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REVIEW ARTICLE **OPEN ACCESS**

Current Regulatory Framework of Medical Devices in India

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ABSTRACT
Medical Device market in India is at the brink of a revolution. The COVID-19 pandemic has brought a lot of issues to the forefront. All over the world, regulatory agencies have done several changes in their guidance documents. In India, the Medical Device Rule 2017 had come into force since 1st January 2018 with several attractive features like the single online portal (SUGAM), provision of notified bodies, essential principles of safety for manufacturer, and requirement of Bureau of Indian Standard and ISO standard. The Medical Device (amendment rules) 2020 along with classification provided for non -notified medical devices & further steps for license application. This would lead to significant changes in the regulation of medical devices in India. This article describes several consequences to the evolving situation & the regulations required for the registration, import, and labelling of the medical device in India as per the new rule & amendments. Some other aspects like post-approval monitoring of medical devices and Materiovigilance are also discussed.
***KEYWORDS**: Medical device, Non-notified, Materio-vigilance, Regulatory authority, Amendments 2020, License, Post marketing surveillance*

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INTRODUCTION

The Indian medical device industry is esteemed at USD 5.2 billion. It subsidizes four to five percent to the USD 96.7 billion Indian healthcare sector.[1] In Asia, India is the 4th largest Medical device marketplace along with being in top 20 medical device market globally.[2] According to United Nation, the population of India will rise to 1.45 billion by 2028,making it the most populated country of the world, with about 10 % of population more than 60 years of age.[3] In addition, the Indian population has become more prone to lifestyle related ailments such as diabetes, stroke and cancer.[4] Due to this upsurge in elderly population and chronic diseases, there will be a greater plea for the advancement in medical device & other healthcare facilities. The Indian medical device industry depends on other countries for import of medical device (mainly on USA, Germany and China). In year 2014-15 the import of medical device was ₹ 23169Cr. This import is increased year by year which lead to erosion of 10-30% domestic market share.[5]. Developing countries like India, is limited in its capacity to conduct research and develop high quality medical device, but from the last two decades Indian healthcare system has witnessed major advancements.[6] Indian government is continuously developing various medical device management systems and guidelines from the past few decades.[7] Few of them are listed below.

- Make in India- In the year 2014, government of India announced Make in India campaign with focus on medical device sector.[8]
- Emergence of task force- In 2014, the department of pharmaceutical constituted a task force which issued recommendations related to the domestic production of high-quality medical device.[9]
- Medical Device parks- In 2015,the government of India announced a scheme for the development of four medical parks in India for reducing import of medical devices.[10]
- Duty structure- In 2016, the Indian government recommended an increase in import duty with a view to promote manufacturing in India.[11]
- Medical device rules 2017- First rule related to medical devices came into effect, which laid down a risk-based classification of devices.[12]

- Grouping guidelines for medical device applications- These guidelines published in 2018 for applying for manufacture, sale or distribution or import license of medical devices.[13]
- Medical Device amendment 2020- Major highlight of this amendment was the addition of CHAPTER IIIA.[11]

According to the report published by WHO in collaboration with Department of Pharmaceuticals, India has various medical device manufacturing clusters which plays a major role in the growth of medical device industries including Haryana, Delhi, Gujarat, Telangana, Maharashtra, Tamil Nadu and Karnataka.[14] As per the "Third WHO Global Forum on medical device" and other reports it was found that the diagnostic imaging is the foremost segment in India medical device industry as shown in figure 1.[10]

