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A global prospective of medical devices and their regulations

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Abstract-- Health of the public is one of the important factors which influence the wellbeing state of a human being. The diagnosis of any chronic disease or disorder & to develop treatment for that particular diseased condition is only possible after the involvement of medical devices & combination products which wasn't possible in previous years. The detailed differentiation of medical devices is based majorly on the risk factor involved from low risk to that of high one. To get the better understanding regarding all the medical devices the regulations

prevailing to particular device can be studied. The goal of developing medical device regulation systems is to protect public's health while also ensuring their safety & performance. These regulations of medical devices products are governed by FDA which also monitors the safety & efficacy of all medical products. Innovation further leads to manufacture of new medical device. As the pharmaceutical sector & engineering department work hand in hand which has played a vital role in the physiology of organs, better performance, & better life span & in complete replacement of that particular organ system. This review highlights basic concept of medical devices, application in the field with uses & also a brief introduction about combination products, challenges & regulations in different countries such as India, European Union, Japan & United States.

Keywords---biological process, combination product, implants, medical devices, physiology, regulation, challenges.

Introduction

Health of the public is one of the key factors in accelerating the progress of a nation. Technological advancements in the field of Health have been increased significantly. But this form of rapid advancement has increased challenges for the government of a nation in maintaining the Standard Regulatory Framework. Medical devices are the only means through which Healthcare professionals can understand the problems of the living body & suggest treatment accordingly. Thus, it becomes extremely important for the government to setup a set of Regulatory Principles right from production to disposal of these Medical Devices. The rapid evolvement in the regulation of medical devices has lead convoluted legalized technicalities likewise in term of lawful & their meaning are occasionally uniform or non-uniform with the system of regulatory. Due to this many regulation it not possible to grasp these complex subject so they formed a Guide which present a common framework integrates five countries regulatory system with most advanced medical devices regulations. This guide many used to teach the risk management & safety procedures for the medical devices, how we can optimize the performance & safety of the medical devices with good life span [1].

In health professional, medical devices increased the health expertise to diagnose, identify & treat the diseases which enormous contribute in healthy person life. This is the most complex & stimulation sector of healthcare in which sue to the close relationship of science & engineering contribute to enhance the new ways to develop such technologies that optimized the best & suitable medical devices that used in biological applications. Due to the contribution of these science & engineers the variety of medical devices are expanded from bandages, disposal gloves, thermometers, stethoscopes to the advanced devices includes prostheses, implants, equipment's & computer software that assist in medical testing such as ultrasounds, CT scan, MRI scan, etc. Nearly about 1.5 millions of medical devices is there having different significance in complexity with its applications which can be used as therapeutics, monitoring or diagnostic purpose. The recent

advancement in the medical devices can replace complete or partial parts of the body & provide full functional support [2].

A medical device is any material, instrument, appliance, apparatus or added object that are intended to be used in separate form or in combination with other equipment's or devices in the human being serving the purpose of diagnosis, prevention, monitoring, treatment, replacement/modification of the physiological process that are affected by different disease conditions. Any equipment, apparatus, appliance, substance, or other object intended to be used for human beings as specified by the Therapeutic Goods Act in 1989 as for the purpose of

- Diagnosis, prevent, monitor, treatment of diseases
- Anatomy or physiological process examination, replace or change.

US FDA is in charge of ensuring the efficacy, safety, & security of biological products, medication, & devices that are going to protect the health of the individuals. In United States of America the FDA has an Office of Combination Products (OCP) whereas in Europe as FDA there is no regulation agency & various combination products shaped by Directives that were included in medical devices, medical products & active implantable medical devices (AIMD) [3]. As per the name, it is especially an organization of drug, device or biological product which has much higher potential effect as compared to the products being utilized individually. Antibiotics being amalgamated with orthopaedic implants for increased effectiveness against infections or spermicidal drugs assimilated within condoms to increase the likelihood of contraception are some of the examples holding a huge market potential which insights a perfect combination of performance, design as well as application & are being developed to surmount the shortcomings of the conventional medical products. Diagnostic devices based on genomics can be used to identify if a treatment is appropriate for a specific patient or to measure the amount of risk associated with its use [4].

