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Review Article

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Regulatory aspects of medical devices in India

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Abstract

Today millions of patients depend on medical device based treatment for the management and diagnose of several diseases. Quality and safety of device is depends upon the regulatory guidelines. Medical device manufacturing in India should be taken seriously due to large population and the potential severity of the consequences of introducing inferior and unsafe products to the market-place. Therefore a law containing adequate guidelines of rules and regulations are required for monitoring the entry of such devices into the use in public health. The regulations define requirements of medical device design, development and manufacture to ensure that products reaching market are safe and effective. Presently in India regulatory body CDSCO is governing regulation for regulation of devices which with time, amendment introducing in the law will provide safety assurance to public health. This review provides a study on different regulatory aspects of medical device implemented in India. The present review discuss about the classification of medical devices and regulations aspects in India.

Keywords: Medical devices, classification, regulatory, license, marketing etc.

Introduction

A medical device is any instrument, apparatus, appliance, software , material used alone or in combination intended for use in diagnosis and treatment purpose to prevent and cure disease .Medical devices differ according to their indications and use. Medical device is a vast system which categorized the products starting from the therapeutic devices with medical uses such as wound healing, or clogged arteries to highly modified computerized medical technologies and diagnostic medical devices. To ensure the safety, efficacy and effectiveness and useful medical technologies and to also increase the uniformity between the national medical device regulatory system , the Global Harmonization Task Force (GHTF) was developed in 1992 by five members mainly : European Union, Unites States, Australia , Japan and Canada where surveillance was between the study groups. GHTF defined a medical devices as any instrument, apparatus, implement , machine, appliance, implant, software material , or any other article which is used for several purposes like diagnosis, monitoring , treatment of any kind of disease or any kind of injury . The medical devices are used to sustain the life of the individual, support the anatomy or replacement of any kind of process, control of the conception and disinfection of medical devices in hospitals and other places, provide the information regarding the sample kits , reagents , chemical used for cleansing , calibrators and software data by means of in vitro examination of particular specimens derived from the human body and which does not achieve its action intended action by pharmacological , metabolic , or immunological means but which may be used in such ways . Medical devices include a wide variety of products such as medical gloves, bandages, contact lenses, disinfectants, X-ray equipment, pacemakers, dialysis equipment, incubators and heart valves.

One of the largest medical devices market in Asia is India, and growing at extensive rate. Till 2005, no regulations for medical devices existed in India. [1] Medical devices form global industry which manufactures and develop healthcare equipment from simple devices like stethoscope and thermometers to form complex devices also like pacemakers, ultrasound and surgical robots.[2] The medical device sector is approximately 5.5 billion till 2016.[3] Today, medical device sector is mainly regulated by multinational big companies which can be said as 75% sales are accomplished by imported medical devices. The importing of medical devices done by supervision of State government & Central government. The central drug standard control organization (CDSCO) headed by DCGI (Drug Controller General of India) is mainly responsible for managing activities of the state drug licensing authorities, policies, and uniform implementation of the act throughout in India. The Act and rules seeks to regulate the import, manufacture, distribution and sale of notified medical devices. The state and central government sees the regulation of notified medical devices. Importing medical devices into India requires few additional legal requirements.

The import of medical devices into India is governed under the provisions of import and export policy. Around 70 % of medical devices are imported in India. Countries from which medical devices are imported are US (29%), Germany (20%) , other EU countries (17%) ,China (8%) , Japan (7%) and other countries (19%) approximately [19]. Notified devices (drug eluting stents, catheters, heart valves, bone cements , etc) by Indian government must register with the CDSCO. Non notified devices (tubual rings,

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surgical dressings . ligatures, sutures etc) which are regulated as drugs under Drugs & Cosmetic Act 1940 and Rules 1945 may be imported into India but do not require CDSCO registration.

Medical device Classification

Medical devices are categorized on the basis of their medical uses or technical model and manufacturing point. But medical devices have been classified by the regulatory authorities according to their safety and efficacy and quality standards to be set around the world. Different criteria are used to determine the risk, affected body system, effectiveness, and other local and systemic effects. The classification of medical devices differs from country to country.

CLASS A- These medical devices are subjected to general controls and referred as low risk devices. Class 1 is subjected to regulatory control. In this category mainly it contains the banned devices, replacement, refund, good manufacturing practices, repair, and notification. Class 1 devices are not used in preventing any impairment to the human health. These are mainly exempt from pre-market notification. These articles are basically simpler approach than other one. Examples- surgical instrument, toothbrush, examination gloves, elastic bandages[4].