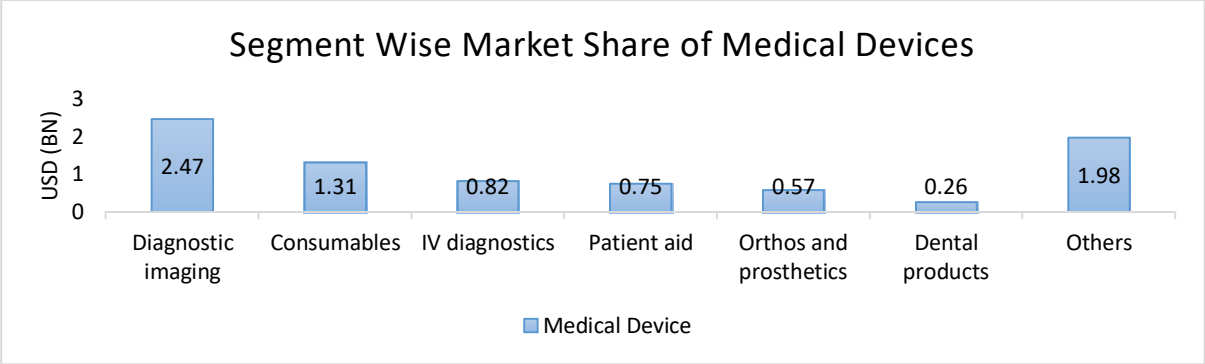

FIGURE 1: SEGMENT WISE MARKET SHARE OF MEDICAL DEVICES IN INDIA

COVID-19 PANDEMIC & GLOBAL GUIDANCE'S

Countries like United states of America, Europe and Canada in COVID-19 pandemic have approved various medical devices to combat corona virus. De Scalene Hypercharge Corona Canon (Shycocan) received the USFDA and EU- class 1 approval.[15] USA in this COVID-19 pandemic brought out a new regulation on 20th March 2020 regarding sterilizers, disinfectants, air purifiers and devicesthrough which these products got approval.[16] In Canada, an Interim Order had been signed to ensure more flexible and quicker approval of medical devices.[17] WHO has also given guidance document on "Priority Medical devices in context of COVID-19. It included various medical equipment, accessories and consumables.[18] One year transitional period for registration of Medical Devices was proposed in April 20202 by Council of EU. In response to COVID-19 pandemic, CDSCO also decided to fast track the regulatory approval process for diagnostics, prophylactics and therapeutics. To encourage the development of in-vitro diagnostics any application for the approval of diagnostics was directed to be processed on high priority.[19] In another welcome move ,the Government of India provided a scheme via gazette notification on July 27 2020 for the creation of medical device Parks. The total financial scheme was for ₹ 400 crores & 4 medical device parks were to be supported. The objective was to create world class infrastructure for the medical device industry. These medical parks will provide common testing & laboratory facilities which will significantly reduce the economic burden of the medical device manufactures in India.[20]

MEDICAL DEVICE (AMENDMENT) RULE 2020

In February, 2020, the Indian government notified the new definition of medical devices along with The Medical Devices (Amendment) Rules, 2020. The effective date of both notifications was April 1, 2020. Definition of medical device according to the medical device amendment 2020 is as follows:

"All devices including an apparatus, instrument, implant, material, appliance or other article, whether used individually or in combination, including an accessory or a software projected by its manufacturer to be used for treating human beings or animals which does not achieve the primary intended action in human body or animal by pharmacological, immunological or metabolic means but may assist in following purpose:

a) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;
b) diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;
c) investigation, replacement or modification or support of the anatomy or of a physiological process;
d) supporting or sustaining life;
e) disinfection of medical devices; and
f) control of conception.[21]

Medical device definition as per the new amendment of 2020 is similar as that of World Health Organization (devices here include apparatus, instrument, implant, material, appliance, accessory, software or other article, whether used individually or in combination. [22] As per Medical Device (Amendment) Rule 2020, the Chapter III A, titled "Registration of certain Medical Devices" was inserted in the Medical Device Rules 2017. 37 categories of devices regulated before MDR Amendment came into effect were not affected and therefore need not register. The registration of medical device was voluntary for a period of 18 months, and thereafter, it would be mandatory. An "Online System for Medical Devices" was used for the registration of medical device by the manufacturer. For the registration of medical device, as per the new amendment rule of 2020, the manufacturer of medical device is required to upload the information listed below :

a) Information about the company and manufacturing site along with the address
b) Brief information about the medical device like its brand name, model number, generic name, use and class of device, its construction material and shelf life and accredited compliance certificates with reference to quality management system (ISO 13485).

For import, free sale certificate from the country of origin is required. After such information is uploaded, a registration number will be generated which should be mentioned on the label of the device. License to import, manufacture, distribute or sell would become mandatory after a period of thirty months for low risk - Class A and low moderate risk - Class B and after a period of forty-two months for moderate high risk – Class C and high risk – Class D devices, respectively from the date of this notification.[23] On September 13 2020, the Central Licensing Authority had given a classification for non-notified category of medical devices that would provide guidance for voluntary registration. It contains 24 categories viz cardiovascular, ENT, dental, urological, operation theatre, oncology software etc under which medical devices have been listed along with the risk class. [32]

