Analysis of Regulatory Environment of Medical Devices in India

By

Janel Dipesh Bharwada

Dissertation submitted for the partial fulfillment of the

MBA Pharmaceutical Management

Academic year, 2017-2019

The IIHMR University, Jaipur

1, Prabhu Dayal Marg, Sanganer, Airport
Jaipur 302029, Rajasthan
Ph: 0141 3924700, Fax: 3924738
Website: **www.iihmr.edu.in**

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IIHMR UNIVERSITY

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This is to certify that Janel Bharwada, student of MBA Pharmaceutical Management from The IIHMR University, Jaipur has undergone internship training at SPAG Asia, Gurgaon from 06th Feb'19 to 06th May'19.

The Candidate has successfully carried out the study assigned to him during internship training and his approach to the study has been sincere, scientific and analytical.

The Internship is in fulfillment of the course requirements.

I wish him all success in all his future endeavors.

Dr. Sandeep Narula
Dean, MBA Pharmaceutical Management
The IIHMR University, Jaipur

Dr. Ashok Peepliwal
Associate Professor
The IIHMR University, Jaipur

1, Prabhu Dayal Marg, Near Sanganer Airport, Jaipur- 302029, Rajasthan, India.
Ph.: 0141- 3924700, 2791431- 32, Fax: 0141 3924738, E-mail: iihmr@iihmr.edu.in, Web.: www.iihmr.edu.in

A Strategic Partners Group Enterprise

The certificate is awarded to

Janel Dipesh Bharwada

In recognition of having successfully completed his Internship in the department of

Advocacy and Government Affairs

and has successfully completed his Project on

"Analysis of regulatory environment of Medical Devices in India"

from 6th February 2019 to 6th May 2019

At SPAG, Gurgaon

He comes across as a committed, sincere & diligent person who has a strong drive and zeal for learning

We wish him all the best for future endeavors

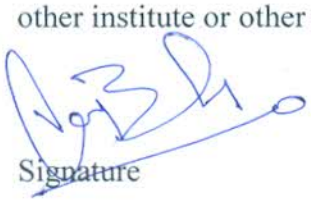
Training & Development

Zonal Head-Human Resources

THE IIHMR UNIVERSITY, JAIPUR

CERIFICATE BY SCHOLAR

This is to certify that the dissertation titled "An Analysis of regulatory environment of medical devices in India" and submitted by (Janel Bharwada) 100 under the supervision of Dr. Ashok Peepliwal for award of MBA in Pharmaceutical Management of the University carried out during the period from 06/02/2019 to 06/05/2019 embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other institute or other similar institution of higher learning.



Signature

Acknowledgment

I would like to express my sincere gratitude towards **SPAG, Gurgaon** for selecting me as a management trainee and giving me an opportunity to work on this project and also for providing a good working ambience for successful completion of this project.

I would also like to express my sincere gratitude towards my faculty guide **Dr. Ashok Peepliwal** for helping me in my project. His guidance and teaching has been of a great help during my project.

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Last but not the least; I would like to express my sincere thanks to my Institute **IIHMR,Jaipur** for providing me all kind of support in my dissertation project at SPAG, Gurgaon.

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Abstract

Looking at the industry scenario and enivoroment where several medical device companies are not happy with the current medical device regulations it was decided to conduct this research in interest to beneit the medical device industry.

The main objective of this research was to keenly study the medical device regulations in India and find the loopholes in it to provide recommendations on the basis of perception of the doctors and industry experts with help of a semi structured questionsaire and FGD's which dealth with several parameters like current environment, patient awareness and Industry scenario.

It was learned that current frame work did not support innovation rather is over focused on affordability because of certain reasons like price capping and trade margin rationalization, with addition to this It was also seen that the level of patient awareness on certain areas like price capping and importance of new technology was not satisfactory and needed some work to be done. As a negative impact, the MNCs withdraw their latest innovated products, affecting the quality of medical services, medical tourism, no investment in research and development of medical device etc.

By conducting FGD's of industry regulatory experts it was observed that:

The Focused group discussion started with discussion on current regulatory framework issues where almost all the experts had a common stance of issue with the proper definition of the Medical Devices and a separate identity of medical devices. It was also seen that several regulatory experts emphasized on the need of a separate medical device act and differentiation of medical devices from D and C act in India When the FGD changed it focus on patient awareness many experts took the stance that the awareness of patients regarding the new technology and various pricing issues of medical devices is low and the need for awareness is very high. Based on the FGD's of industry experts it was learned that the current medical device industry has been facing a lot of issues in the area of pricing whereas the industry believes that the government should use the Trade Margin Rationalization approach. It was also observed that the industry is not satisfied with the current framework of medical devices.