CLASS B- This class mainly includes the general control and specific controls. It requires more regulatory control than class 1. These are referred as the low medium risk devices. These need certification by the notified body. These are performed as indicated without causing harm to patient or user. These include special requirements, post marketing surveillance. Examples- sterile items surgical gloves, urinary catheters, stomach tubes, needles, tracheal tubes etc.

CLASS C- these devices are referred as the medium high risk devices, they need certification by the notified body for the design and manufacturing of medical devices. They follow the quality management system. Examples – blood bags, condoms, non absorbable sutures, anesthesia machine, contact lens care products.

CLASS D: General controls and specific control with premarket approval. These are referred as the high risk medical devices. These devices required premarket approval to ensure the device effectiveness and safety. These devices usually sustain human life. It is useful in preventing impairment of human health or risk of injury (Figure 1). Examples – pacemakers, vascular grafts, angioplasty catheters. Heart valves, implantable defibrillator [4] .

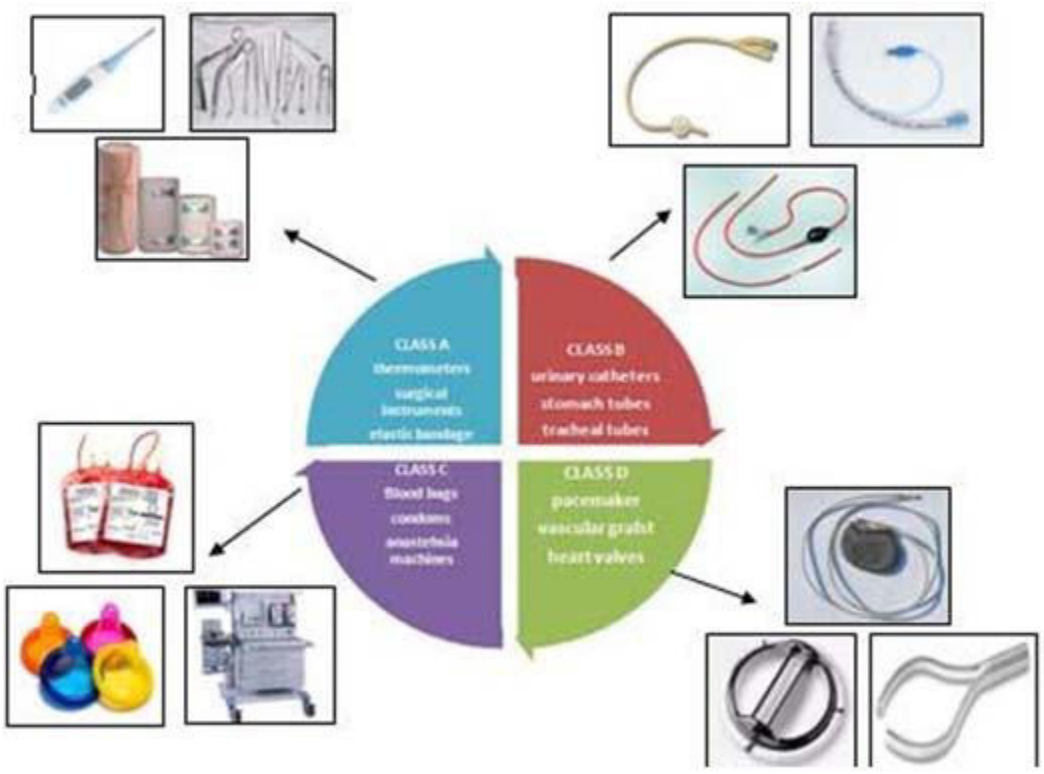

Figure 1: Classification of Medical Devices

The list of medical devices with their date of notification is explained in Table 1 which has been regulated by Ministry of Health and Family Welfare Govt. of India

Table 1- Notified Medical Devices with their date of notification , indication , and medical class division