IMPACT OF AMENDMENT 2020

Till date, only a selected category of devices &*in-vitro* diagnostics had been notified. From April 2020, the government of India had changed the definition of medical device to include various categories which essentially meant all medical devices were to be regulated. This move ensures availability of quality products to Indian citizens. Previous registrations of medical devices needed a relook & manufactures were to comply with the new regulations within a stipulated timeframe. Another important point to note is that stand-alone software also came under the purview of this definition. The term Software as a Medical Device is defined by the International Medical Device Regulators Forum (IMDRF)as "software intended to be used for one or more medical purposes, that perform these purposes without being part of a hardware medical device." With current revolution in technology in India which uses standalone software to measure heart rate, imaging, diagnostics etc. it is important to further bring out further clarifications as per various other international guidance's. [24]

MEDICAL DEVICE RULE 2017

After the voluntary registration period was over, the manufacturers/ importers needed to comply with the MDR 2017 for import or manufacturing license. To safeguard the growth of Indian medical device industry, Medical Device Rule 2017 came into force since 1st January,2018. The Indian medical device industry is embraced of over 800 Indian manufacturers, of which nearly 65% have a turnover of worth $1.5 million and 2% of over $73 million.[25] The most important aspect becomes the classification of the category of medical device for registration. The classification is fully reliant on the sternness of risk associated with a particular device. Medical devices are classified into four classes: A, B, C and D. There are other parameters also, which helps to classify the medical device before approval process. Prior to the MDR, sutures, disinfectants, intra uterine devices, blood bags, surgical dressings, condoms, umbilical tapes, ligatures, blood grouping sera, and vaginal tube rings were considered as drug but now they are regulated as medical device under Medical device rule (MDR) 2017.[26] All medical device are required to go through assessment procedures to for confirming the safety and quality standards before they are get approval to be sold in India. BIS and ISO) standards are acceptable by MDR 2017 for Quality Management System.[27]

Salient features of medical device rule 2017

1. MDR 2017 is pertinent (relevant) to both medical device and *in vitro* diagnostics.
2. There are eight schedules under this medical device rule 2017, which are listed in figure 2.

First Schedule :	**Classification of MD &IVD**
Second Schedule :	**Fees**
Third Schedule:	**Notified bodies function and registration**
Fourth Schedule:	**Documents requirement**
Fifth Schedule:	**QMS**
Sixth Schedule:	**Post approval changes**
Seventh Schedule:	**Clinical investigation requirements**
Eighth Schedule :	**Exemptions**

FIG 2: SCHEDULE UNDER MEDICAL DEVICE RULE 2017

3. Registration certificate of medical device is valid for 5 years and if applicant want indeterminate validity of the certificate, retention fee of 20,000 rupees needs to be paid by the holder, every five years from the date of registration.
4. MDR 2017 involve the provision of notified bodies and essential principles of safety and performance for manufacturer.
5. Quality management system have been adopted in line with ISO 13485.
6. Medical devicesare required to meet the standards of by Bureau of Indian Standard or if such standard is not available, then ISO or IEC standards are to be followed.
7. The Rule comprises of eleven chapters including information about the various bodies and authorities, import of medical device, labelling, duties and power of notified body and other offices.
8. Online portal is used for the registration of testing laboratories, import and manufacturing license and also for proposing post approval modification in medical device.[28]
9. Foreign manufacturing sites may require inspection by Notified body and the applicant has to pay $6000 as inspection fee.
10. Additional clinical investigation is not required if the medical device is already approved in United States, Australia, United Kingdom, Canada or Japan and the device is marketed in that country for at least 2 years.[29]
11. Clinical investigation is not required if free sale certificate is already issued for the device by United States, Australia, United Kingdom, Canada, Japan and EU countries.

CLASSIFICATION OF MEDICAL DEVICES

Classification on the basis of intended risk

a) **CLASS A –** Device don't have a direct bearing on the wellness of the patient, this class typically signifies low risk medical devices. The manufacturer of class A medical device must follow GMP in accordance with set standards. Ex- Surgical dressings, alcohol swabs, nasopharyngeal catheter and umbilical occlusion device

b) **CLASS B –** Device that represent a low to medium risk are grouped under class B. Ex- Tracheobronchial suction catheter, arterial catheter, bone marrow needle and IV flow regulator.

c) **CLASS C –** Device which possess moderate to high risk. Ex – Intraocular lens, Vein and thermal ablation device, Bifurcation stent & vena cava filter sets.[30]

d) **CLASS D -**Device possess high risk to the wellness of the patient. This includes medical devices that are used to treat circulating and nervous system disorder and are come in contact with sensitive tissues as heart and spine. Ex - Drug eluting stents, cardiovascular prosthetic devices, heart valve and breast and retinal implants.[31]

