CODEN [USA]: IAJPBB ISSN : 2349-7750

INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES
SJIF Impact Factor: 7.187

Available online at: http://www.iajps.com *Research Article*

STUDY ON INDIAN MEDICAL DEVICE LEGISLATIONS IN COMPARISION WITH UNITED STATES OF AMERICA AND EUROPEAN UNION WITH SPECIFIC REFERENCE TO SELECTED HIGH RISK MEDICAL DEVICES

R GNANA RAMYA[1*], M. V. NAGABHUSHANAM[2], Y. RATNA SINDHU[3], T SUKANYA[4], SK SANJUDA[5], BRAHMAIAH BONTHAGARALA[6], G. RAMAKRISHNA[7]

[1]Department of Pharmaceutical Regulatory Affairs, Hindu College of Pharmacy, Amaravathi Road, Guntur, Andhra Pradesh, India-522002.

Article Received: July 2022 **Accepted:** August 2022 **Published: September** 2022

Abstract:

In order to market any medical device, marketing authorization from Regulatory authority is required. The process of gaining authorization is complex, multistep and requires review of information by competent authorities. Upon scrutinizing the information furnished by Manufacturer, marketing authorization is granted by the concerned Regulatory authority. In the USA, manufacturers are required to apply to United States Food and Drugs Application (USFDA) for Marketing Authorization. There are two types of applications in USA; 510 (k) and Pre-Market Application (PMA). In EU, National Authorities give approval for marketing medical devices. A system of third party compliance is followed, where Notified Bodies (Third Party) ensure Quality Assurance, pre and post approval. In India, Central Drugs Standard Control Organization (CDSCO) approves devices for sale and import. Medical Devices are regulated under CLAA scheme. The Drug Controller General of India (DCGI) is the central licensing authority for medical devices. This paper attempts to capture information on regulations of Medical Device in three regions namely; USA, EU and India and compare provisions of Market authorization in the respective regions, and further, for the readers, make this complex subject easier to grasp.

Keywords: *In vitro diagnostics, Indian regulations, medical device regulations, medical device rules 2017, medical devices.*

Corresponding author:

R GNANA RAMYA,

II/II M.Pharmacy, Department of Pharmaceutical Regulatory Affairs, Hindu College of Pharmacy, Amaravathi Road, Guntur, Andhra Pradesh, India-522002.

QR code

Please cite this article in press R Gnana Ramya et al, ***Study On Indian Medical Device Legislations In Comparison With United States Of America And European Union With Specific Reference To Selected High Risk Medical Devices*** *., Indo Am. J. P. Sci, 2022; 09(9).*

INTRODUCTION [1-5]:

The Drugs and Cosmetics Act, 1940 is a central Act of the Parliament of India, enforced by both central and state governments and extended to whole of India. The main objective of Drugs and Cosmetics Act, 1940 and Rules, 1945 is to ensure safety, efficacy and quality of drugs, biologicals, medical devices, cosmetics and veterinary drugs. As per Drugs and Cosmetics Act, 1940 the government regulatory agencies will monitor the quality of drugs by periodic inspections of the manufacturing and sales premises for confirmation to the provisions of Drugs and Cosmetics Act, 1940 and monitoring the quality of drugs moving in the market by carrying out post market surveillance. According to Drugs and Cosmetics Act, 1940 manufacturers are responsible for quality of drugs manufactured by them. The clinical trials, new drug approvals, exports of drugs are regulated by the Rules. Drugs and Cosmetics Rules, 1945 covers the provisions for classification of drugs under given schedules and also contains the rules/guidelines for the storage and sale1.

Medical Device:

A medical device can be any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, material or other similar or related article, intended by the manufacturer to be used, alone or in, software combination for a medical purpose.

Medical Device in India as per CDSCO:

Medical Devices as. “Devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or. Animal.Under the Drugs and Cosmetics Act, CDSCO is responsible for approval of New Drugs, Conduct of Clinical Trials, laying down the standards for Drugs, control over the quality of imported Drugs in the country and coordination of the activities of State Drug Control Organizations by providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.

Medical Device in USA as per USFDA:

A medical device is an instrument, apparatus, implant, machine, tool, in vitro reagent, or similar article that is to diagnose, prevent, mitigate, treat, or cure disease or other conditions, and, unlike a pharmaceutical or biologic, achieves its purpose by physical, structural, or mechanical action but not through chemical or metabolic action within or on the body.

- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

Medical Device in Europe as per EMA:

Medical devices are products or equipment intended for a medical purpose. In the European Union (EU) they must undergo a conformity assessment to demonstrate they meet legal requirements to ensure they are safe and perform as intended. They are regulated at EU Member State level, but the European Medicines Agency (EMA) is involved in the regulatory process.

Medical Device classifications:

Table-1-Classification of medical Devices as per CDSCO

CLASS	RISK LEVEL	MEDICAL DEVICES EXAMPLES
CLASS A	LOW RISK	Absorbent cotton wools ,Surgical dressing Alcohol swabs etc.,
CLASS B	LOW MODERATE RISK	Thermometer, Bp, Monitoring Devices, Disinfections etc.,
CLASS C	MODERATE HIGH RISK	Implants, Hemodialysis, Catheter etc.,
CLASS D	HIGH RISK	Angiographic Guide Wire ,Heart Value etc.,

Table-2-Classification Of Medical Devices as per USFDA

CLASS	RISK LEVEL	EXAMPLES	CONTROLS
CLASS A	LOW RISK	Adhensive bandages ,hospital beds	General controls
CLASS B	MEDIUM RISK	Blood pressure cuffs ,sutures	General controls and special controls
CLASS C	HIGH RISK	Peacemaker ,vascular graft	Special controls

The process of device development from conceptualization to post-marketing surveillance (PMS) is explained in Figure 1