Name of device	Date of notification	Indication	Type of medical class division
Disposable hypodermic Syringes	17-03-1989	Used to inject liquid or gases into body tissues	Class 2
Disposable Hypodermic Needles	17-03-1989	Used in treating shock	Class 2
Disposable Perfusion Sets	17-03-1989	Cardiac Surgeries	Class 2
In vitro Diagnostic Devices for HIV, HBsAG & HCV	27-08-2002	Provide information for diagnosis and monitoring	Class 2
Cardiac stents	06-10-2005	Used in Angioplasty	Class 2
Drug Eluting Stents	06-10-2005	Prevents fibrosis and used in angioplasty procedure	Class 3
Catheters	06-10-2005	Hip Fracture repair, dementia	Class 1
Intra Ocular Lenses	06-10-2005	Cataract surgery	Class 2
I.V Cannulae	06-10-2005	Administer intravenous fluids	Class 2
Bone Cements	06-10-2005	Implant fixation	Class 2
Heart Valves	06-10-2005	To maintain the unimpeded forward flow through heart.	Class 3
Scalp Vein Set	06-10-2005	Used for venipuncture	Class 2
Orthopaedic Implants	06-10-2005	To support damaged bone	Class 2
Internal Prosthetic Replacements	06-10-2005	Used for elbow replacement , for fixation of spine [11].	Class 2 and 3

The following products are regulated as 'Drugs' (Non Notified Medical Devices) under Drugs and Cosmetic Act & Rules as follows [11] -

1. Blood Grouping Sera
2. Ligatures, Sutures, and Staplers
3. Intra Uterine Devices (CU-T)
4. Condoms
5. Tubal rings
6. Surgical Dressing
7. Umbilical tapes
8. Blood/blood Component bags

Importance of Medical Devices

Medical devices must be able to meet the standards and should be designed in a specific way so that patient health and safety can be achieved. Population of India was a big factor for the growth rate of medical device due to the patients health care , increased awareness among people regarding healthcare facilities and health insurance policy . Regulation of medical devices in India is done as drugs by the Drug Controller General Of India (DCGI) AND Central Drugs Standards Control Organization (CDSCO). Medical devices must be able to meet the standards and should be designed in a specific way so that patient health and safety can be achieved. The compliance and conformation procedures for Class A medical devices can be done by the manufacturer itself but ISO along with Bureau of Indian Standards (BIS) will issue the notified bodies for the conformity procedures of Class B and Class C. Notified bodies will be responsible for the examination of the device whether they are able to meet the ISO standards. Medical devices must have Indian Conformity Assessment Certificate mark, after conformation of standards by the notified bodies and they will be able to placed directly into the market. Schedule M-III (Quality Management System deals with the design, development, storage, production, management, and distribution of medical devices) is responsible for the import of medical devices in India. International Organization for Standardization (ISO) is responsible for the requirements of QMS and organization needs to submit demonstration of medical devices and services to meet customer needs and requirements. [6]The Ministry of Health and Family Welfare, Government of India in 2009 notified an amendment that tends to strengthen the law against counterfeit medical devices in India.[3] Pharmacist can play a major role in the regulation of medical devices in India. Pharmacy personnel should be actively involved in the standards documentation to ensure that the materials, process are fit for the

purpose. Safety, risks, effectiveness and performance of the medical devices need to be well established and regulated properly. Now the medical device sector grown tremendous within last few five years and valued around USD 4.9 Billion .India accounts for the top market of medical devices in country . India medical devices growing at a rate of 15% CAGR at an estimate of 10 years .Now, only 14 devices are notified as medical devices but other devices are treated as 'drugs' under Drugs & Cosmetic Act 1940, and Rules (Table2) .

Table 2- Indian medical device sector growth

Type of device	% growth	Examples
Equipment and instruments	53%	Ultrasound machine, X-ray machine , dialysis machine etc.
Disposables	27%	Medical gloves, syringe, nebulizer, infusion pump etc.
Implants	7%	Pacemaker, coronary stent, intrauterine devices etc.
Patient aids	13%	Hospital beds, home oxygen, glucometer , etc.

For further growth of medical device industry in India by the government India announced 'Make In India' campaign which aims making at global manufacturing of medical devices and bringing capital into the country (Figure 2). The government of India started the process of following recommendations and differentiates medical devices from the drugs and allowing 100 % Foreign Direct Investment (FDI). [13]