Although the products are used in combination being consumed in various countries but except for United States, there is neither official definition of these products in the respective regulatory legislations nor there is a separate description for these specific products & these are regulated conferring to prominent purpose as per the regulatory legislation. For example in situation of a drug-device combination if the prime function is physical, then it is treated as per the standards of medical device & in case if the primary role is chemical, then it is being treated as under the drug division. Combination products will become more intricate with the emergence of advanced technologies & thus the challenges associated with the development of regulatory pathways would become more challenging [5].

Hence the medical devices seen further significant growth & success in the healthcare sector, they categorized in different sub categories as sector or areas, industries or we can say that filed such as diagnostics, cardiovascular devices, imaging or scanning devices, surgical as well as orthopaedic devices. The diagnostics medical devices/apparatus/equipment's are used to diagnose the various aspects of the patient's health by the help of observing & measuring the health conditions, once it's completed, the clinical professional can prescribed the

appropriated treatment plans & medicine to the particular patients. FDA has specific branch named as Centre of Devices & Radiological Health (CDRH) to protect & promote health of public to ensure the safety of medical devices. In US the medical devices are distinguished in majorly three sub class having different safety aspects on the basis they are categorized & shown in following table [6].

Table 1
Medical Device Classification

RISK FACTORS	CLASS	EXAMPLES
Low risk	Class I	Bandages, surgical equipment that can be carried in one's hand, nonelectric wheelchairs, & so on.
Intermediate or Moderate risk	Class II	(CT) Computed tomography or infusion pumps for IV etc
High risk	Class III	Pacemakers, deep-brain stimulators, etc

Here are the few examples we all widely seen or used in our daily lives for diagnosis purposes. Some common medical devices are mentioned here

Stethoscope is the most known medical devices used for diagnostic purpose widely used to examine the sound of heart, even the flow of blood in the veins & arteries & the lung also. This is widely used in the diagnosis of many diseases such as

- Pneumonia
- Bronchitis
- Heart palpitations
- Heart disease
- Arrhythmia
- Heart valve issues

Blood pressure is measured using stethoscopes & a sphygmomanometer. Nowadays electronic stethoscopes are also present in the market which have improved the quality of sound while diagnosis the heart beat it can listen the low pitch sound as well as high pitch sounds very clearly which are linked to a system that collect, record & save the sound so that it can be distribute with the different professional so that they calibrate the stethoscope [7].

Sphygmomanometer is the medical devices that proven the blood pressure are very important now days to acquire the good health. This is used in many disease diagnoses such as

- Diabetes
- Hypertension & hypotension

- Hardening of Artery
- Arterial plaque

High blood pressure is cause of several diseases, having few medical devices that are used for observing & measuring the blood pressure & display them well. Manual sphygmomanometer considered as most reliable & trusts worthy because the mercury manometers do not require any calibration but in case of aneroid sphygmomanometer there is chance of calibration due to bumps caused in the mercury manometers which commonly occurred. Digital sphygmomanometers are monitor based blood pressure device by putting it on the figure & its show the blood pressure. These are easily used due to its manual & automatic working. Digital sphygmomanometer measure the blood flow through arterial which translated into the systolic & diastolic pressure which converted into the values [8].

Ophthalmoscopes are the medical tools easily handheld used by the physicians to observe the fundus of person's eye. These are widely used in diagnosis of physical & out-patients examinations. Other uses of these as under-

- Bacterial infections
- Detached retinas
- Glaucoma

These tool is develop in two special form one is direct ophthalmoscopes & other one is indirect ophthalmoscopes having two different working & magnification range. Direct ophthalmoscopes can produce the upward image having 15 times magnified as we held this We held the tool 25 to 30 inches distance away from the eye of patients since indirect ophthalmoscopes can invert the image by 2 to 5 times, so we kept it near to the eye. In both the indirect ophthalmoscopes has good source of light that why they are more effective than the direct ophthalmoscopes while used in examination [9].