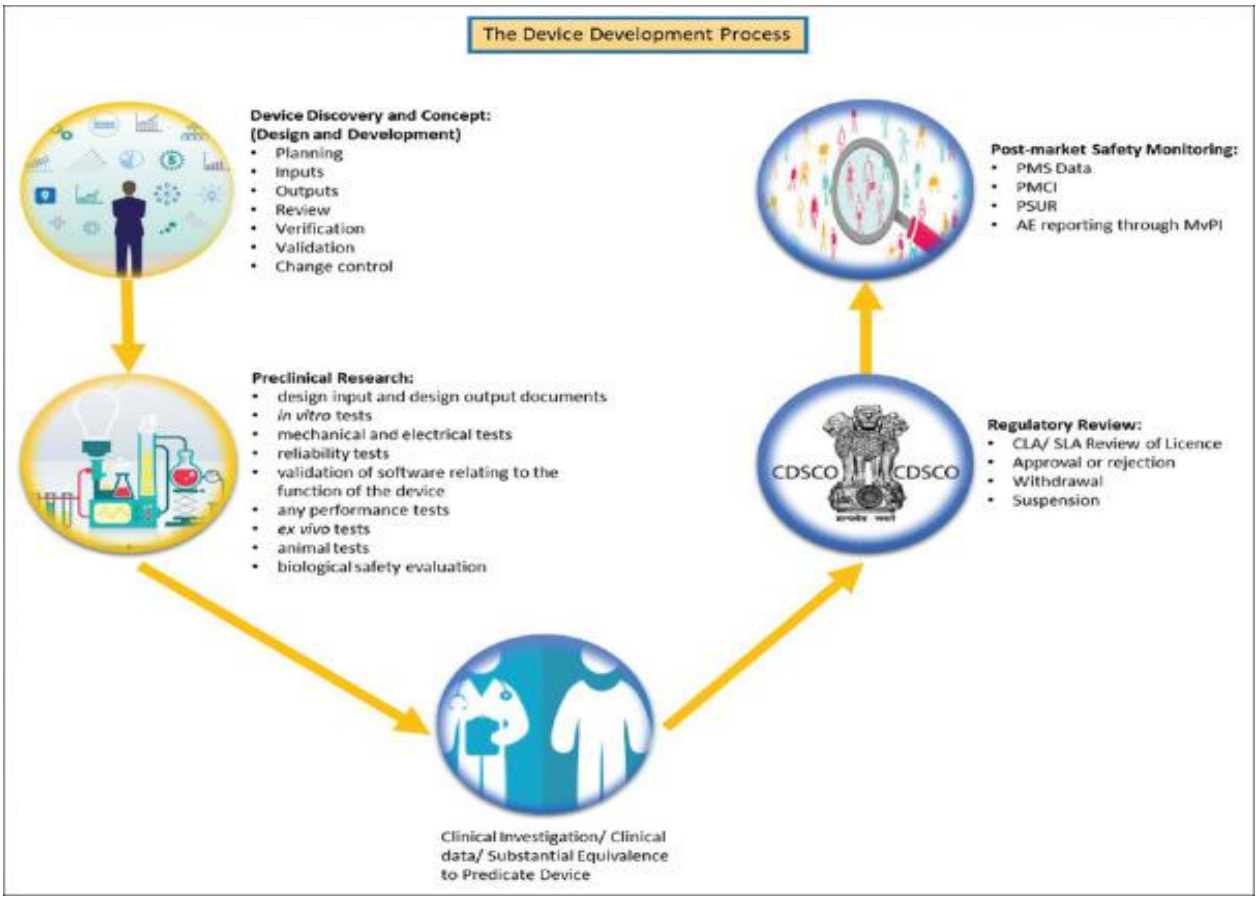

Figure 1: Medical device development and approval process. CLA: Central Licensing Authority; MvPI: Materiovigilance Program of India; PMCI: Post Marketing Clinical Investigation; PMS: Post Marketing Surveillance; PSUR: Periodic Safety Update Report; SLA: State Licensing Authority.

NEW MEDICAL DEVICE RULES:

As medical devices deal with the health and safety of the patients, their manufacturing is done in a strictly regulated environment, and they fulfill stringent regulatory requirements and guidelines. While the drug regulations in India are well established for decades, a well-defined regulation for medical devices was missing for long. Nevertheless, the Indian regulatory regime for medical devices has recently been very active.[10] Medical Devices and Diagnostics Division of Central Drug Standard Control Organisation (CDSCO) has developed structured regulations for medical devices, IMDR which was released in January 2017 and came into force from January 2018.[5] IMDR was amended in February 2020 as "Medical Devices (Amendment) Rules, 2020"and came into force in April 2020. The 2020 amendment was released with an addition of "registration of certain medical devices".[6] Though many of the medical devices still continue to be controlled as drugs under the Drugs and Cosmetics Act, 1940, the advent of the IMDR and other

supporting guidelines has paved the way for India to move its first step towards enhanced patient safety with respect to medical devices. Future amendments of IMDR can focus on fulfilling the gaps that would have equated these regulations with that of MDR and IVDR of EU, which are the mostrecent international regulations for medical devices for device safety and performance. A roadmap of the development of the regulatory system for medical devices in India is presented in Figure 2.