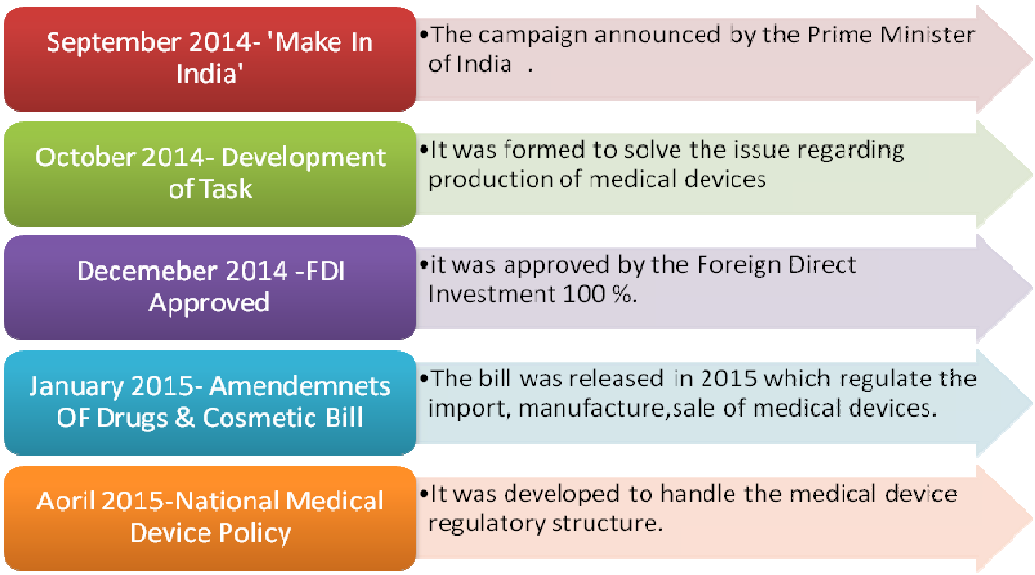

Figure 2- Regulatory framework of medical devices according to 'Make In India ' campaign.

The medical device sector has experienced changes due to the shift of regulatory systems. The transistion can be seen by producing high quality products for the industry from low end products. The change shows the high quality standards of medical devices at affordable prices due to development of regulatory status (Table 3).

Table 3- Changes in medical device field following regulatory modifications

Old regulatory system	Current regulatory system
Initiative promising regulatory system	Strong regulatory system
Low cost products results in lower margin	More cost effective
Not much investments made in manufacturing facilities	Increasing manufacturing facilities leading to the high quality standards
Lack of technical facilities	More developed technologies

Background of regulatory profile in India

The government of India is responsible for developing regulatory aspects to ensure the efficacy, safety, requirements and performance of medical devices in India. The first regulatory control announced by the government of India in 2005 and guidelines were started issuing in 2006 for product registration. This regulatory system was established for the betterment of healthcare sector and to develop the industry. Although the regulatory process experienced its false starts. the legislation was controlled in the parliament and in the Ministry of Health and Family Welfare (MoHFW) and Drugs Controller General of India (DCGI).The state regulatory authority of Maharashtra found that Drug Eluting Stents were not approved by the DCGI in 2005 & banned within the state. The issue was intercede by the Bombay HIGH court and asked government of India to resolve the issue. Notification 627 was passed in October 2005 by MoHFW which contained a list of 10 products which can be sold, distributed in India by the Central government.

The guidelines were adopted in march 2006 after some difficulties and it worked in the right direction. Some of the changes in guidelines were done by the CDSCO as government of India wanted to make sure the safe and effective medical technologies in India. Due to renew current guidelines industry experience delays and confusion. in 2007 law was made to advance India medical device and centralized regulatory authority development. Two bills were forwarded for regulatory framework by the department of science and technology(DST) and other by central drugs authority (CDA)covering all products . The CDA proposed that all the power of CDSCO should be changed into the new regulatory system. CDA would be responsible for permission of fees to conduct clinical trials for drugs and medical devices. The chief executive office and legal representative of CDA would be DCGI and responsible for day to day activities.

A new approach of adding separate chapter was given by the Parliament Committee head in 2008 that would be responsible for handling the administration of medical device regulation. CDSCO would be responsible for the licensing and in maintaining work at zonal and subzonal level. A separate medical device division was recommended by the Committee within the central drug administration. After an year of studies the committee released the report on Drugs and Cosmetic (amendment) Bill, 2007 and it was presented in Rajya Sabha in December, 2008 and it reported redrafting the bill according to the Committee's recommendations. Laws which were responsible for the regulation of medical devices was in drift. But now legislations are now being followed up more than 3 years. [8]

Development of regulatory aspects of medical devices in India

Earlier, India used to follow US regulatory scheme but because FDA follows a procedure centralized with time India switched over to European regulatory scheme which work by decentralized procedure. For the reasons of cost, India is attracted to the EU's structure with de-centralized network of private sector and bodies are appointed by the Competent Authority of each member state. The Central Drugs Standard Control Organization (CDSCO) is mainly responsible for regulation of medical devices in India under Ministry of Health and Family Welfare. All products must be registered before the company's products introduced into the Indian market with CDSCO. In late 2008 the DCGI prepared an expanded list of medical devices which require registration. The list includes over 160 medical devices.