Introduction

The era of newer development and technology has diminished the morbidity and mortality of life. The medical development in terms of medicine and devices has led to the strong modification within the lifetime of the individuals (as offered by the cosmetic treatment, dentist, face and medical specialty devices). Medical devices have extended the flexibility of physicians to diagnose and treat diseases, creating nice contributions to health and quality of life.
Medical devices area unit terribly essential parts for patient care. they'll even be uncomplicated devices utilized throughout medical examinations, like tongue depressors and thermometers, or refined life-saving implants like internal organ stents, knee implants and hip Implants.

According to world harmonization task force in harmony definition of the term "medical device" means that "any instrument, apparatus, implement, machine, appliance, implant, in vitro chemical agent or calibrator, software, material or different similar or connected article supposed by the manufacturer to be used, alone or together, for kinsfolk for one or a lot of of the precise purpose(s) of designation, prevention, monitoring, treatment or alleviation of sickness or designation, monitoring, treatment, alleviation of or compensation for associate degree injury or investigation, replacement, modification, or support of the anatomy or of a physiological method or supporting or sustaining life or management of conception or medical aid of medical devices or providing info for medical or diagnostic functions by means that of in vitro examination of specimens derived from the bod and that doesn't attain its primary supposed action in or on the bod by medicine, medical specialty or metabolic means that, however which can be power-assisted in its supposed function"

Medical devices area unit currently a pervasive a part of fashionable medical aid. they're in several cases related to quality of care. In some cases, the utilization of devices has improved quality. In different cases, devices have related to several issues. The approach to quality of devices has depended for the most part on regulation. in line with world statistics, eighty fifth of the medical devices area unit factory-made within the USA, in Japan and in world organization countries. that's the explanation why it's matter of issues to the yank and European regulation systems. Like medicines and different health technologies, they're essential for patient care at the side, at the agricultural health clinics or at the massive, specialized hospitals. Medical devices conjointly raise the nancial burden on the govt health sector. The medical devices market is showing a double-digit growth.

The internal organ devices alone area unit growing at twenty per cent. In India, the expansion of the market is calculable to be between 10-15 per cent. there's a transparent indication that the penetration levels area unit higher within the country. this can be due to affordability by patients, multiplied awareness on health care, improved hospital infrastructure and therefore the multiplied sickness patterns.

Previously in several countries medical device laws seldom existed and there have been restricted restrictive controls to ban the utilization of low-quality devices. thus, there was a compulsion to draft restrictive policies on medical devices to assess their quality, safety and effectivity. luckily, since the first Nineteen Eighties, the restrictive paradigm for medical devices has modified exceptionally. currently with the supply of various laws of the countries or region on medical devices, there's a desire to harmonize laws so as to curtail restrictive hurdles and expedite access to top quality, safe and efficacious medical devices.

Medical devices are a multi-billion-dollar global business with continuous growth opportunities because of advancements in technology and new innovations. However, innovations and new advancements don't perpetually reach patients because of a scarcity of clarity associated with the approval method of such innovations and tight rules by national health authorities. These rules will create challenges for innovators, makers, and exporters to get approval for market distribution in Republic of India. This project can offer an summary of the new Medical Devices Rules, 2017 free by India's Ministry of Health and Family Welfare enforced on 1 January 2018, in addition as recommendations for addressing known gaps within the rules, less obvious options of the regulation, and a list of changes to the rules.

India is one of the top 20 markets for medical devices in the world, valued at EUR 4.6 billion (approximately $5.4 billion) and the fourth largest medical device market in Asia. The medical device industry in India alone is expected to reach EUR 8.6 billion (approximately $10.1 billion) in 2020, having a reported Compound Annual Growth Rate (CAGR) of 11% between 2008 and 2015 with an estimated 10-year CAGR of 15%. The major segments for growth are equipment and instruments, consumables and disposables, implants, and patient aids. India's medical device market is currently 70% import dependent with the instrument and diagnostic imaging equipment segments accounting for 66% of the overall market. Only 38% of devices manufactured in India are exported from India; therefore, there is a very low level of export competency. To curb these challenges and to overcome the import market, the Ministry of Health and Family Welfare of India drafted Medical Devices Rules, 2017.