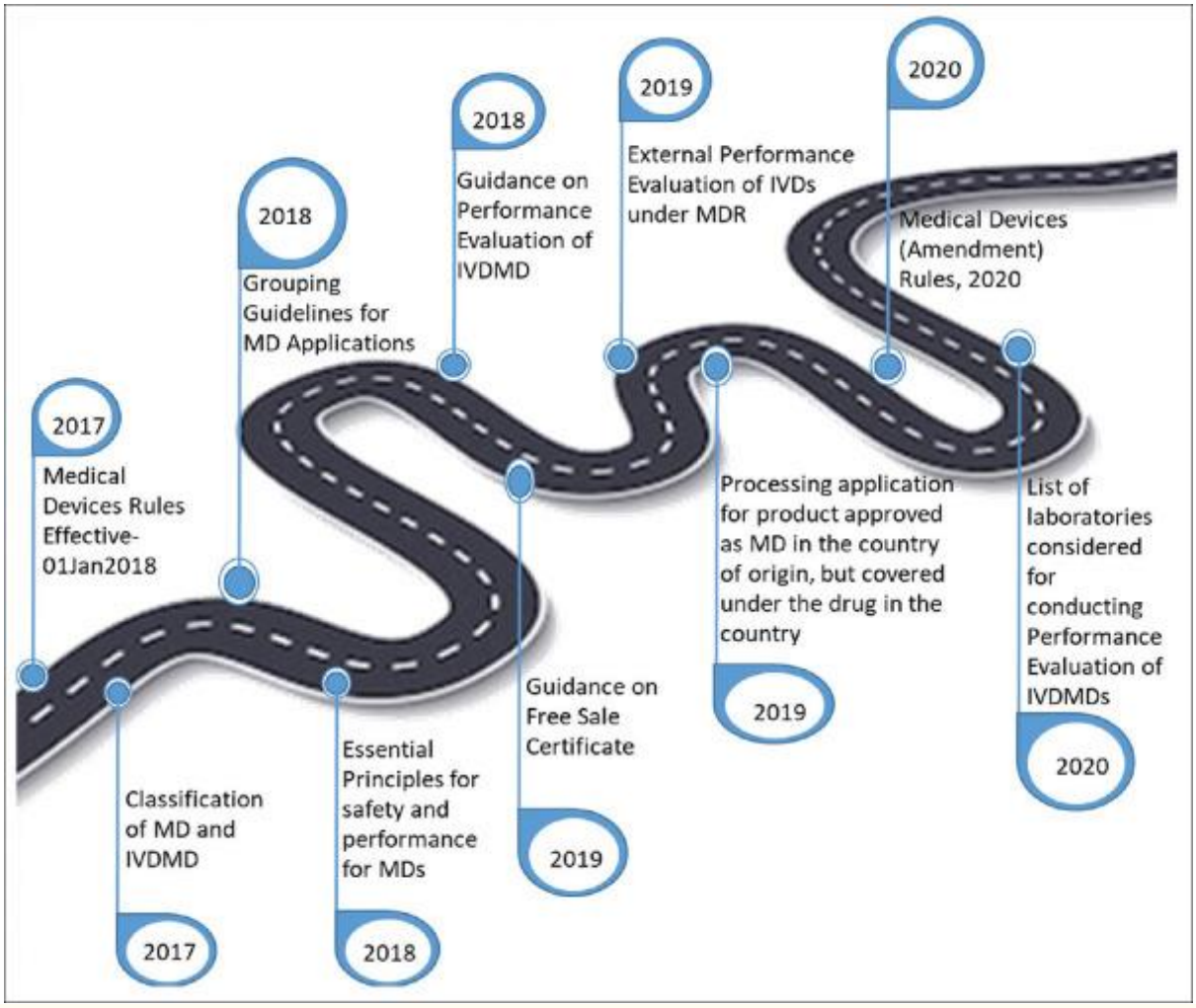

Figure- 2-Roadmap of Indian regulations on medical devices. IVDMD: *In vitro* Diagnostic Medical Device; IVDs: *In vitro* Diagnostics; MD: Medical Device

As per the IMDR, rules are applicable to both medical devices and IVDMDs that:

- Can be licensed for-import; manufacture for sale or for distribution; and sale, stock, exhibit or offer for sale
- May be manufactured for the purpose of clinical investigations, test, evaluation, examination, demonstration or training.

The IMDR talks about all the regulatory aspects of the medical devices, including regulations covering classification, grouping, essential principles, and product standards; governing bodies and authorities; registration; manufacture; import; labeling; clinical investigation or clinical performance evaluation; duties of officers and governing bodies; lab registration; sale of medical devices; parameters of classification; fees; notified body; grant of license; quality management system; post-approval changes; PMS, and exemptions [Figure 3].