Regulatory scheme The DCGI formed a small core group associated with the government of India to form a regulatory scheme of CDSCO officials and other industry representatives. "Road Map" was discussed by the industry representatives and officials of Govt of India. It includes status review and guiding principles and follow up phases to make it a comprehensive process. "Proposals for Implementation "a paper was presented by the industry .The final recommendations made would be checked by the DCGI and they would be responsible to report to the core group. Two government laboratories were identified by DCGI which are capable of testing Medical Devices . [8]

Regulatory Guideline Required For Manufacturing Of Medical Device In India

In India import, manufacture, sale and distribution of Medical devices is regulated under Drugs and Cosmetics Act, 1940; and Rules, 1945 and guidelines is given by CDSCO headed by DCGI of India. DCGI grant permission by reviewing the manufacturing site and document submitted by manufacturer or Indian agent for manufacturing medical device in India. For manufacturing and sale of notified medical device under Central Licenses Approval Authority (CLAA) scheme in India, CDSCO provide form 28 which is filled by manufacturer with required appropriate document under drug and cosmetic rule. Drug and cosmetic rule 76 describe the data and document required for grant permission of manufacturing license. Applicant fill form 27 for the grant of license for manufacturing of medical device in India. Application is submitted to the concerned State Drugs Licensing Authority, The concerned CDSCO Zonal/Sub-Zonal Office. The Drugs Controller General of India with requisite fee prescribed in the drug and cosmetic rule. Documents required to be submitted in the manner and order given below for grant of license in form-28 for Manufacture of Medical Devices in India: -

1. Covering Letter – It is the most important part of the application which specify the intent of application duly signed by authorized signature (name and designation). List of document required under guidelines was provided in the covering letter.

2. An Authorization letter- Director /company secretary/ partner agent issue an authorization letter with name and designation of person authrorized to sign on the behalf of firm in the legal document like form 27.
3. Filled Form 27: Signed and stamped on the form 27 by the Indian agent with name and designation.
4. The requisite fee (under Drugs & Cosmetics Act & Rules): A) License fees of Rs.6000/-B) Inspection fees of Rs. 1500/- (Total Rs. 7500/- for 10 items for each category of Device) and C) Additional fees at the rate of Rs.300/- for a each additional item of Device.
5. Constitution Details: Documents relating to constitution of firm viz. partnership-deed, memorandum and article of association etc. and
6. Approved Manufacturing Premises: Plan/Layout approved by the Drugs Licensing Authority should be submitted as stated in Site Master File.
7. Full particulars of competent and regular technical staff for manufacturing and testing of Medical Devices with Educational Qualification, Experience Certificate etc

8. Site Master File: document containing specific and factual GMP information about the production and control of pharmaceutical manufacturing operations by manufacturer. It contain a) general information about the manufacturing premises b) personnel information handling the manufacturing of device c) Facilities available in premises like plan layout, description on rooms for manufacturing, texture and fitting, ventilation system etc. d) brief description of equipment used e) sanitation, production quality control, storage, safety etc

9. Specific Environmental Requirements: as per guideline like moulding assembling and packing is done under HVAC (heating ventilation air conditioning) technique. Testing facilities for requisite tests carrying out Chemical and Physico-Chemical testing of medical devices and of raw materials used in its own premises.
10. Device Master File: It have duly signed document contains information about medical device. it have executive summary about the medical device, device description and product specification, including variants and accessories, labeling, essential principal which give conformity about the standard applies on the medical device manufacturing, risk and analysis summary, product verification and validation, biocompatibility, description on medical substance(if incorporated with device), biological safety data, sterilization, animal testing and model, stability data and at last vigilance report.
The other documents which are included for the manufacturing of medical devices are list of Medical Devices along with undertaking in prescribed pro-form given in guideline, Details of Standards followed by manufacturer, Promotional literature, package inserts, device labels etc,. ISO 13485:2003 Certificate (if any), Full Quality Assurance Certificate, CE Design Certificate (if any), Declaration of Conformity (if any) and any other approvals (e.g US FDA). [10]

Regulatory guideline required for registration of notified medical device in India