Current regulations prevailing in some nations of the world

After the end of World War II, there were tremendous technological advancements in the arena of medical devices industry & nowadays these are manufacturing its products worth of billions, enhancing the public health of a nation by making proper diagnostic analysis, timely preclusion & management of serious diseases easier accompanied by efficiency. With the passage of time & the very rapid growth of technology, there is a pressing need for effective rules for a variety of medical devices to address issues with identifying flaws & gaps in the development process. However, the regulations of medical devices that needs to be incorporated is often complicated by legal terms such as patent status, market approvals in other countries & technical conditions such as safety & efficacy facts, industrial features due to the rapid change within these industries. Various National as well as some Global Regulatory Authorities has also originated with suitable guidelines from time to time [10].

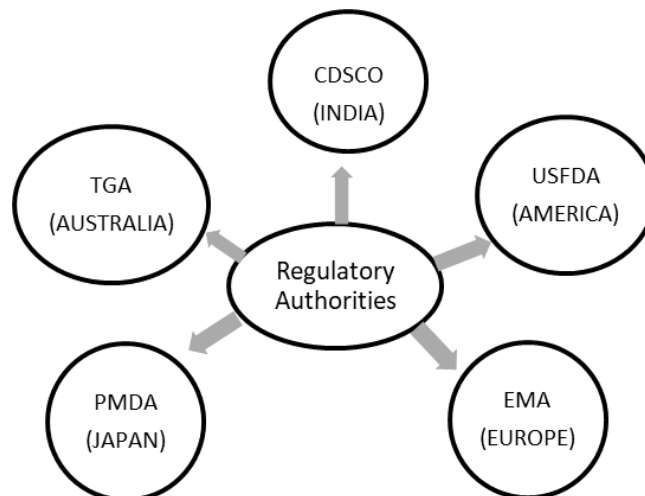


Fig 1. Regulatory Authorities globally

Overview of Central Drug Standards Control Organization of India (CDSCO)

The CDSCO, which is overseen by the Ministry of Health and Family Welfare Directorate General of Health Services, provides standard medical device in India. The Drugs & Cosmetics Act of 1940 & its Rules of 1945 oversee medical devices, which are divided into four different category such as: Class A, Class B, Class C, & Class D. The Drugs & Cosmetics Rules recommend procedures for registration & import licenses, which are required for the import of medical devices in India [11]. Class A Devices don't requires Regulatory Approval in India & the manufacturer is required to follow Good Manufacturing Processes in accordance with set standards. Class B Devices used for disinfection & sterilization as well as devices that provide energy for other implantable devices in the body. Class C Devices are used to describe devices for skin injuries that have breached the dermis. Class D Devices are used in treating circulatory & nervous disorders & are in contact with sensitive tissue such as the heart, spine & brain. Medical devices which are being imported & have already obtained approval in of the USFDA or the European Union (by CE Marking) can be marketed inside Indian jurisdiction without any other compliance estimation procedures [12].

Overview of United States Food & Drug Administration (USFDA)

In the United States of America, the Federal Drug & Cosmetic Act organizes numerous medical equipment. The approval should be taken before marketing the product into United States and the application is filed with FDA. The USFDA's Center for Devices & Radiological Health (CDRH) is the body responsible for overseeing marketed activities of Medical device. The US Food & Drug Administration (FDA) have adopted a risk-centered categorization system that gives a three-tiered structure for the risk developed with the usage of a device [13]. General rules on labeling, manufacture, & post-market surveillance apply to Class I devices. Formal scrutiny is never necessary for maximum Class I devices earlier the market launch. For Class II devices, general controls are insufficient to institute safety & efficacy & thus sufficient data are required to validate special

controls. Before a Class II device may be launched, the FDA must approve a pre-market statement, often known as the 510(k) process, in which the manufacturer must provide proper records showcasing the new device's functionality similar to a legitimately marketed item. Class III devices are moreover life-sustainable or have a significant impact on preventing deterioration of human health, thus they must have FDA pre-market approval (PMA) before being released [14].

