generic Name
- Brand Name
- Composition of device
- Specification /standard of device
- Qualitative and quantitative particulars of constituents
- Generic Name
- Brand Name
- Composition of device
- Specifications/standard of device
- Qualitative and quantitative particulars of constituents
- Information on sterility and stability of the product
- Labelling details
- Variations in shape, style or size of the device, if applicable
- Physician manual and promotional literature (Literature insert) in English (if any)
- Packaging description including pack sizes
- Risk classification
- List of accessories or device to be used in conjunction with subject medical device
- Indication w.r.t which clinical study is to be carried out
- Name and address of the manufacturing / contract manufacturer (s)
- Regulatory status of the subject device

ii) Technical Data to be Submitted Along with the Application for the Subject Medical Device: for all Medical Device
- Design Analysis Data
- Biocompatibility

iii) For Moderate / High Risk Medical Devices
- For phase I study
- For phase II/III study

3. Requisite fee
- Feasibility study
- Pivotal study

4. Delegation of responsibility.

5. Protocol: should include following points.
- Title page
- Table of content

6. Global regulatory status.
7. Investigator's undertakings.
8. Ethics committee approval letters.
9. Informed consent form.
10. Case record form.
11. Patient record form.
12. Relevant published literature.
13. Investigator's brochure.
14. Suspected unexpected serious adverse reaction (SUSAR).
15. Any other specific relevant information w.r.t subject device.
16. Clinical study report structure, contents and format for clinical study report.

LICENSING

Document of guidance prerequisites for form - 28 license issuance for medical device production in India. Form 27 must be used in order to apply for a license to manufacture medical devices in India.
1. Covering letter
2. An authorization
3. A duty filled forms 27
4. The requisite fee
5. Constitution
6. Approved manufacturing premises plan.
7. Full particulars of competent and regular technical staffs for manufacturing and testing of medical devices along with copies of educational qualification, experience certificate, appointment letter, acceptance letter, etc.
8. Site master file
9. Device master file
10. Specific requirements
11. List of medical devices along with undertaking in prescribed pro - forma.
12. Full quality assurance certificate
13. CE design certificate

14. Declaration of conformity
15. Any other approvals In the table below, we have listed the name of the authority who will issue the license to important and manufacturing along with prescribed deadlines.

Table No. 1: Classification of Licensing.

Class of medical device	Licensing authority	Stipulated timeline for processing application	Deadline for obtaining license
Class A and B (import)	DCGI	Up to 9 months from the date of application	September 30, 2022
Class C and D (import)	DCGI	Up to 9 months from the date of application	September 30, 2022
Class A (manufacture)	State-level Licensing authority	Up to 45 days from the date of application	September 30, 2022
Class B (manufacture)	State-level Licensing authority	Up to 140 days from the date of application	September 30, 2022
Class C and D (manufacture)	DCGI	120-180 days (estimated)	September 30, 2022

Duties of medical device officer

- It is the responsibility of the medical device officer, subject to directives from the central Licensing Authority or State Licensing Authority, as applicable, to inspect all manufacturing sites licensed by the central Licensing Authority or state Licensing Authority, as applicable, with in the assigned area, at least once a year.

- Stated that, when it comes to large-sized medical devices, the Medical Device officer may not feel it is physically feasible to take samples of them. In such cases, the medical device officer will inspect the devices at their storage location, either with or without the assistance of an expert, and the Medical Device Testing officer will evaluate or test them to look for any suspicious.

Prohibition of Sale

- In accordance with clause (c) of sub-section (1) of section 22 of the Act, no person in possession of a medical device about which a medical device officer has issued an order may sell or otherwise dispose of any stock of that medical device in violation of that order.

Procedure for Dispatch of Sample to Medical Device Testing Officer

- The medical device officer must send a sealed packet containing a memorandum in Form MD - 38 with an outer cover addressed to the medical Device Testing officer. The packet must be sent by registered post, courier, or hand. A copy of the memorandum and a specimen impression of the seal used to seal the packet must be sent to the medical device testing officer separately by registered post or given to the officer by hand. The medical device or portion thereof sent by the medical device officer to the medical device testing officer for test or evaluation under sub-section (4) of section 23 of the act.

Sales of Medical Devices

1. By 2023, the Indian medical device industry is projected to be valued at $11billion.
2. Approximately 252 billion US dollars are spent on medical equipment worldwide.
3. $ 3 billion was sold in the Indian medical equipment sector in 2011.
4. The majority of the products produced by domestic producer are low-level items such as syringes, needles, catherers, blood collection tubes, medical electronics, equipment's, and implants.
5. The growth of health insurance will help the Indian medical equipment business.