This document may also be applicable for submission of application for registration and Rules Related to Registration of notified Medical Devices (excluding notified IVD's) in India.
After taking import license of a notified medical device in India, Manufacturer or Indian agent have to fill application to registered the device in India by filling and submitting Form 41 with required document given under rule 24-A, 25-B, 27-A, and 28-A of drug and cosmetic rule.
1. Covering Letter – It is the most important part of the application which specify the intent of application duly signed by authorized signature (name and designation). List of document required under guidelines was provided in the covering letter.
2. An Authorization letter- Director /company secretary/ partner agent issue an authorization letter with name and designation of person authrorized to sign on the behalf of firm in the legal document like form 41.
3. Filled Form 27: Signed and stamped on the form 41 by the Indian agent with name and designation.
4. Requesting Fee: The requisite fee as prescribed in the Drugs & Cosmetics Act & Rules
1500USD- registration of manufacturing premises
1000 USD for one device and additional 1000 USD for each new device addition for import
This requesting fee is payable as a treasury Challan in notified bank of Baroda branches under the head of account. Receipt of fee payment is attached along with application for registration.
Manufacturer may pay the requesting fee directly by electronic clearance system (ECS) from any bank in the country of origin to the bank of Baroda, Kasturbha Gandhi Marg New Delhi under the head of account. It is treated same as bank Challan but subject to approval when they receive the payment.
5. Power of Attorney – Manufacturer had to give authorisation to his Indian agent by documenting power of attorney executed and authenticated by first class magistrate or the equivalent authority in its origin country, which is attested by the Indian embassy of said country. The power of attorney should be signed and stamped by both manufacturer and Indian agent giving their whole detail like name and address. It should also notify the list the name and detail of proposed device.
6. Attested copy of wholesale license (In India) for sale and distribution under drug and cosmetic rule in form 20-B and 21-B.
7. Attested or notarized (by Indian embassy of country of origin) and valid copy of free sale certificate of each device issued by national drug regulatory authority of the country of origin and same certificate of marketability issued by one of the country viz. USA, Canada, Australia and European Union.
8. Duly notarized/ Attested (by Indian Embassy in the country of origin) and valid copy of ISO 13485 Certificate in respect of the legal and actual manufacturing site (s).

9. Duly notarized/ Attested (by Indian Embassy in the country of origin) and valid copy of CE Full Quality Assurance Certificate/CE Production Quality Assurance Certificate/ CE Type Examination Certificate/ CE Product Quality Assurance in respect of the legal and actual manufacturing site.
10. Duly notarized/ Attested (by Indian Embassy in the country of origin) and valid copy of CE Design Certificate in respect of the proposed Device (s) in generic and Model name, if applicable.
11. Duly notarized/ Attested (by Indian Embassy in the country of origin) and valid copy of Declaration of Conformity in respect of the proposed Device (s), if any.
12. Copy of latest Inspection/Audit Report carried out by Notified bodies/National Regulatory Authority/Competent Authority.
13. A duly filled Schedule D (I) along with the undertaking as per the Performa prescribed in the Drugs & Cosmetics Act & Rules, signed & stamped by the manufacturer indicating the name and designation of the authorized given in guidelines by CDSCO.
14. Submit Pant/site master file contains data given in CDSCO guidelines
15. Submit Schedule D(II)Device Master File contains data given in CDSCO guidelines.

Requirements for Import License of Notified Medical Devices in India

The following documents are required to be submitted in the following manner and order for issue of the Import License in Form 10 of the medical devices for import into India: -
Requirements for import of medical devices in India
1. Covering letter – it is an important part of application which specify the intent of the application (whether the application of proposed device is being submitted for the first time or renewal application). The list of document required under guideline was provided in it. The covering letter should be duly signed and stamped by the authorized signatory (name and designation).
2. An Authorized letter-issued by the director/company secretary/partner of the Indian agent firm along with the name & designation of person authorized to sign on behalf of the firm.
3. Filled Form 8 –Application for license to import drugs (excluding those specified schedule X) to the Drugs & Cosmetic Rules, 1945 signed & stamped by the Indian agent with name and designation.
4. Filled Form 9- application for an import license as per perfoma described in the Drugs & Cosmetic Rules) signed & stamped by the Indian agent with name & designation.
5. The Requisite Fee as prescribed in the Drugs & Cosmetic Act & Rules