It is expected that the changes settled by Medical Devices Rules, 2017 can encourage a lot of transnational firms (MNC) to line up medical device producing facilities in Asian country, that successively can permit innovative product to achieve patients in Asian country quicker. These rules, supported world Harmonization Task Force (GHTF) pointers, can considerably improve the domestic market friendliness to the medical device business. necessary certifications by the Bureau of Indian customary (BIS) and International Standards Organization (ISO) can guarantee quality standards area unit practiced, promote domestic producing, and need product testing and certifications, as recognized by the govt. of Asian country. Most of the foundations concentrate on the classification of devices, clinical investigations, and registration and post-marketing license necessities and procedures.

The current health-care setting in doesn't have a separate framework for control the medical device in Asian country. Medical devices area unit still notified as medicine Section three (b) (iv) of the act. however, there's would like of a separate framework for Medical devices. medical devices area unit regulated as medicine by the drug controller general of Asian country (DCGI) of the Central medicine customary management Organization (CDSCO).

The lack of a drug/device distinction has created difficulties for foreign firms within the medical device market. there's no single list (you should merge many lists) of regulated devices with completely different rules for various devices, and a few devices aren't regulated in the least. In sure cases, product registration and producing standards supposed for medicine area unit applied to the manufacture of devices.

Regulatory scenario under NDA government

Figure 5: Regulatory Time-line in NDA Government

Literature Review

Chakravarthi I. Medical technology in India: Tracing policy approaches. Indian J Public Health 2013;57:197-202

The history and timeline of regulatory process and developments in medical devices is divided into two periods since independence to end of 20th century

- 1950-1970
- 1980-1990

1950s-1970s

The patriot development had offered ascend to the thought of financial confidence, which melded the arranging procedure following autonomy. Endeavors were made to diminish reliance on created nations and make residential research potential. It was upheld by import-substitution approaches to ensure home markets, (for example, patent routines and levy obstructions for import of innovation) and advance a good domain for indigenous developments and items. India was aided these endeavors by universal guide from different sources. In the period of an arranged economy received since 1951 and the modern strategy therefore pursued, a unique job was concurred to little and medium endeavors (SMEs), built up in practically all significant parts in the Indian Industry —, for example, in designing, electrical and gadgets; synthetic concoctions and pharmaceuticals, electromedical gear, plastic items and so forth.

Despite a few impediments, SMEs made noteworthy commitment toward residential generation, innovation improvement and fare. They were managed assurance until 1991, when the arrangements of advancement and globalization were received. During the 1950s therapeutic innovation additionally gotten consideration as a piece of the getting ready for wellbeing administrations. The Bhore and Mudaliar Committees explicitly made suggestions to gauge their prerequisites, to set up principles and to build up indigenous assembling limit.

The Bhore Committee suggested the arrangement of a board, specialized, to inspect the accompanying issues:

- What are the medications and other therapeutic requirements fundamental for general uses in this nation?
- What reasonable advances ought to be taken to guarantee their production in this nation in adequate amounts and their deal at a value, which will make them accessible to all who need them?
- What should be the fields of the legislature and of private venture in the assembling of these prerequisites?
- What help and help ought to be given to private organizations in such cases and under what conditions?
- What hardware ought to be set up to create look into with respect to drugs and other therapeutic necessities and their generation in India and to guarantee coherence and co-appointment of such research?

In the advisory group's view "it should be conceivable sufficiently to accommodate these basic needs through a mix of private endeavor appropriately helped where essential and generation by the state where this is observed to be in the open intrigue." It prescribed setting up of a board of trustees to set gauges for restorative foundations and hardware.

As indicated by the Mudaliar Committee: "While some advancement has been made by the pharmaceutical business in numerous ways, the equivalent is sadly not valid if there should arise an occurrence of the indigenous production of instruments, medical clinic apparatuses, research Centre gear, and so on by and large, the exertion is sporadic and disorderly with no long-haul plan and targets. Notwithstanding this the import limitations have unquestionably given an extraordinary filip to indigenous assembling, which with appropriate help and direction is positively fit for delivering instruments and machines of a quality equivalent to the best-imported articles".

The Mudaliar Committee underscored the requirement for gauges and details for therapeutic hardware stretching out specialized help to business people. It additionally underlined the requirement for confidence, "it will obviously be important to confine lastly stop imports inside and out of the things incorporated into the assembling program."