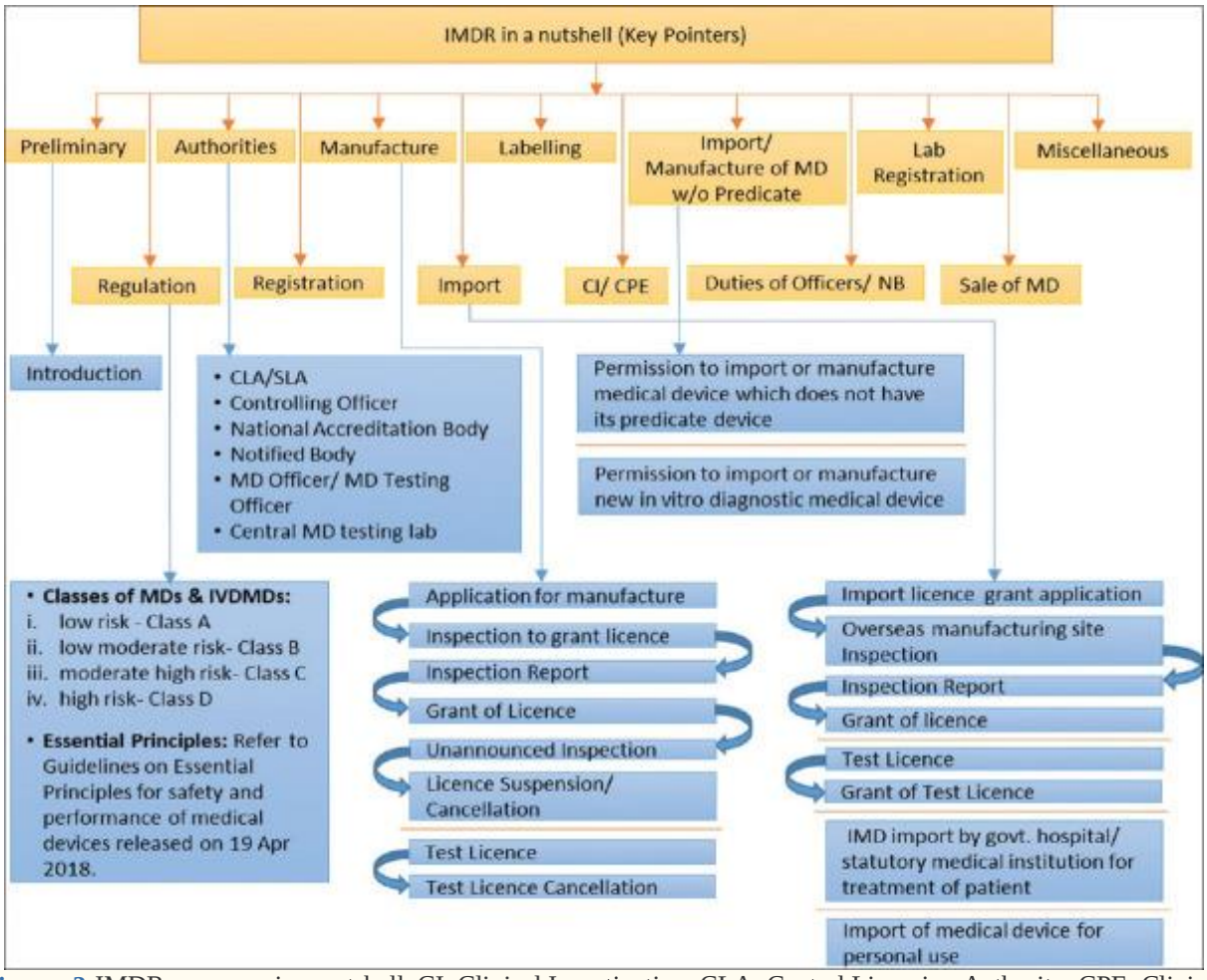

Figure -3-IMDR summary in a nutshell. CI: Clinical Investigation; CLA: Central Licensing Authority; CPE: Clinical Performance Evaluation; IMDR: Indian Medical Device Rules, 2017; IVDMD: *In vitro* Diagnostic Medical Devices; MD: Medical Device; NB: Notified Body; SLA: State Licensing Authority; w/o: without

CLINICAL INVESTIGATION OR CLINICAL PERFORMANCE EVALUATION [6-8]:

Similar to approval of drugs, a clinical investigation of an investigational medical device is required in or on human participants to assess its safety, performance, or effectiveness. For a new IVDMD, a clinical performance evaluation is required on specimens collected from human participants to assess its performance. Clinical investigation or clinical performance evaluation are performed based on the clinical investigation plan or clinical performance evaluation plan respectively, which are detailed documented protocols for their conduct [Figure 5].[5] Furthermore, during this process, the rights, safety, and wellbeing of the subjects should be protected consistent with the ethical principles laid down in the Declaration of Helsinki. down in the Declaration of Helsinki.

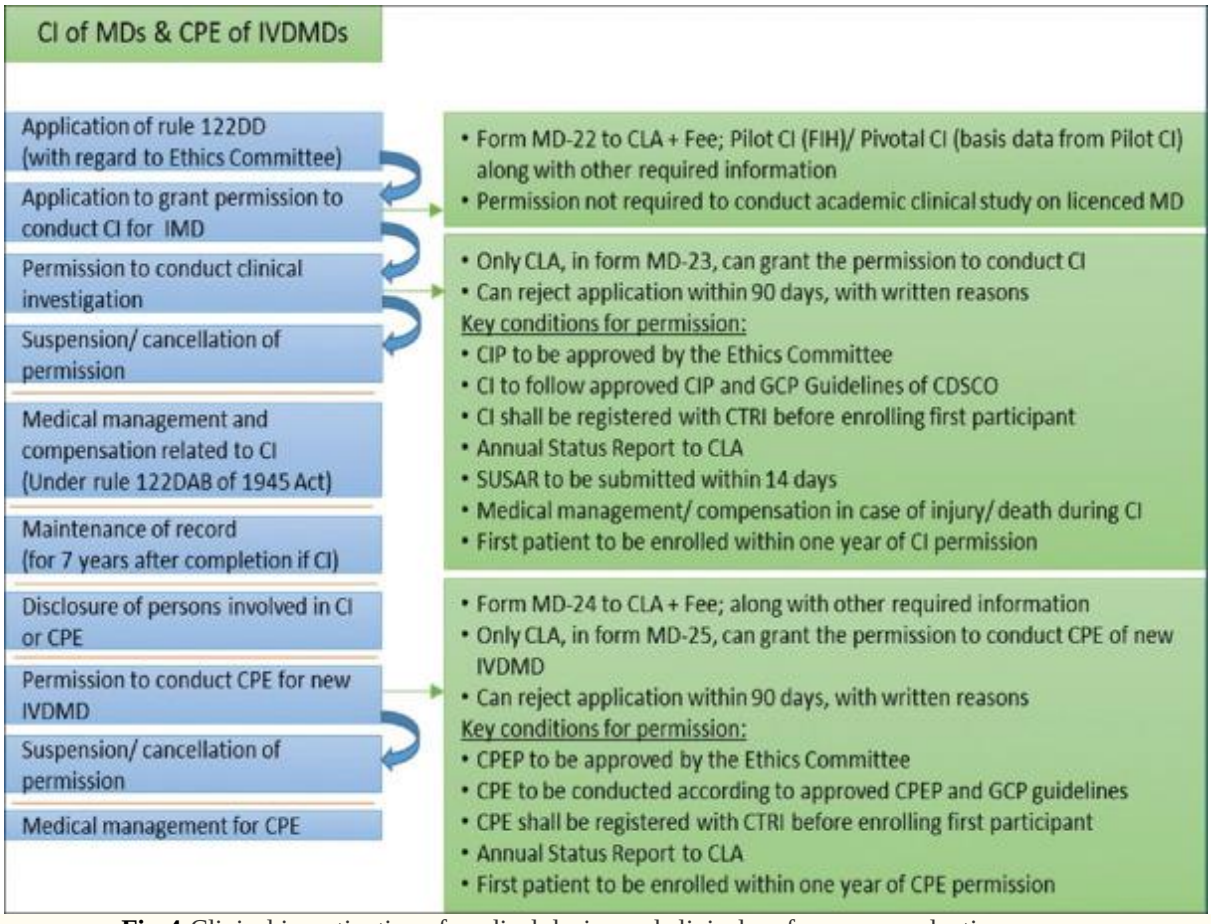

Fig-4-Clinical investigation of medical device and clinical performance evaluation process

In India, Clinical Investigation is required for all class B, C, and D medical devices if the device is an investigational medical device that does not have a predicate device and is manufactured in the country; or if it is a new IVDMD. However, Clinical investigation is not required to grant the import license, if the device is already marketed for at least 2 years in Australia, Canada, Japan, Europe or the United States and the respective CLAs are satisfied with the available clinical evidence. In such cases, CLA may require post-marketing investigation based on subject expert committee's review and recommendation.

VIGILANCE REPORTING/POST MARKETING SURVEILLANCE DATA [9-12]:

The medical device manufacturer has an obligation to make a vigilance report or a PMS data from medical devices that have been placed in the market. This report should contain reporting procedure, complaints received, and corrective and preventive action for that.