1000 for each proposed device
100 for additional device

This requesting fees is payable as a treasury Challan in notified bank of Baroda branches under the head of account. receipt of fee payment is attached along with the application fore registration manufacturer my pay the requesting fee directly by Electronic Clearance System (ECS) from any bank in the country of origin to the bank of Baroda, kasturba Gandhi Marg New Delhi. It is treated same as bank challan but subject to approval when they receive the payment.
6. Wholesale license attested by gazette officer for sale or manufacturing license under Drugs & Cosmetic Rules which is issued by the State Licensing Authority.
7. Registration Certificate copy in Form 41 which issued by CDSCO with respect to Proposed device.
8. Import license copy in Form 10 which is issued by CDSCO with respect to proposed device.
9. The required documents as per registration in Form 41 issued by the CDSCO if applicable.
Name and address of the manufacturer, Name and address of the manufacturing premises, Name and address of the Indian Agent and Name of the medical devices proposed to be imported should correlate with the name mentioned in the Registration Certificate in Form 41. If approval is needed for existing license a copy /details (License No., Date of issue & Validity) of the Form 10 License along with it's endorsements should be attached with the application. [11]

Marketing potential of medical devices

Medical devices plays a major role in the treatment and cure of diseases. It helps in restoring patients to normal lives like physiotherapy rehabilitation centers. Indian medical device industry is growing at a tremendous rate due to its immense potential in healthcare. Role of medical devices across the healthcare includes screening, diagnosis, restoration, and monitoring. To overcome the adverse effect of low quality devices or products post marketing surveillance must be conducted for the reliability of medical device used in the healthcare.

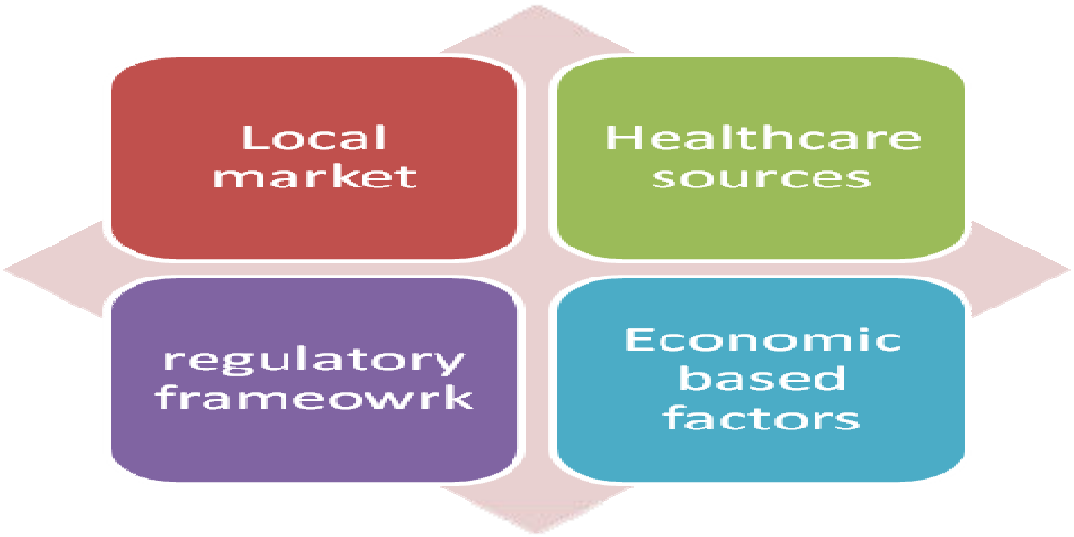

Figure 3: Factors affecting medical device industry

Indian medical device industry is affected by the country's GDP, healthcare sources, expenditure on the sources, public awareness among the healthcare (Figure 3). According to World bank India spends only 1% GDP on the public health. The Indian medical device industry expected to grow 520billion USD by 2020. By making changes in the economic and regulatory system medical device industry expected to grow at a tremendous rate. The important steps for the establishment of medical device industry must consider the main points (Figure 4)