Pilot trials for gathering initial information and pivotal trial for collecting information regarding adverse event and the evidence of effectiveness of the medical device is done for only Class C and D devices, If the device is already approved in Australia, Canada, Japan, European Union or the US then there is no need of conducting local clinical trial for the import or marketing of that devices.[33]

Other parameters for classification of medical device- Basic principle

- Classification of medical device shall only be done on the basis of intended purpose of the device.
- In case of any combination devices, the classification rule will be applied to each of the device separately.
- Software falls in the same class as that of medical device

- The higher classification shall be applied to the device if more than one rule influences the classification of medical device. Classification of medical device on the basis of purpose and risk associated with the medical device is given in the table 1.[12]

TABLE 1- OTHER PARAMETERS FOR THE CLASSIFICATION OF MEDICAL DEVICE

Parameter Device lassification	**CLASS A**	**CLASS B**	**CLASS C**	**CLASS D**
Non-invasive medical device	Devices used for wounds which have not breached the dermis. Devices used for directing or storage of body liquids or tissues for infusion or introduction into a human body.	Devices used with wounds which have breached the dermis. Devices connected with any active medical device or used for channelling blood or any other body fluid or their storage.	Devices used for wounds which have breached the dermis and cannot be heal by primary intention. Blood bag which doesn't contain a medicinal product.	
Invasive medical device	Device for transient use. Device used in oral cavity, nasal cavity or in the ear canal up to ear drum for short term only.	Device for short term use. Device used on external surface of an eyeball. Device intended to be connected to an active medical device.	Device that are not accompanying to an active medical device but used for longer time. Device used in oral cavity, nasal cavity or in the ear canal up to ear drum for long term.	
Surgically invasive medical device for short term use		Device meant to be placed into tooth.	Device undergo chemical change in the body. Device used for the transmission of energy in ionising radiation form or for the administration of medicinal product.	Device used in direct contact with circulatory system or CNS or wholly absorbed by body or have some biological effect.
Surgically invasive medical device for long term use and implantable medical devices		Long term use device that is intended to be placed into tooth.		Device intended to be an active medical device or life sustaining device or absorbed wholly or mainly by human body.
Medical devices used for disinfection or sterilization		Device used for disinfecting other medical device earlier the latter is enduring end point disinfection.	Device which is used for sterilizing another medical device. Device for disinfection, cleaning or hydration of contact lenses.	
Active therapeutic medical devices for administering or exchanging energy			Device use for administration or energy exchange to or with human body.	Device use for exchange of energy done in hazardous manner (ex. by emission of ionising radiation)
Medical devices incorporating medicinal product		Device incorporate medicinal product that is exempted from the licensing requirement of D & C Act 1940 and rule 1945.		Device includes as an essential component of substance or may be considered as a medicinal product.
Device incorporating animal or human cells tissues or derivatives	Device made up of non-feasible animal tissues or derivatives used in contact with intact skin only.			Device made of or incorporates cells & tissue of human, animal, microbial origin or recombinant origin.

For the grouping of medical devices, government of India has provided one more document i.e. Grouping Guidelines for Medical Devices Applications. This guideline explains the concept of family, IVD test kit, cluster or a group. According to these guidelines, a single medical device is the one that is sold as a

distinct packaged entity. A medical device family is a collection of medical devices when, each medical device isfromthe same license holder; belongs to same risk classification class; have a common intended indication; have the same design and is manufactured by the same process and whatever variations are present are falling within the permissible limits.[34]

PRE-MARKET APPROVAL PROCEDURE FOR MEDICAL DEVICE IN INDIA

Any person who want to manufacture a medical device for sale or distribution in India have to take approval and manufacturing license by the state licensing authority (SLA) for class A & class B and by central licensing authority (CLA) for Class C and class D medical device. Application must be succumbed through SUGAM portal (an online licensing portal for the submission of application for registration of medical deviceand drug), along with the challan fees.[33] The 2018 guideline laid down essential principles and defined conformity assessment. In case of foreign manufacturer, an authorized Indian agent must be appointed by the foreign manufacturer for the approval process.[27]

MANUFACTURING LICENSE APPROVAL PROCESS FOR CLASS A & CLASS B MEDICAL DEVICES

An application in FORM MD 3 for obtaining license and MD 4 for loan license need to submitted on government'sonline portal with the required fees and documents to State Licensing Authority. SLA scrutinize the documents and may cause audit of manufacturing site of class B medical device by notified body as clearly shown in figure 3.