Manufacturers are required to conduct a post marketing clinical investigation (includes additional drug-device interaction, safety studies, investigation designed to support use under the approved indication, e.g. mortality or morbidity studies, etc.) for testing the safety and performance of an investigational medical device which does not have its predicate device.

To monitor the clinical safety, a PSUR for each medical device is required to:

a. Report all the relevant new information from appropriate sources
b. Relate these data to patient exposure
c. Summarise the market authorization status in different countries and any significant variations related to safety; and
d. Indicate whether changes will be made to product information to optimize the use of the product.

The PSUR also captures any significant changes to the reference safety information within the reporting interval. Such changes include information relating to contraindications, warnings, precautions, adverse events (AE), and important findings from ongoing and completed clinical investigations and significant nonclinical findings.

For risk minimization and sustaining a better risk-benefit ratio, Indian Pharmacopoeia Commission runs Materiovigilance Program of India (MvPI) for the vigilance of medical devices. With continuous monitoring, it helps in assessing and detecting adverse effects of medical devices, malfunctions, etc. that can result in mortality and morbidity. Since the launch of this program, MvPI has played a vital role in keeping unsafe products at bay and till date a total of 16 medical devices have been recalled from the Indian market.

The medical device manufacturer has an obligation to make a vigilance report or a PMS data from medical devices that have been placed in the market. This report should contain reporting procedure, complaints received, and corrective and preventive action for that.

Manufacturers are required to conduct a post marketing clinical investigation (includes additional drug-device interaction, safety studies, investigation designed to support use under the approved indication, e.g. mortality or morbidity studies, etc.) for testing the safety and performance of an investigational medical device which does not have its predicate device.

To monitor the clinical safety, a PSUR for each medical device is required to:

a. Report all the relevant new information from appropriate sources
b. Relate these data to patient exposure
c. Summarise the market authorization status in different countries and any significant variations related to safety; and
d. Indicate whether changes will be made to product information to optimize the use of the product.

The PSUR also captures any significant changes to the reference safety information within the reporting interval. Such changes include information relating to contraindications, warnings, precautions, adverse events (AE), and important findings from ongoing and completed clinical investigations and significant nonclinical findings.

For risk minimization and sustaining a better risk-benefit ratio, Indian Pharmacopoeia Commission runs Materiovigilance Program of India (MvPI) for the vigilance of medical devices. With continuous monitoring, it helps in assessing and detecting adverse effects of medical devices, malfunctions, etc. that can result in mortality and morbidity. Since the launch of this program, MvPI has played a vital role in keeping unsafe products at bay and till date a total of 16 medical devices have been recalled from the Indian market.

Some of the top medical devices companies by revenue (in no particular order), 2017, in India include [7]:

- Johnson & Johnson.
- General Electric Co.
- Medtronic Inc.
- Siemens AG.
- Baxter International Inc.

PROCEDURE OF MARKETING AUTHORIZATION IN THE UNITEDSTATES OF AMERICA [12-16]:

In the United States of America, Medical Devices are regulated by Food and Drug Administration (FDA). FDA's Centre for Devices and Radiological Health (CDRH) is responsible for regulating firms who manufacture, repackage, re-label, and/or import medical devices soldin the United States.

A system of Device classification is followed in the US. Devices are classified into Class I, II or III. Each device is assigned to a panel (Cardiovascular, Anaesthesiology etc.). The panel determines the Classand special controls and exemptions applicable to the device.

General Controls include:

- Establishment Registration by manufacturers, distributors, repackages and re-labellers,
- Medical Device Listing with FDA of devices to be marketed,
- Manufacturing the devices in accordance with GoodManufacturing Practices,
- Labelling medical devices in accordance with the labellingregulations, 21 CFR 801 or 21 CFR 809,
- Medical Device Reporting of adverse events as identified by the user, manufacturer and/or distributor of the medical device.

Special Controls may include:

- Adherence to performance standards, guidance documents,
- Implementation of post-marketing surveillance measures,
- Special labelling.

The FDA has established classifications for approximately 1,700 different generic types of devices and grouped them into 16 medical specialties referred to as panels. Each of these generic types of

devicesis assigned to one of three regulatory classes based on the level of control necessary to assure the safety and effectiveness of the device. The Devices are placed in Class I, II or III. All the classified devices are available on the website of FDA.

Class I devices are defined as non-life sustaining and present minimal harm potential to user. These devices are typically simple in design, manufacture and have a history of safe use. Their failure posesno risk to life and hence are subject to general control and require least regulations, these devices have to comply with Quality System Regulations (QSR) laid in 21 CFR Part 820 and labelled according to21 CFR Part 821. Although most are exempt from 510 (k) pathway andsome are even exempt from QSR. For example tongue depressors are exempt from 510 (k) but stethoscopes are not.

Class II medical devices are devices where General Controls are not sufficient to assure safety and effectiveness and existing methods/ standards/guidance documents are available to provide assurances of safety and effectiveness. In addition to compliance with General Controls, Class II devices are required to comply with Special Controls.

Special Controls may include:

- Special labelling requirements,
- Mandatory performance standards, both International and UnitedStates,
- Post-marketing surveillance,
- FDA medical device specific guidance.

Information on Class II exempt devices is located within the device regulation, 21 CFR 862 through 892. Devices falling in these class are cleared for sale only through 510 (k) regulatory pathway, where the applicant demonstrates that the 'Device' is substantially equivalent toan existing device called, 'Predicate device' and Clinical Trials may be required for devices falling in this class. The information required in a 510 (k) submission is defined 21 CFR 807.87.

Class III devices usually support or sustain human life, are of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury to the patient. Devices falling in this class have to demonstrate safety and efficacy through Clinical Trials.

For Class III medical devices, sufficient information is not available to assure safety and effectiveness through the application of General Controls and Special Controls. Typically a Pre-Market Approval (PMA) submission to the FDA is required to allow marketing of a Class III medical device. Section 515 (c) (1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) specifies the required contents of a PMA.

Some devices falling in Class III includes replacement heart valves, PTCA balloons, implanted cerebella stimulators, Pacemaker. These devices mandatorily require Phase IV trials data. A few Class III medical devices are required to only have a 510 (k) cleared by the FDAto be marketed.