The base for a local restorative gear industry in this way got laid with setting up of generation offices for routine electro-therapeutic instruments, including X-beams, during the 1950s. Neighborhood fabricating exertion in therapeutic electronic gear started in the mid-seventies. Little consumables (syringes, intra-venous sets, gloves, blood-sacks, catheters, and so on.) and "low innovation" hardware, for example, traditional electrocardiography (ECGs), defibrillators, bedside screens, indicative X-beam gear and treatment hardware, for example, diathermy-ultrasound-electrotherapy, careful diathermy, breath screens, ultrasound scanners, diagnostic gear for obsessive and biochemical investigation (spectrophotometers, colorimeters, platelet counters, pH meters), hatcheries, pacemakers and other such instruments and gear are fabricated in the nation.

The 1970s was a time of addressing of current science and innovation and of developments for "fitting innovation" and middle of the road innovation. The clinic loped biomedical model of social insurance administrations was addressed from numerous quarters. The idea of essential medicinal services (PHC) rose up out of disappointments of the technocentric vertical projects and developments in network wellbeing.
The Alma Ata Declaration of 1978 on PHC gave a chance to re-situate and set up an arrangement of fundamental wellbeing administrations, imagined in the prior arranging time frame, in light of neighborhood needs and limits (confidence) and to move from the utilization of exceptionally advanced therapeutic innovation to less refined or locally fitting ones. However, these propositions were not truly actualized. Rather, the PHC pushed by universal foundations was embraced, which re-implemented the vertical projects for country zones, to be conveyed through network wellbeing laborers. Then again, therapeutic training proceeded with its accentuation on specialization and urban introduction. Restorative innovation diffused into the nation in various ways: through medicinal training, research and missions; global corporate exchanges; specialized help ventures supported by the World Health Organization; and reciprocal outside guide programmes. By the mid-1970s specific advances (ultrasonic foetal examination, fiber optic endoscopy, cardiovascular catheterization, renal dialysis, cobalt isotopes for radiotherapy, open heart medical procedure and laser shaft treatment) had been presented in government instructing institutions. Much of this innovation had been secured through the state and set in open establishments and general wellbeing programs. A double arrangement of therapeutic consideration created because of such approaches and ill-advised execution of the arrangement goals — of preventive drug for country zones, which contained some specialized mediation just for explicit vertical projects to be conveyed through wellbeing laborers, para-medicals and not well-prepared rustic wellbeing focuses. What's more, another of therapeutics and cutting-edge care for the urban regions to be given through very prepared restorative experts found to a great extent in all around prepared urban emergency clinics. The administration chose not to see to suggestions to re-arrange the current example of therapeutic instruction, to make it not so much technocentric but rather more network based and to incorporate the indigenous frameworks of drug. Accordingly, the nation keeps on creating a huge number of very prepared specialists, who select to work in the urban zones or to emigrate. The preparation and introduction of these specialists gives them get to not exclusively to the best advancements, yet to research and preparing in western nations, to the corporate clinics and worldwide markets in social insurance.

1980s-1990s

During the 1980s, the circumstance started to change worldwide with the finish of the Cold War and the rise of the mantra of "globalization" and the "worldwide town" and accentuation on getting ready for financial development. The recent import-substitution models and indigenous innovation-based models left design. The new improvement worldview was a "send out based" one, including creating "novel" innovative abilities. Consequent wellbeing arranging, and arrangement did not refer to about medicinal hardware and their necessities, accessibility, and so

on. Strangely, the report of a working gathering on gadgets industry for the eighth 5-year plan period (1992-1997) gives a thought of the improvements in the restorative hardware area in the past decades. According to this report:

- There was an adequately solid indigenous base for meeting the general prerequisites of analytic and remedial hardware for a medium measured medical clinic. Albeit essential skill and a specific measure of foundation existed in the nation, the nearby business had not developed to the required degree.
- Overseas makers, who worked at a lot higher volume of creation, had the capacity to offer relatively alluring costs, nearby makers working at low volume of generation. In this way, there was "a solid case to survey present financial and limited time measures in order to advance the nearby business and check over the top imports without influencing the human services program of the nation."
- An extensive number of electronic hardware was lying unutilized in different wellbeing foundations because of absence of appropriate upkeep. Among the suggestions of the Group were: Establishment of a quality and security accreditation system to advance adequacy of indigenously made hardware among the restorative network; and developing a gathering for discourse on different parts of medicinal electronic gear, for example, nearby accessibility, issues of the neighborhood business, monetary measures and necessities of human services experts.