Overview of European Medicines Agency (EMA)

Medical device Directive is the primary legislation for the production, safety & marketing of medical devices within Europe which follows a 4-Class order: Class I (including Is & Im), Class IIA, Class IIB & Class III. Medical equipment cannot be manufactured or marketed in the European Union unless they comply with the rigid protocols of Medical device Directive for the European Union. Organizations must reveal Conformities "Europe" Enne (CE) marking on the products, to certify that the medical devices are safe as well as suitable for the proposed consumption. CE marking is approved by various authorized private administrations called as Notifying Bodies (NBs) which are autonomous private-enterprise having the authorization to award formal marking crucial for specified medical devices. Functions of these NBs include accreditation of medical devices, description of device category, quality systems assessment as well as authentication & design records for high risk devices [15]. Class II & III devices, as well as Class I devices having a measuring or sterility function, that must provide evidence of compliance with the relevant EU Directives & the particular mentioned throughout the conformity review process. Other Class I medical devices are not subject to pre-market compliances, but must adhere to mandatory safety & effectiveness principles in their design, manufacture, & labeling requirements [16].

Overview of Pharmaceuticals Medical Devices Agency of Japan (PMDA)

PMDA is Japan's regulatory agency, which studies, assesses, & makes recommendations to the Ministry of Health, Labor, & Welfare (MHLW); however, it has no ability to make final decisions. A new law, known as the New Pharmaceutical Affairs Law, was introduced in 2005. A producer must adhere to the rules set out by the Market Authorization Holder (MAH) procedure, which holds the manufacturer exclusively liable for the end product's trade & supply [17]. Class I medical devices include Devices for General Control, Controlled Medical Devices, & Specially Controlled Devices. Class II medical devices include Devices for General Control, Controlled Medical Devices, & Specially Controlled Devices. There are two classes: Class III & Class IV. Medical devices in the Class I category just need to be notified, while those in the Class II category need a device certificate, & those in the Class III & Class IV categories need to be approved. Clinical trials are not necessary for Class I devices, are infrequently required for Class III devices, & are required for Class IV devices. In Japan, Good Vigilance Practice (GVP) is a legal requirement [18].

Overview of Therapeutic Goods Administration of Australia (TGA)

TGA is Australia's primary medical device regulator. Before being released into the market, medical devices must be recorded in the ARTG repository. Class I Devices (Supplied Sterile or Measuring Device), Class II Devices (IIa & IIb), & Class III & Active Implantable Medical Devices are the three different categories of medical devices (AIMDs). Both the created devices & the manufacturing process must fulfill the Therapeutic Goods Administration's criteria [19]. A conformity assessment certificate is a document issued by a regulatory agency that verifies that a manufacturer has been inspected & has made all of the necessary preparations to produce a device. The three papers necessary to register a Device in Australia are Conformity declaration, certificate of Conformity assessment and lastly application to include the Medical device in the Australian register of Therapeutic Goods [20].

Table 2
Salient Features of Comparison of Medical Devices of some countries

Countries	Legislation	Supervising Authorities of Medical Devices	Approval System	Risk Classification
India	Drugs & Cosmetics Act, Medical Device Rules 2017, ISO 13485	(CDSCO) Central Drug Standard Control Organization	Class A: Device Notifications to State Licensing Authorities Class B: Device Approval by State Licensing Authorities Class C & Class D: Device Approval by Central Licensing Authority	Class A Class B Class C Class D
United States	21 CFR Part 820	FDA	Class I: General Controls Class II: Premarket Notification or 510(k) Process Class III: Devices need Premarket Approval (PMA)	Class I Class II Class III
European Union	Directive 90/385/EEC, Directive 98/79/EEC, ISO 13485	Medicines & Healthcare Products Regulatory Agency for UK & European Medicines Agency for a Member State	Manufacturers need to show CE Marking on their Products	Class I Class IIA Class IIB Class III
Japan	Pharmaceutical Administration Law	Pharmaceuticals Medical Devices Agency	Class I: Device Notification Class II: Device Certificate Class III & Class IV: Device Approval	Class I Class II Class III Class IV
Australia	ISO 13485	Therapeutic Goods Administration	Manufacturer has to show that both Device as well as Manufacturing Process is adhering to the Therapeutic Goods Legislation	Class I Class IIA Class IIB Class III Active implantable Devices