Manufacturers are required to submit their application for review. Depending on the complexity of the new or modified medical device, the FDA Review of a 510 (k) submission takes between 20 and 90+ days. The more complex the changes or comparison required to support the safety and effectiveness of the new or modified medical device, the longer the FDA review process.

The FDA has a statutory 180-day review cycle for PMA applications. Often PMA applications require medical advisory board review prior to the FDA granting approval to market the medical device. A facility inspection verifying the manufacturing systems present to manufacture the medical device is usually performed prior to FDA PMA approval. FDA approval of a PMA often requires significantly more than 180 days [4].

The FDA reviews the application (510 (k) or PMA) and if satisfied with, data posts online a 510 (k) clearance letter or PMA Approval Letter. Following which a device could be marketed in the USA. Any changes to constitution of device shall be informed to FDA through supplement filing as per the prescribed timelines.

Steps for marketing approval in USA:

- Classify Medical Device.
- Implement Quality Management System (GMP Requirements).
- Submission of Clinical Trial data, If Applicable (Investigational Device Exemption (IDE).
- Submission of Marketing Approval Application (510 (k) Premarket Notification, Premarket Approval Application).
- FDA 510 (k) Clearance Letter or PMA Approval Letter.
- FDA Quality system inspection of Manufacturing

Facility.
- Medical Device Listing in FURLS System.
- Establishment Registration in FURLS System (Figure 3).

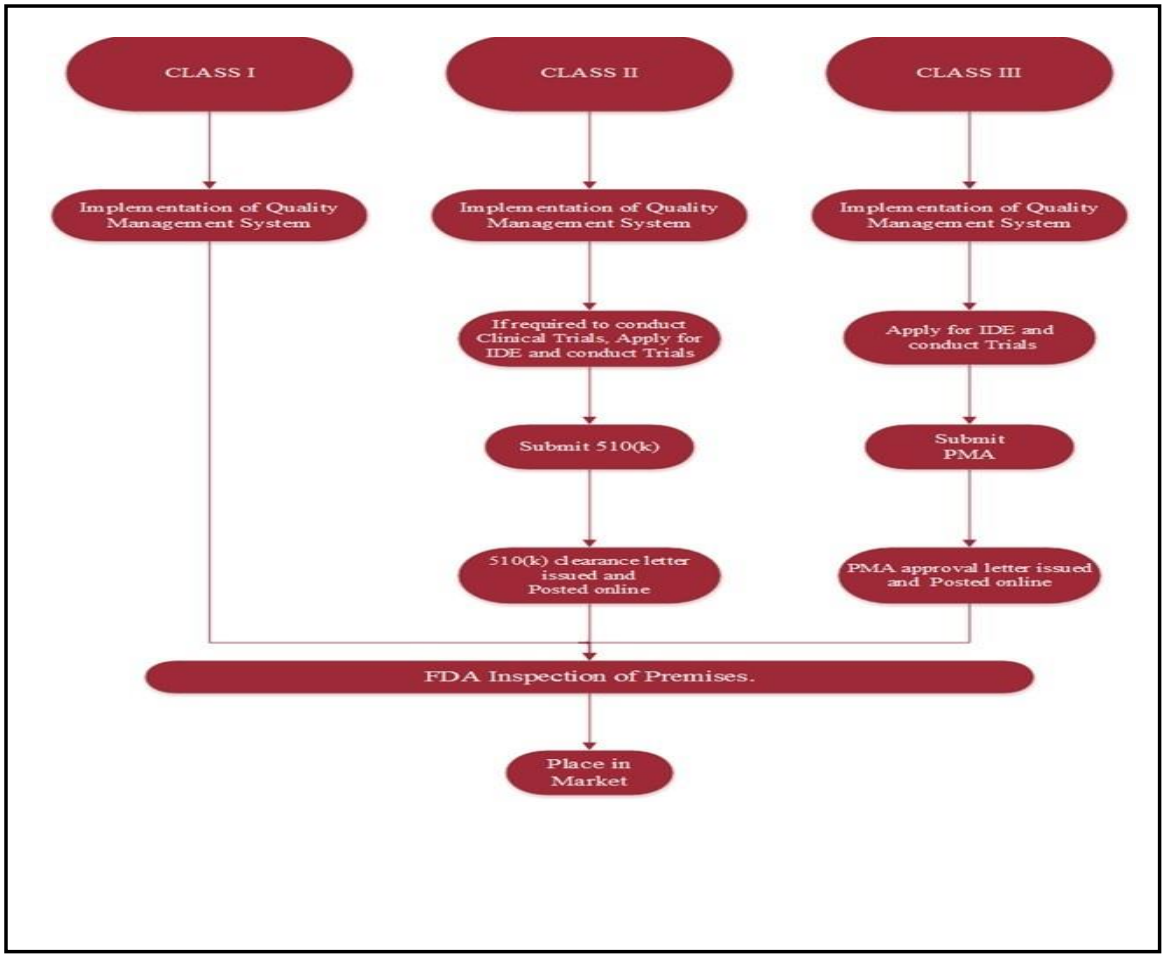

Fig-5-: Regulatory approval pathways in USA

PROCEDURE OF MARKETING AUTHORIZATION IN EUROPEANUNION [15-18]:

In EU, there is decentralized procedure of marketing authorization as no single body regulates Medical devices. A system of third party compliance is followed. Notified Bodies are the third party that issue Quality Assurance certificates and ensures post approval compliance toQuality Management System (QMS).

Medical Devices are regulated by Medical Devices Directive, which consists of three directives that regulate the safety and marketing of medical devices in Europe. The three directives are:

- Medical Device Directive (MDD 93/42/EEC),
- Active Implantable Medical Device Directive (AIMDD 90/42/EE),
- *In vitro* Diagnostic Medical Device Directive (IVDMDD 98/79/ EC).

These directives are regularly updated. The directive 93/42/EEC has been thus far, amended five times. The last amendment was 2007/47/EC, which came into effect in March 2010.