In 1992, an examination by the Ministry of Science and Technology, of the status of assembling of restorative hardware/frameworks in the nation, under its plan "Projects went for Technological Self-dependence" uncovered a few vital findings with respect to assembling and imports of medicinal equipment, like those of the working gathering on gadgets. It called attention to that: "Capacity existed in India for production of a few electromedical hardware, for example, Diagnostic and portable X-beam gear, fluoroscopy defibrillators, ultrasound scanners (counting transducers); ECG machines and screens; diathermy units; pulse and breath screens; heart checking frameworks with focal observing unit; outside pacemakers, foetal screens and entire body figured tomography scanners. In any case, indigenous assembling was still to take off, and their generation represented under 1% of the all-out hardware creation in the nation". It re-iterated the need to 'audit the fiscal and special measures and the import approach, to advance the nearby business and check unreasonable imports and spare valuable remote trade'. As indicated by the investigation, most of the innovation concentrated gear was as a rule unreservedly imported and advertised in the nation because of the current changed import strategy.

The imperative findings of this investigation were as per the following:

- Without a solid assembling base, different refined restorative gadgets gear was being imported.
- The liberal import arrangement joined with absence of powers over exchanging of electro-therapeutic gear had prompted mushrooming of neighborhood offices speaking to remote producers.
- The neighborhood specialists were commonly not prepared to meet the after-deals administration necessities and to offer item bolster (aside from the well-established ones).
- The outside organizations are not obliged to give preparing nor guarantee that vital foundation is accessible for fix.
- There was no commitment with respect to the exchange or the business to meet security or quality certification. Indian gauges were accessible just for certain classifications of electro-therapeutic gear. This had brought about ceaseless channel on the remote trade stores of the nation and amassing of unacceptable, unrepaired and uninstalled gear worth crores of rupees.
- Purchase of costly hardware and their halfway usage because of hole in data among doctors regarding accessibility of suitable gear abroad and inside the nation.
- The operators/vendors of the indigenous little scale makers, where material, were unequipped to give after-deals administration, nor did they have the essential presentation to the specifiurban communities of bio-medicinal applications.
- The dependability of the indigenous gear, especially those made in the little scale area required improvement since the venture levels were low regarding quality control, gathering and test hardware.
- There was likewise absence of talented labour for production, task, fix and support in the

restorative hardware industry. The job of biomedical architects in emergency clinics was yet to be perceived.

The working gathering on restorative hardware for the ninth 5-year plan period (1997-2002) mentioned indistinguishable objective facts with respect to the bigger extent of imports when contrasted with the deficient generation and that a significant piece of the prerequisites could be effectively met by the indigenous business, given legitimate motivations and development atmosphere. One more vital perception was that while the advancements in hardware and developments in analytic, helpful and correspondences advances had been broadly used in the tertiary and optional human services, the requirements of the PHC setup had not been tended to. For instance: There was requirement for there was requirement for light, cheap, electronic gauging machines for grown-ups for early discovery of under-nourishment; of straightforward haemoglobinometers that could be utilized by the ANM to check for frailty in pregnant ladies; of light, reasonable electronic circulatory strain observing contraption; of correspondence joins with the CHC/area clinic. All these were cheap, however there was hesitance to make them. For the first run through in 1996 the arranging commission set up a working gathering to audit the necessities for strong and symptomatic administrations at essential, optional and tertiary dimension wellbeing services.
According to this gathering:

- Medical hardware the executives and upkeep were imperative
- While capital expenses were rising, yet restorative hardware was a broadly bungled asset in the administration human services offices
- An expected 30% of the all-out medicinal services spending plan was spent on hardware of which 5-10% was on cutting edge restorative designing frameworks, for example, imaging frameworks, lab analyzers and straight quickening agents
- Nearly 40-60% hardware was non-operational because of insufficient upkeep. 80-85% of the flaws were straightforward and could be taken care of with prepared faculty. (The investigation of the restorative electronic gear industry alluded to before indicated out that due absence of sufficient supports government clinics ceased from yearly administration contracts past guarantee period. This brought about reliance on non-specific, specially appointed administration plans, made as and when some hardware moved toward becoming non-useful). Such a circumstance contributed straightforwardly to breakdown and decrease in working existence of hardware.
- There was no arrangement on necessities of bio-therapeutic architects in the general wellbeing labour methodology

This working gathering proposed the setting up a medicinal gear the board unit in the service of wellbeing, to manage finding out hardware needs, determination, obtainment, establishment, preparing, upkeep, and so forth., which would be likewise in charge of keeping up gear in all administration clinics. It additionally made suggestions regarding diagnostics hardware and innovations suitable for each dimension of consideration and strong administrations including prerequisites of staff and space and asset portions, to be executed in the IX plan period (1997-2002).