Status of medical devices in india & challenges associated with it

In the early part of 20th century, pharmaceutical industries of India were almost inactive & most of the products were introduced from the developed nations. Even in the begin nine of the era of independence, pharmaceutical market of India was dominated by western multinational companies as 80%-90% of pharmaceutical products were directly imported from these western countries. At the time, western pharmaceutical companies possessed 99 percent of the various pharmaceutical items under Indian patent authority. Later the Government of India framed policies for enhancing the production of pharmaceutical products in India domestically. To accelerate the autonomous source of pharmaceutical products within the domestic region of India, Government of India instituted 5 government owned pharmaceutical companies. Consequently, the share held by western manufacturers within domestic Indian market somewhat declined & to fill that gap, local firms rushed which made finally India self-sufficient in many of the pharmaceutical products & even made it a global exporter in some of the pharmaceutical products [21].

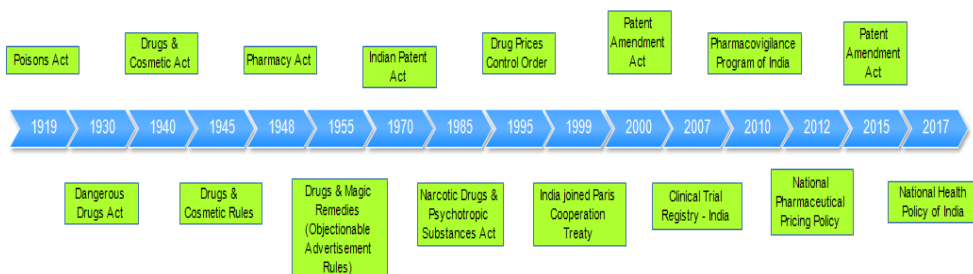


Fig. 2. Evolution of Pharmaceutical Industry in India through Legislation

Current status of medical devices in India

It is a multi-product industry, which produces a diverse range of products in India. India is emerging as a very dynamic market for medical devices in addition to diagnostics. From 2009 to 2015, Indian medical device market more or less doubled in valuation. In 2015, it accounted for roughly 1.7% of the worldwide medical device market & 4% of the Indian market for healthcare. By 2025, India's medical devices industry is expected to grow to 352,450 crore (US\$50 Billion), up from 77,539 crore (US\$ 11 billion) in 2020 [22].

Medical devices sector is a very important sector which has been given due importance under the umbrella of Make-in-India campaign, launched in 2014 as an initiative by the Government of India to transform the worldwide image of India as a global manufacturing hub. To enhance investments in medical devices sector, Cabinet has permitted foreign direct investment of up to 100% under the automatic route for production of medical devices liable to certain criterion. Numerous schemes are incorporated as well as some schemes are in the pipeline to enhance the medical devices industry of India. Arrangement for funding common facility centers at medical device parks is projected within the umbrella of "Development of Pharmaceutical Industry" to craft out the network for high-end medical device production & substituting the import scenario with global export.

The Government of AP (Andhra Pradesh) has established the (APTMZ) Andhra Pradesh MedTech Zone that can house all high-investment research facility, laboratories, & other facilities, & will be leased to businesses as needed. Setting up of a Medical Device Promotion Council at Vishakhapatnam has also been proposed in collaboration with Andhra Pradesh MedTech Zone (APTMZ) acting as assistance in publicity for marketing of domestic medical devices.

Noida is also expecting to have the Northern India's first medical tools & system Manufacturing Park by the year of 2022. Ministry of Health & Family Welfare (MOHF&W) together with Central Drugs Standard Control Organization (CDSCO) has started to execute various necessary initiatives to enhance the export of medical devices in the global market such as: re-examination & implementation of Schedule Mill, state licensing authority to extend free sales certificate validity from 2 years to 5 years to allow exports, publish a list of manufacturers to export licensing for simple access by regulatory bodies all over world [23].