A system of product classification is followed in EU, whereby Medical Devices are classified into classes I, IIa, IIb and III, depending upon the risk involved with usage of device. The criteria for class determination are laid in Annex IX of MDD 93/42/EEC. These criteria take into account the

following:

- Duration of contact,
- Invasiveness of device,
- Source of Energy of device,

Active Principle of Device, if used in combination, as for DrugEluting Coronary Stents.

Some examples of devices and their class are:
Class I: Blood Pressure Cuff, Hospital Bed;
Class IIa: Hearing aid, X ray diagnostic equipment; Class IIb: Ventilator, Blood bags;
Class III: PTCA balloon, Drug Eluting Coronary Stent.

It is worth mentioning that all devices all devices which are of human blood derivative and or utilizing animal tissues or derivative fall in Class III.

All devices used for contraception or the prevention of transmissionof Sexually Transmitted Diseases are in class IIb, unless implantable forlong term invasive devices which fall in Class III. Medical devices intended for recording of X-ray diagnostic images are in Class IIa.

Medical Devices cannot be placed on European Market without conforming to the strict safety requirements of EU. A device must bear CE mark, except for Custom-made devices; Devices for clinical investigation, health protection-urgent unusual circumstances; humanitarian use and In-house use.

Devices are labelled as per Annex I of Council Directive 93/42/EEC in national language and use of appropriate symbols is recommended. Conformity assessment of the Device is performed by a Notified Body.

Technical Documentation should be submitted to the NB for assessment. Documents are accepted in IMDRF format (STED) or as per Notified Bodies Medical Devices (NB-MED) recommend document (NB-MED/2.5.1/Rec 5) 'Technical documentation'. STED and NB-MED format include comprehensive information on device.

The Notified Body is effectively responsible for pre-market evaluation of medical devices. They monitor all aspects of the evaluation from manufacturing process to post-market surveillance.

They review all data (including clinical data), conduct regular inspections (including impromptu on-site inspections) and collect reports regarding safety. Adverse event reporting to the Competent Authority is mandatory for the manufacturer. Once a device is reviewed and deemed acceptable, it receives the CE marking [8].

Once NB clears a device, manufacturer can declare conformity and place the device in market. An NB can conduct surprise audit toensure conformance to QMS by the Manufacturer. Documents must bekept at disposal of Competent Authority for five years (Fifteen Years for implantable Devices).

The timelines for gaining approval differs for different class of devices, complexity of design and risk to the user with use of device. After being approved for marketing class I devices' validity is indefiniteand for Class II and III devices validity is for 3 years.

Any change in the constitution of device, thereafter, has to be informed to the Notified Body as per prescribed timelines (Figures 4-8).

The CE conformity marking shall consist of the initials 'CE' taking the following form:

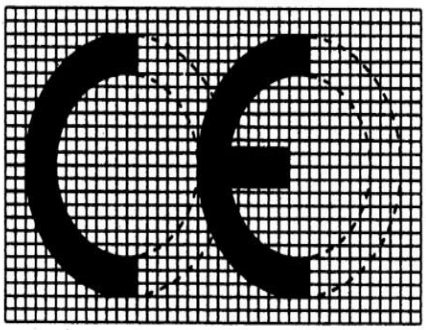

Figure 4: CE mark.

Steps for marketing approval in Europe:

1. Determination of MDD that applies to the device.
2. Determine the Class using Annex IX.
3. Choose conformity assessment procedure/route.
4. Appoint an authorized representative located in Europe.
5. Audit of QMS and Technical Documents by Notified Body.
6. Register Device with Competent Authority of Member State.
7. Prepare Declaration of Conformity stating Medical Device complies with applicable Directive
8. Affix CE mark.
9. Place in Market.

PROCEDURE FOR MARKETING AUTHORIZATION IN INDIA [18-20]:

The Government of India regulates medical devices through a specialized division called, Medical Device and Diagnostics Division, CDSCO, Ministry of Health and Family Welfare. Only a few Medical Devices and Diagnostic kits, called Notified Devices, are regulated under Central Licensing Approval Authority (CLAA) scheme for the purpose of Manufacture, Import, Sale and Distribution. Drug Controller General of India (DCGI) is the Central Licensing Authority.

The regulation of Notified Medical Devices is overseen by both, the central government and the state governments. Under the applicable regulatory framework, the functions of manufacture, import, distribution and sale of medical devices require licenses or permissions, as the case may be.

Import, manufacture, sale and distribution of Medical devices are regulated under Drugs and Cosmetics Act, 1940; and Rules, 1945. At present following notified Medical Devices are regulated under the Act (Table 1).

Further the following products are regulated as "Drugs" under Drugs and Cosmetics Act and Rules there under which are considered 'Medical Device' in the Country of Origin. This provision is ambiguous and inconsistent with Harmonized Standards of Medical Devices. Manufacture for sale of these products is regulated by the concerned State Drug Licensing Authority only]

Items classified as drugs in India:

- Blood Grouping Sera.
- Ligatures, Sutures, Staples.
- Intra Uterine Devices (Cu-T).
- Condoms.
- Tubal Rings.
- Surgical Dressing.
- Umbilical Tapes.

The Government of India, through CDSCO, published guidance documents in 2012 regarding marketing authorization of Medical Devices. In these documents the CDSCO outlined its expectation for grant of License for Import and Manufacture of Medical Devices.

These Guidance documents are:
CDSCO/MD/GD/CLAA/01/00: Guidance Document on application for grant of License in Form-28 for Manufacture of Medical Devices in

India under CLAA scheme.

List of items for Grant of License in Form-28 for Manufacture of Medical Devices in India as outlined in CDSCO/MD/GD/CLAA/01/00

- Covering Letter,
- Authorization Letter,
- A duly filled Form-27,
- Requisite Fee (License fee Rs. 6000/- and Inspection fee Rs.1500/-),
- Constitution Details of firm,
- Approved Manufacturing Premises Plan/Layout,
- Full Details of competent and regular technical staff,
- Site Master File (SMF)
- Specific Environmental Requirements,
- Device Master File,
- Details of Standards,
- Promotional literature, package insert, device label etc.,
- ISO 13485:2003 Certificate (if any), CE mark (if any), any otherapproval (if any).

CDSCO/MD/GD/IL/01/00: Guidance Document on Common Submission format for Import License in Form 10 of Notified Medical Devices in India.