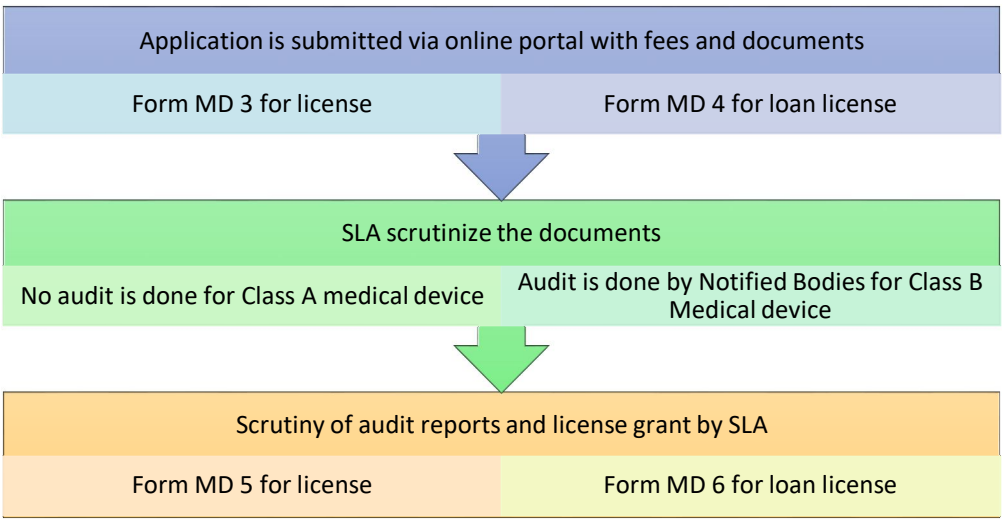

Figure 3: APPROVAL PROCESS FOR CLASS A and CLASS B MEDICAL DEVICE

On the basis of audit report, SLA will take decision on the approval or rejection of license for Class B medical device. In case of rejection of license application, a reason must be given within 20 days from the date of receipt of audit report by SLA.[12] There is a period of 45 days in which the afflicted person files an appeal against the rejection of application. According to the amendments made in the medical device rule 2020, there is a period of 18 months for the voluntary registration of medical device from the instigation of CHAPTER IIIA.[23]

DOCUMENTS REQUIRED FOR REGISTRATION OF CLASS A MEDICAL DEVICE

- Device description including the use and details of the construction material.
- Descriptive document containing use and working principle of novel technology involved in medical device (if any).
- User manual, package insert and Labelling information.
- Information of any serious adverse event reported, and action taken on it by regulatory authority or manufacturer.
- Plant master file.
- Checklist for demonstrating conformity to essential principle of performance &safety.[18]

CHAPTER IIIA of Amendment Rule 2020 describes the registration of medical device under clause b of section 3 of Drug and cosmetic Act (cardiac stents, drug eluting stents, heart valves, catheters, scalp vein set, intra ocular lenses, I.V cannula, internal prosthetic replacements, bone cements, orthopaedic implants). Registration of these devices must be done via "online system for medical devices" established by CDSCO. Documents required for their registration include detailed description of medical device and company, certificate of compliance with respect to ISO 13485.[23]

MANUFACTURING LICENSE APPROVAL PROCESS FOR CLASS C & D MEDICAL DEVICES

The applicant has to submit Form MD 7 to Central licensing authority for seeking grant of manufacturing license for the sale and distribution of medical devices belonging to Class C and Class D. Within 45 days CLA verify the application and may cause inspection if needed as briefly describer in figure 4. After the submission of inspection report, CLA will take decision whether to grant license to the applicant or not.