MICELLANEOUS RGULATIONS

Export of medical devices

The central Licensing authority may bd contacted for this purpose, along with the fee outlined in the second schedule, by anyone who intends to export any medical device manufactured in India and requests a certificate in the form of a free certificate or a certificate regarding quality, safety, and performance in relation to the medical device as required by the authority concerned of the importing country. If the requirements are met, the said authority will issue a certificate to the applicant.

Rejection of Application

After providing the applicant with an opportunity to be heard, an application will be summarily rejected if any documents submitted by the applicant for a license to import, manufacture, permit for personal use, import or manufacture an investigational medical device, a new in vitro diagnostic medical device, permission to conduct a clinical investigation or permission to evaluate clinical performance is found to be false, fraudulent or fabricated.

Cdsco Registration Process of Medical Devices

1. Determination of the product
2. Risk based classification of product
3. Appoint IAA(Indian Authorized Agent)
4. Techical documentation

5. Obtain registration and license.

Approval of New Medical Devices

Application in form44 as per schedule Y TR6 challan of Rs.6000.
↓
Review of clinical trialprotocol, published reports, literature, package insert etc. by CDSCO.
↓
Evolution by medical device advisory.
↓
On basis of Recommendations of MDAC.
↓
Permission under Rule-122A granted.
↓
Identify your distribution in India (holding forms 20B and 21B).
↓
Apply for import license using forms 8&9 available from CDSCO. you must Identify your chosen distributors on these forms as well.
↓
Obtain import license (Form 10) from CDSCO. License valid for for up to 3 Years or until the Registration Certificate expires.

Registration of Medical Devices in India

The following steps are followed to register of import medical devices in India.

1. Appoint a local agent in India to be the application and license holder.
2. Prepare a Device Master File (DMF).
3. Prepare a Plant Master File (PMF).
4. Prepare application Form supporting documents.
5. Submit above documents to DCGI with fees.
6. DCGI reviews and sends back an enquiry letter.
7. Application responds and addresses inquiries by the DCGI.
8. DCGI may request technical presentation.
9. Approval granted, if the information provided by applicant suffices the requirements.

Factors Need to be Considered in Medical Devices Design Process

- Precision
- Life time
- Travel limits
- Mechanical safety
- Debris
- Fringe cases
- Usability

Salient Features of Medical Devices Rules

- Risk based classification.
- Provision of notified bodies.
- Quality management system in line with ISO 13485 has been adopted.
- Provision related to "essential principles of safety and performance" for manufacturer have been specified in the rules.
- Separate provisions for regulation of clinical investigation of investigational medical devices (new devices) have been made as per with international practice.
- Provision is made to designate or establish central government medical device testing laboratories to verify conformance with quality standards.

Top Medical Device Companies in India (2024)

- Medtronic
- Johnson & Johnson
- Abbott Laboratories
- Siemens Healthiness
- Medline
- Stryker
- GE Healthcare
- BD
- Roche
- Philips healthcare
- Baxter
- Boston scientific
- Danaher
- Sbraun
- Fresenius

Figure No. 3: Top Medical Device of India 2024.

Rules and Responsibility of Medical Device Officer in India

To improve device incident reporting and learning within organisations, the position of medical device officer (MDO) must be established. promoting the safe use of medical devices within the company and offering knowledgeable device assistance are two of the Medical Device Officers primary responsibilities. The Medical Device Officer will be the crucial link between the identification and execution of medical device safety initiatives and the day - to - day activities to enhance the safety of medical devices, in addition to enhancing the calibre of reporting.

Adverse Effects of Medical Devices

An adverse effect describes an adverse event related to the use of an investigational medical device. This includes adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical device.

Common Minor Side Effects of Medical Devies

In general, minor side effects are those that could cause discomfort for the patient but do not pose a risk to their health or are so severe that the device needs to be fixed or removed. Surgery is the primary method od addressing most minor side effects or issues related to medical devices. This could entail an implanted device or a tool used during surgery.

Common Minor Side Effects and Complications from Medical Devices Includes

- Bruising around the surgical site
- Mild allergic or other reaction
- Minor infection
- Numbness
- Pain
- Redness
- Swelling

Comparison of regulatory requirements of medical devices in India with Spain

Table No. 2: Comparison of India and Spain.