List of items for Common Submission Format for Import License in Form 10 of Notified Medical Devices in India as outlined in CDSCO/MD/GD/IL/01/00 (Table 2).

- Covering Letter,
- Authorization Letter,
- Duly filled Form-8,
- Duly filled Form-9,
- Requisite Fee,
- Duly attested (notarized) and valid copy of Wholesale License for sale and distribution of drugs and Manufacturing License, Under D&C Act by State Licensing Authority,
- Registration Certificate in Form-41 by CDSCO,
- Import License in Form-10 issued by CDSCO,
- Required documents as per registration certificate in Form-41issued by CDSCO.

Steps for Import License in India

a. Determine whether the device requires registration under D&CAct.
b. Grant India Agent Power of Attorney to manage registration inIndia.
c. File application for Device Registration with CDSCO throughForm-40.

Device manufacturers new to India require Form-45 in supportof Form-40.

e. Obtain Registration Certificate Form-41 from CDSCO, valid for3 years.
f. Identify distributor in India (holding Forms 20B and 21B).
g. Apply for Import license using form 8 & 9(6,9-12).

CONCLUSION:

The primary goal of the pre-marketing assessment process is to protect the safety of patients who will potentially benefit from a new device. It might be useful for regulatory agencies to develop regulatory apparatus for assessment of medical devices before granting permission to place a device in the market.

In USA, medical device regulation is performed by CDRH. Strict conformity to desired principles is required to obtain marketing authorization. 510 (k) and PMA are the regulatory pathways for obtaining marketing authorization in USA. The choice of regulatory pathway adopted by companies depends primarily upon the complexity of design, potential risk to health of user and safety of device.

In European Union, CE marking/certification is mandatory for any device to be marketed. Medical devices are regulated through Notified Bodies and National Authorities in a very novel fashion. The Notified Body ensures compliance to Quality and Safety standards and approvesdevices for CE marking, whereas marketing authorization is granted by Competent Authority of the member state.

In India, CDSCO regulates handful devices through gazette notifications. These devices are called notified devices. A few productsare classified as drugs in India but are classified as devices in other countries. This system is not in consonance with international standards. Existent system appears to be rudimentary in character when compared to regulatory systems of USA and EU. Therefore, revamping of current regulatory system is required for administration of devices moving in commerce and creating harmonized standards ofmedical devices.

REFERENCES:

1. Deloitte, NATHEALTH Medical devices making in India-a leap for Indian healthcare. 2016. [Last accessed on 2021 Mar 04]. Available from: https://www2.deloitte.com/content/dam/Deloitte/in/Documents/life-sciences-health-care/in-lshc-medical-devices-making-in-india-noexp.pdf .
2. India – Overview of Medical Device Industry and Healthcare Statistics. Available via EMERGO. 2016. Jul, [Last accessed on 2020 Jun

30]. Available from: https://www.emergobyul.com/resources/market-india .
3. Union Budget of India 2020-21, Rebuilding Momentum. Available via PricewaterhouseCoopers Private Limited. 2020. Feb, [Last accessed on 2020 Jun 20]. Available from: https://www.pwc.in/assets/pdfs/budget/2020/pwc-union-budget-analysis.pdf.
4. Markan S, Verma Y. Indian medical device sector: Insights from patent filing trends. BMJ Innov. 2017;3:167–75. [Google Scholar]
5. Medical Device Rules, 2017: Ministry of Health and Family Welfare, Government of India. Available via CDSCO. [Last accessed on 2020 Jun 08]. Available from: https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/Medical-Device-Diagnostics/
6. Medical Devices (Amendment) Rules, 2020: Ministry of Health and Family Welfare, Government of India. Available via CDSCO. [Last accessed on 2020 Jun 08]. Available from: https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/Medical-Device-Diagnostics/
7. Brahmaiah Bonthagarala, Regulatory Requirements for Registration of Generic Drugs in "BRICS" Countries, International Journal of Pharmaceutical Science and Health Care, ISSN 2249 – 5738, Issue 6, Vol. 6 (November-December 2016), 20-39.
8. Brahmaiah Bonthagarala, Current Regulatory Requirements for Registration of Medicines, Compilation and Submission of Dossier in Australian Therapeutic Goods Administration, International Journal of Advanced Scientific and Technical Research, ISSN 2249-9954, Issue 6 volume 6, November-December 2016, 144-157.
9. Brahmaiah Bonthagarala, Comparison of Regulatory Requirements for Generic Drugs Dossier Submission in United States and Canada, International Journal of Pharmaceutical Science and Health Care, ISSN 2249 – 5738, Issue 6, Vol. 6 (November-December 2016), 1-19.
10. Brahmaiah Bonthagarala, Nanomedicine Clinical Use, Regulatory and Toxicology Issues In Europe, Journal of Drug Delivery and Therapeutics, 2019; 9(4-s):846-848.
11. Brahmaiah Bonthagarala, A Review on global harmonization task force (GHTF) - principles of in vitro diagnostic (IVD) medical devices classification, The Pharma Innovation Journal 2018; 7(7): 667-672, ISSN (E): 2277- 7695.
12. Brahmaiah Bonthagarala, Compilation of Chemistry Manufacturing Controls In Abbreviated New Drug Application, Journal of Pharma Research, Vol-08, Issue 08, 2019.
13. http://www.qrasupport.com/FDA_MED_DEVICE.html
14. Ministry of Health and Family Welfare (2013) Guidance Document on Common Submission Format for Import License of Non Notified Diagnostic kits in India. Central Drugs Standard Control Organization.
15. https://www.emergogroup.com/resources/regulations-india
16. http://companiesinindia.net/top-10-medical-device-companies-in-india.html
17. World Health Organization (2010) Clinical evidence for medical devices: Regulatory processes focussing on Europe and the United States of America. Medical Devices.
18. Ministry of Health and Family Welfare (2010) Guidance document on application for grant of Licence in Form-28 for manufacture of Medical Devices in India under CLAA Scheme. Central Drugs Standard Control Organization.
19. Ministry of Health and Family Welfare (2012) Guidance Document on Common Submission Format for Import License in Form-10 of Notified Medical Devices in India. Central Drugs Standard Control Organization.
20. European Council (2007) Council Directive of 14th June 1993 concerning medical devices. Council of the European Communities.