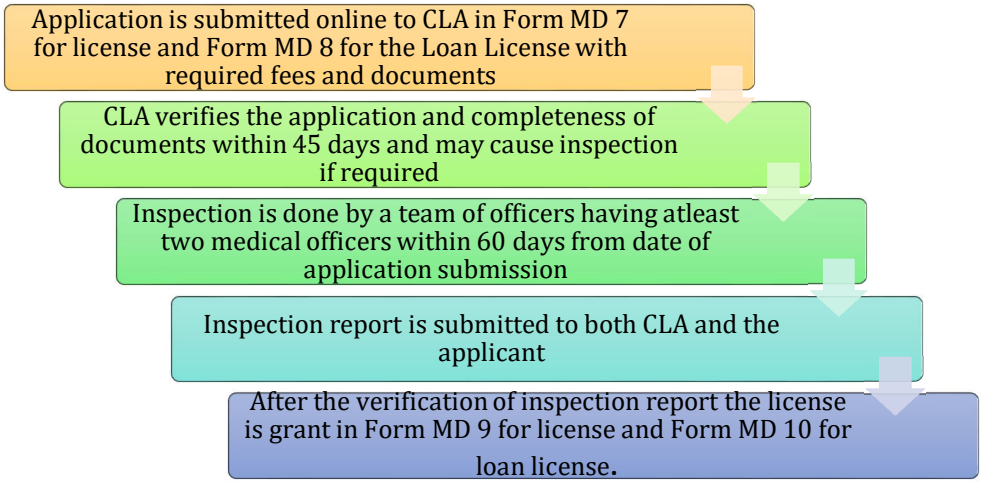

FIGURE 4: APPROVAL PROCESS FOR CLASS Cand CLASS D MEDICAL DEVICE

DOCUMENTS REQUIRED FOR CLASS B, C & D

- Site master file
- Device master file
- Test license obtained for testing and generation of QC data (if any)
- Structure details of manufacturer or authorized agent.
- Checklist for demonstrating conformity to essential principle of performance & safety.
- Quality assessment report (QAR).[12]

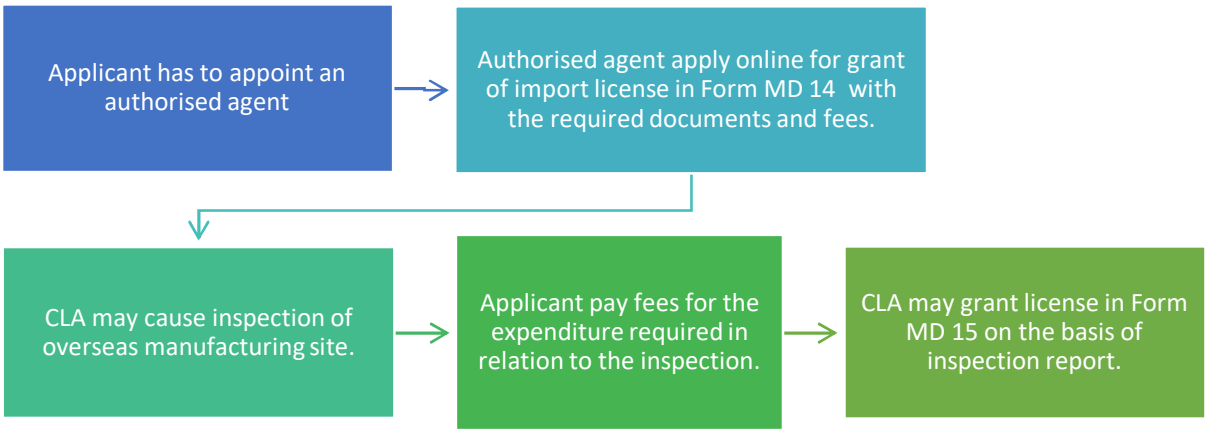

FIGURE 5: APPROVAL PROCEDURE FOR IMPORT LICENSE

APPLICATION FOR GRANT OF IMPORT LICENSE

India has the capacity to be the world largest market due to the high population, it attracts the manufacturer of medical devices for import possessing to its large population.[35] India dictates a regulatory context which is a mandatory for the import of medical devices. A person keen to import medical device in India, he has to acquire license from central licensing authority (CLA) for import. The manufacturer has to appoint an authorized Indian agent for this procedure. Applicant has to pay inspection fees if CLA cause inspection of overseas manufacturing site. Approval procedure for import license is briefly described in figure 5. In case of rejection of an application, applicant may appeal within 45 days and government must pass an order in relation to the appeal within 90 days based on facts and documents. In India the Free Sale Certificate is issued by Central Licensing Authority. If FSC for CLASS C & CLASS D device is issued by countries other thanEurope, Australia, Canada, Japan and United states of America then clinical investigation has to be done in India for authenticating the safety and effectiveness but in case of CLASS A & B safety and performance of device can be predictable through published

literature or data or clinical investigation in the country of origin. Import license is mandatory to be present in the licensed premise.[33]

DOCUMENTS REQUIRED FOR IMPORT LICENSE-Documents requirement for import license is same as that of the documents for license of manufacture for sale or distribution.