Regulatory authorities in India

Central Licensing Authority – The national monitoring organization of India is the CDSCO (Central Drugs Standard Control Organization) which comes under the Directorate General of Health Services within Ministry of Health & Family Welfare & commanded by the DCGI (Drugs Controller General of India). The objectives of CDSCO are to enrich & safeguard the community health by ensuring safety, effectiveness along with value of drugs and medical devices [24]. The major roles of CDSCO are:

- Frame policy & procedures for harmonized enactment as well as assist in setting & implementation of standards of the requirements of Drugs & Cosmetics Act, 1940 & Rules, 1945.
- Coordinate & liaise with international organization such as, US Food & Drug Administration (USFDA), World Health Organization (WHO), WHO Regional Office for South East Asia (SEARO), European Medicines Agency (EMA), European Directorate of Medicines & Healthcare (EDQM), Pharmaceuticals & Medical Devices Agency (PMDA) of Japan, BRICS Nations – Brazil, Russia, India, China & South Africa & other counterparts, South Asian Association for Regional Cooperation (SAARC).
- Exercise supervision as well as control over the medicines import, new medicines authorization & clinical trials through drugs testing laboratories for various testing samples, steer consultations with the Drugs Technical Advisory Board (DTAB) & Drug Consultative Committee (DCC) & act as Central License Approving Authority (CLAA) for sanction of different licenses.
- Conduct joint inspections under GMP (Good manufacturing practices) along with market surveillance & control through zonal offices & organize activities with the Drugs Controllers of the respective state.



Fig 3. Quality Management System of CDSCO

State Licensing Authorities

There are authorities known as Food & Drug Administration (FDA) for every state & specified licensing authority for Union Territories, which are maintained by Centre [25]. Supervision, production, trade & supply of drugs as well as medical devices are predominantly the interest of state authorities. Functions of State Licensing Authorities are:

- Approval of drug examination laboratories, scrutinizing quality of drugs & cosmetics marketed as well as inspection & prosecution observing breach of legal provisions [25].
- Licensing of drug production sites, including API & completed formulations, as well as drug trade & supply within the jurisdiction [25].

Challenges associated with the medical device innovation in India

- **Import Centric** – India imports 75 - 80% of the total diagnostic instruments from other countries which is treated as drugs under the Drugs & Cosmetics Act. Central Drug Standard Organization need to balance both the inundation of imports as well as manufacture of indigenous medical devices [26].
- **Inadequate Distribution** – Insufficient supplies as well as poor working conditions of some of the medical devices as well as compiled role of rural-urban disparity in availability of medical devices enhances the great cause of the broken Indian healthcare system [26].
- **Limited Funding** – Although there are various global funding institutions such as Welcome Trust, Foundation for Innovative New Diagnostics, Bill & Melinda Gates Foundation etc. There are also a lot of Indian funding departments like Department of Biotechnology, Department of Science & Technology, Central Science & Research Institute, All India Council of Technical Education, University Grants Commission, Defense Research &

Development Organization etc. But the amount available is quite meager [27].

- **Proper Training & Education** – Government & reputed private organizations employ laboratory trainees with recognized educations & skills & occasionally they also organize for the trainings as per the necessity. But in case of private establishments, they generally employ trainees with no proper education & training which further declines the pioneering research structure [27].
- **Fragile Technology Transfer Process** – There is a vast mismatch between technological needs of industries & ongoing research of academics. Most Indian institutions were not boosting in-house research projects due to unavailability of capital. Also the consultancies play a huge role for collaboration for research projects but those consultancies don't prefer large-scale projects with huge investments. Insufficient knowledge of IPRs also degrades the rate of innovation [28].