SL.NO	Requirements	India	Spain
1)	Regulatory Bodies	CDSCO (Central Drug standard control organization).	AEMPS: Spanish Medicines and Medical Device.
2)	Classification Categories	Class A: low risk level Class B: low to medium risk Class C: Medium to high risk Class D: High risk.	Class 1: low risk Class1a: low risk for measuring device Class b: low risk for sterile device Class ii a: medium risk Class ii b: medium to high risk Class iii: high risk.
3)	Application submission format and application fee	Form 44 has to be submitted according national format. Fees required in phase I II III is Rs. 50000, Rs. 25000, Rs. 25000 respectively	Marketing authorization applications (MAA's) Clinical trials applications (CTA's) Post marketing surveillance eCTD (electronic common technical documents) Includes modules on quality, safety, efficiency Online portal (SIMED) fees clinical trials application - initial application (500-2000) - Annual (200-1000).
4)	Approval timeline	Class A- 1-3 months Class B- 4-6 months Class C&D- 6-12 months.	Class I - 1-2 months Class II a – 2-4 months Class II b – 4 - 6 months Class III – 6-12 months.
5)	Institutional Review board	DCGI and Ethics committee approval required.	AEMPS; Spanish agency of medicines and medical devices.
6)	Regulatory pathway	Medical devices are regulated in India by ministry of health and family welfare's CDSCO.	AEMPS is national regulatory overseeing the approval, registration pre market regulatory surveillance and post market surveillance medical devices.

7)	Device registration process	Online registration with CLA voluntary till Oct 2021. Upload details of the devices, t 13485 compliance certificate and undertaking registration No. generated.	*Determine device classification (class I, IIa, IIb, III) *Obtain CE marketing certificate (notified body) *Establish unique device identifier (UDI) *Prepare technical file and documentation *Submit registration application to AEMPS *Pay registration fees *Receive registration certificate.
8)	Performance of evaluation	Design and development validation performed for the IVDMD. A requirement for import and / manufacture of the IVDMD.	Evaluation criteria 1. Regulatory compliance. 2. Device safety and efficiency Regulatory requirements 1. Medical device regulation 15592/2009 2. SCO/386/2009 (Guideline form M.D Registration) Performance indication 1. Devices required product 2. QMS certificate rates
9)	Stability conditions	30^0 C/ 70% RH	15^0C / 80% RH
10)	Device registration process	Online registration with CLA voluntary till oct 2021. Upload details of the devices, ISO 13485 compliance certificate and undertaking registration No. generated.	1. Submit application to AEMPS 2. Pay registration fees 3. Receive AEMPS evaluation and approval 4. Obtain unique device Identifier 5. Update registration information
11)	Risk minimization measures	Anticipating and assessing risks, monitoring them.	1. Routine RMMs: product labelling, packaging, and supply status. 2. Additional RMMs: Educational tools for healthcare providers or patients, controlled access, and pregnancy prevention programs.
12)	Licensing	Valid CDSCO Wholesale license is required in the form of 20B and 21B. Import license is required in the form of 8&9 to market medical devices in India.	1. Submission of applications: Submit application to AEMPS. 2. Documentation: Provide required documentation, including; Device description and technical specifications. CE-Certificate, ISO-13485 certificate, clinical evaluation report. 3. Evaluation: AEMPS evaluate application and verifies compliance with regulations. 4. Inspection: AEMPS may conducts inspection to verify manufacturing and quality control process. 5. Licenses Insurance: License issued upon approval, valid for 5 years.

CONCLUSION

Understanding the regulatory reforms imminent in India will be crucial for foreign companies looking to enter or expand the business in India's medical market. It is hoped that the guidelines are implemented and regulated properly with effective outcome. This article highlights current regulation pertaining to applications for medical device registration certificates, medical device clinical

trials, and medical device manufacturing/importation licenses.

REFERENCE

1. The Medical Devices Rules 2017, published vide Notification No. G. S. R. 78(E), dated 31st January 2017; last updated 17th October. Available from: URL:http://www.bareactslive.com/ACA/act2713.htm.
2. Medical devices and diagnostic CDSCO. Available from:URL:https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/
3. Indian approval process for medical devices and IVD's. Available from: URL:https://www.emergobyul.com/resources/india-approval-process-medical-devicesivds.
4. India medical device registration and approval process-CDSCO. Available from URL:https://asiaactual.com/india/medicaleviceregistration/#:~:text=Medical%20device%20registration%20in%20India%20is%20overseen%20by%20the%20Central, Authority%20(NRA)%20of%20India.
5. List of notified bodies registered with CDSCO under MDR, 2017. Available from: URL:https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic_NOticesFiles/ListofNotifiedmd.pdf.
6. Regulation of medical devices in India. Available from: URL:https://www.tuvsud.com/en-in/industries/healthcare-and-medicaldevices/medical-devices-and-ivd/medical-device-market-approval-andcertification/Regulation-of-medical-devices-in-India.
7. List of notified bodies registered with CDSCO under MDR, 2017. Available from: URL:https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic_NoticesFiles/ListofNotifiedmd.pdf.
8. Available from: URL:https://www.tuvsud.com/en-in/industries/healthcare-and-medical-devices/medical-devices-and-ivd/medical-device-market-approval-and-certification/regulation-of-medical-devices-in-india.
9. Available from: URL:https://nationalgovernment.co.za/units/view/433/south-african-health-products-regulatory-authority-sahpra.