- Detailed information about the authorized agent
- Site master file
- Device master file
- Checklist of essential principle
- Notarized copy QA certificate or quality management system.
- Copy of any latest inspection or audit report within last 3 years carried out by national regulatory authority.

As per the medical device rule 2017 there are different type of forms has to be filled by the applicant according to their need. Types of forms and licenses are listed in table 2.[12]

S.no.	Type of License	Application	Grant
1.	Notified body registration	MD1	MD2
2.	License to manufacture for sale and distribution of medical devices belonging to: • Class A or Class B • Class C or Class D	 MD3 MD7	 MD5 MD9
3.	Loan license to manufacture • Class A or Class B • Class C or Class D	 MD4 MD8	 MD6 MD10
4.	Import license	MD14	MD15

TABLE 2- TYPES OF LICENSE AND THEIR RESPECTIVE FORMS

LABELLING REQUIREMENTS FOR MEDICAL DEVICE

Any information allied with a device targeted to the patient is called as the labelling of medical device. It is used to assure that the device is safely and effectively used by patient. Labelling of device assists patients in understanding the device, its operation, maintenance, care and any disposal and safety issues.[36] General information regarding labelling of medical device sold in India can be found in Chapter V of Medical Device Rule 2017.Medical device must contain the following information on the shelf pack or on the outer covering -

- Medical device name and use
- Manufacturer name and address, manufacturing license number.
- Manufacturing date & expiry date shall be written mentioning the month and the year
- Lot number, batch number and any distinct storage and handling state
- For imported device, the import license number, with full details including the name & address of the importer, the address of site of manufacturing along with the date of manufacturing and symbol recognized by BIS (Bureau of Indian standard) or ISO is required.
- In case of small device, it should include the information necessary for identification and safety of medical device.[37]

NOTE- From 1st January 2022 all devices approved in India for sale, import or distribution must have Unique device identification (UDI). Unique device identification proposed to allocate a unique identifier to medical device because it will improve electronic tracking capabilities. Device identifier includes the global trade number & production identifier includes the serial number, the manufacturing lot number, the batch number details in addition to the manufacturing and expiry date.[36]

FEES FOR LICENSE

Applicant has to pay fees for their respective purpose as per the fees described in the medical device rule 2017. Fees requirement as per the new rules is given in the figure 6. For the retention of manufacturing license, applicant has to pay 5000 for Class A & B and 50000 for Class C & D. Electronic mode or challan is used to submit the prescribed fees in any bank notified by in case of fee payable to the central licensing authority.Notably, the new rule still has not divulged the fee amounts that industry has to pay for the services provided by the Notified Body.[38] Figure 6 shows the Fees required as per the Medical device rule 2017.

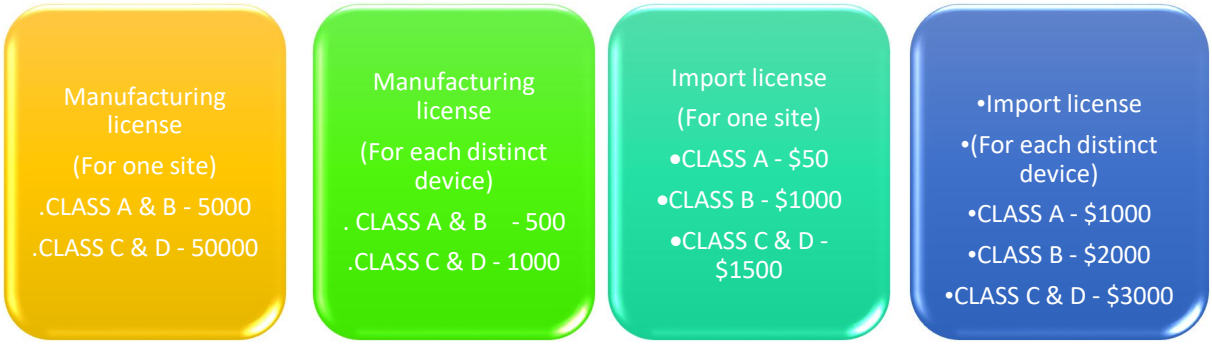

FIG 6: FEES AS PER THE MEDICAL DEVICE RULE 2017

POST MARKETING SURVEILLANCE

In India a programme was launched on 6 July 2015 by Drug Controller General of India (DCGI) at Indian Pharmacopoeia Commission (IPC) Ghaziabad, called Materiovigilance Programme of India (MvPI) for ensuring the safety of medical device and seamless reporting of adverse event due to medical device. Materiovigilance is the study and follow up of incidents that might result from using medical device by means of having a system in place and includes identification, collection, reporting undesirable occurrences and taking action or corrective measures after the post marketing phase.[39]