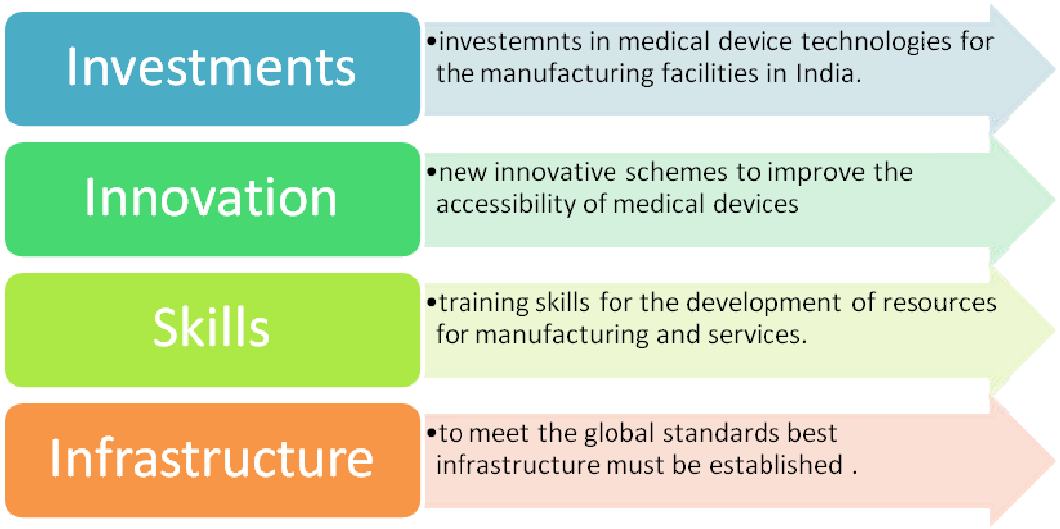

Figure 4: steps needed for the better growth of medical device industry

In today's context there need to be a change from developing and manufacturing of high tech products to the manufacturing of low and mid tech products (Figure 5).

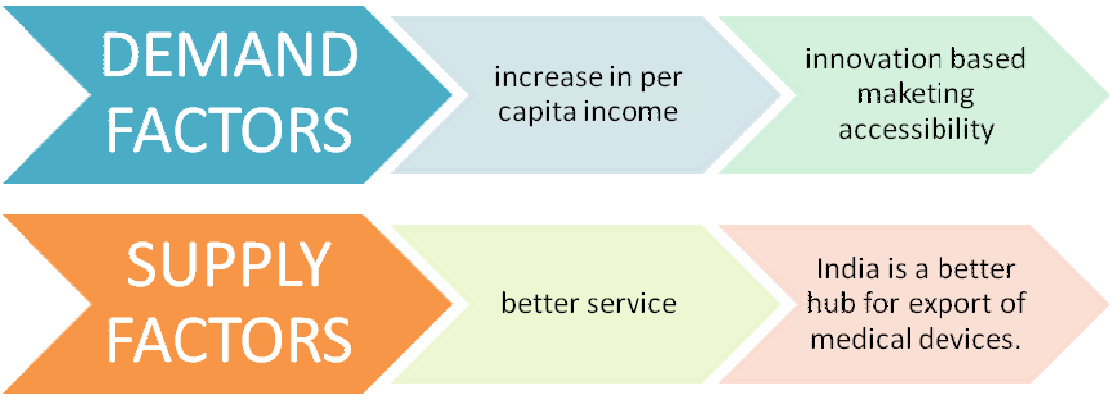

Figure 5: Demand and supply side for the manufacturing of medical devices in India

Medical Device Draft Policy

The rules of medical devices were given by the Central Government by the Ministry of Health and Welfare, 2016. These rules may be called as Medical Devices rules, 2016. These rules comes into act after the date notified by the central government after their final publication in the official gazette. Regulation of medical devices shall be done on the basis of severity of risk corresponding to medical devices. The DCGI shall be the Central Licensing Authority responsible for the execution of these rules related to import, manufacture, clinical investigation, evaluation of medical devices. An application shall be made for the manufacture of medical devices through online portal to the Central Licensing Authority. License for import of medical devices shall be granted by the Central Licensing Authority and applicant shall make an application in the form MD12 to obtain the license. No person shall conduct any clinical investigation of medical devices without the permission granted by the Central Licensing Authority. An applicant can apply for clinical investigation in the form MD20 to the Central Licensing Authority. "Sale of Drugs Other than Homeopathic Medicines" of the Drugs and Cosmetic Rules, 1945 shall be applicable mutatis mutandis in respect of sale of medical devices.[16]

Conclusion

Regulatory guidelines required for approving new medical devices must provide effective pathways for innovators but also ensure the safety of patients. The major purpose of making rules and regulations stringent for medicinal devices is to provide safety to public health. It is the responsibility of these regulatory authorities to ensure that the companies abide to the rules and regulations to safeguard public health. This article helps the readers to find knowledge about the implemented regulations on medical devices in India started from submitting applications for medical device registration certificates to medical device clinical trials and medical device manufacturing/importation licenses in India.

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Declaration of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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