Innovation in the area of medical device

An invention is a unique or novel device, basically a method or composition or even a product development process which is a sudden breakthrough in the area of Medical device ideas that lead to the introduction of new goods or services, or improvements in the delivery of goods & services, are implemented. Innovation leads to eminent model which connect between invention of new technologies & market. There is a requirement for the Healthcare technologies to get the regulatory approval & enter into market along with substantial inference with product life cycle, cost of R&D & effectiveness. The innovation of medical device company focuses on nation's health criteria, clinical trials, regulatory body approvals, price specifications & other factors involving for the safe & effective device that should be considered into the framework conditions making the health department distinctive [29].

Healthcare practitioners will need to collaborate with academics, developers, & executives from a variety of industries to promote the future of innovation. Technology is ever-evolving to bring new, advanced developments in how patients & physicians can track medical conditions. In the multi product medical device sector, innovation refers to the development of a medical device over its entire life cycle, from conception through disposal [30]. Many disruptive technologies have emerged in various industries over the last two decades, but the highly regulated medical device market has been less affected than other industries, allowing the medical device industry to leapfrog & tackle fundamental & sweeping challenges that will last for years to come. New & innovative medical equipment are being brought to healthcare facilities & patients' home as a result of breakthroughs ranging from the introduction of technologies to 3D printing [31].

Conclusion

Need is the root of every invention, & these inventions can lead to many other innovations till it's being regulated with restrictions. But when a gap develops between the inventions & regulations, it would only result into a mass scale loss to human life & property. Thus, the need of regulations for the medical devices

becomes inevitable which are meant to safeguard the public health from unsafe products as well as welcoming innovation of products, which are favourable to the general health of public. In this regard, early alliance between product developers as well as regulatory authorities can subsidize to split prevailing obstacles standing against innovation, but all these barriers can only be removed significantly if the regulatory agencies create the rules & standards in line with the advancement of new technologies without jeopardising the balance of quality, safety, & efficacy. Cooperative monitoring investigation as well as device assessment by the medical device developers along with regulatory authorities can assist in amending the existing regulatory pathways which would further fuel the road towards innovation on proper lines, & the disputes that arise during registration or authorization as a result of tight regulatory procedures would also be significantly reduced.

One of the noteworthy opposition towards the regulatory pathway are the combination products which can be classified as both drugs or devices according to their primary utilization as per the existing legislations but classifying it according to its particular component would overlook the regulatory standards of its other components. This fact necessitates to a distinct regulatory body to monitor the combination products. As a result, collaboration among stakeholders can significantly contribute to overcoming current problems in designing regulatory pathways for these combination products, & because combination products are still a relatively new domain, the responsibility for ensuring the safety & efficacy it is not only the responsibility of national regulatory agencies, but also of researchers, to ensure the safety of technology, manufacturers & physicians in the early stage of development.

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Abbreviations

AIMD-Active implantable medical devices, AMPTZ-Andhra Pradesh MedTech Zone, API - Active Pharmaceutical Ingredient, CDSCO - Central drug standards control organization, CLAA - Central License Approving Authority, CE - Conformity Europeenne, DCC - Drug Consultative Committee, DTAB - Drugs Technical Advisory Board, EDQM - European Directorate of Medicines & Healthcare, EMA - European Medicines Agency, FDA - Food & drug administration, GVP - Good vigilance practice, IoT - Internet of Things, IPRs - Intellectual Property Rights, MAH - Market Authorization Holder, MHLW - Ministry of Health Labor & Welfare, MOHF&W - Ministry of Family & Family & Welfare, NBs - Notifying bodies, OCP - Office of combination product, EU - European Union, PAL - Pharmaceutical Affairs Law, GMP - Good Manufacturing Practice, PMA - Pre-market approval, ARTG - Australian Register of Therapeutic Goods, PMDA - Pharmaceuticals Medical Devices Agency, R&D - Research & Development, SEARO - South East Asia Regional Office, SSARC - South Asian Association for Regional Cooperation,

TGA - Therapeutic Good Administration, USFDA - US Food & drug administration, WHO - World Health Organization, CDRH- Center for devices & radiological health.

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