ADVERSE DRUG REPORTING

In India, all adverse events related to medical device can be reported whether they are known or unknown, frequent or rare, and serious or non-serious. MvPI has prepared a two-page adverse event reporting form containing detailed information of the patient, the device, the adverse event and the reporter. The adverse event reporting form is freely available on the official website of IPC(www.ipc.gov.in) andcan be directly sent to the Medical Device Monitoring Centre (MDMC) or to the National Collaborating Centre. The reporter can also call 1800-180-3024 helpline number of NCC-MvPI. MvPIhas identified few medical colleges in India as MDMC. The completeness of reporting form is reviewed by MDMC, assessed for causality and the report is then sent to NCC, where it analysed for signal detection and the result is then communicated to National Coordinating Centre. National Health System Resource Centre, Government of India, New Delhi, is recognized as technical support and research Centre (TSRC). TSRC offers technical support to National Collaborating Centre and National Coordination Centre in preparing SOP for causality assessment, training manuals and guidance documents.

As per the amendments notified by the CDSCO, the manufacturer must report unexpected death or serious injury or a serious community health menace within ten days of knowing about the event. Manufacturer must report all other related events within thirty elapsed days. [40] After the implementation of Medical device rule 2017, each applicant shall provide Periodic Safety Update Reports (PSURs) to the central licensing authority. For example, various safety alerts have been issued by authorities like Medtronic Mini Med insulin pumps having potential cyber risks and pre mature battery depletion because of the crack in the device capacitor in certain Medtronic pacemaker. For the first two years of the device approval, PSUR should be submitted every 6 months and after that it has to be submitted annually for subsequent two years. Nevertheless, all unexpected serious adverse events needs to be reported within fifteen days to the licensing authority. The main aim behind the submission of PSUR is to report the new information and to summarize the market authorization status of medical device in different countries. PSUR also indicates the changes made to the medical device information.[39]

PSUR STRUCTURE

a) Title Page: It include the information regarding medical device (name, indication, reporting interval, license information etc.)
b) Introduction: This section captures the introduction of medical device, its class, mode of action, use and principle.
c) Status of device in other countries: Brief description of the countries where the device is either withdrawn or approved.
d) Actions taken during the reporting interval for safety reasons: Detailed description of actions taken by license holder, sponsor, regulatory authorities for safety reasons.
e) Changes to reference safety information: Information about the significant changes made by the applicant in the reference safety information (precautions, warnings, contraindications, adverse events, and significant findings obtained from the clinical investigations).
f) Estimated patient exposure: This section must provide information about the methods used to estimate the population exposed to medical device specially the nature and size of the exposed population.

g) Presentation of individual case histories: This section provides brief medical history indication treated with suspected medical device and causality assessment.
h) Studies: This section of PSUR shall captures the findings from literature, non-clinical, clinical and nonconventional studies.
i) Other information: Information related to Risk management plan and signals.
j) Overall Safety Evaluation of the device must be on the basis of the risk benefit assessment for the approved indication.
k) Conclusion: Conclusion include the safety profile and the action taken by license holder.
l) Appendix: It includes Individual Case Safety Reports, copy of marketing authorization in India.[12]

CONCLUSION

Prior to 2017, there were no strict regulations for manufacturing, import and clinical investigation for Medical Device in India. By implementing Medical Device Rule 2017, the world's most populous country has paved way for improved quality in healthcare. The Indian Medical device industry faces many challenges like lack of innovation and technology, high import dependency and lack of quality standard and focus in maintaining healthcare ecosystem. The COVID-19 pandemic has made regulatory authorities globally to relook their guidance's. Indian government with Medical device amendments 2020 coupled with the initiative to create Medical Device Parks is expected to bring out a revolution in the medical device market. The robust post marketing surveillance program in India is an important check to safeguard the health of the patients. Overall, one can expect a significant change in medical device industry in India.

CONFLICT OF INTEREST

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