Since the 1990s, with auxiliary modification and predominance of the neo-liberal philosophy, arrangement of restorative consideration has turned into a business generally for benefits and is being sorted out along business lines. The significance joined to monetary development, the administrations part, outside trade, and so on., is being abused by the "human services industry" to extend and develop into a productive "social insurance advertise." This 'medicinal services showcase' is presently being treated by all sections of business, including the therapeutic hardware industry, as a chance to extend, develop and make benefits.

The medical device industry in India [Internet]. 2016. available from https://www.skpgroup.com/data/resource/skp_the_medical_device_industry_in_india_.pdf

The existing regulatory framework for medical devices in India is inadequate for a USD 6 billion industry. Medical devices were unregulated in India until recently. At present, 22 medical devices have been notified by the MoHFW and are treated as 'drugs' under the Drugs & Cosmetics Act (DCA), 1940 & Rules.

The MoHFW released the first draft of The Medical Device Rules in July 2016 and after consulting the industry and stakeholders, released the second draft in October 2016. In January 2017, the MoHFW notified the Medical Devices Rules, 2017 and announced that they would be effective from 1 January 2018, thereby giving the industry time to adapt to the new Rules. The Rules clearly separate medical devices as being distinct from drugs, clearing some hurdles for the industry However, medical devices continue to be defined as drugs under the DCA and going forward ideally the government should pursue a full separation of medical devices and drugs with each having distinct and separate regulations.

The Rules generally adhere to the framework laid down by the Global Harmonization Task Force (GHTF) on medical devices and are on similar lines with global standards. The Rules further address procedural issues such as the need for constant re-approval of manufacturing licenses, while eliminating the need to apply for a registration as well as an import license. The process of tracking applications for licenses is made easier with online systems. While the new Rules attempt to plug various loopholes within the existing framework, it has caused ambiguity amongst medical device companies. It is anticipated that as the Indian market and manufacturers mature, the perception of devices manufactured in India will also improve and these rules is will help quality improvement.

Annexure-1 LIST OF MEDICAL DEVICES AND IN VITRO DIAGNOSTICS ALONG WITH THEIR RISK CLASS AS PER THE PROVISIONS OF RULE 4 OF THE MEDICAL DEVICES RULES 2017 (A) List of Medical Devices under provisions of sub-rule (1) rule 4 of the medical devices rules 2017 [Internet]. Available from- http://www.cdsco.nic.in/writereaddata/Classificationwiselistof MD and IVDs17.pdf

The Litrature review of this CDSCO document has helped to identify the current regulatory scenario of medical devices in India and how the medical device rules are framed. This data has also helped to find the ambiguities and loopholes in the current policy and rules.

Highlights from the current Medical Device Rules, 2017

The Medical Devices Rules, 2017 consist of the 12 chapters described in Table 2

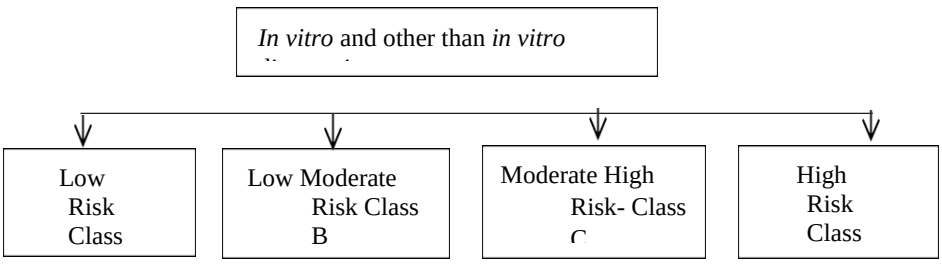
Chapter	Chapter Title
I	Preliminary
II	Regulation of Medical Device
III	Authorities, Officers, and Bodies
IV	Manufacture of Medical Devices for Sale and Distribution
V	Import of Medical Devices
VI	Labelling of Medical Devices
VII	Clinical Investigation of Medical Device and Clinical Performance Evaluation of new *In Vitro* Diagnostic Medical Device
VIII	Import or Manufacture Medical Device Which Does Not Have Predicate Device
IX	Duties of Medical Device Officer, Medical Device Testing Officer and Notified Bodies
X	Registration of Laboratory for Carrying out Test or Evaluation
XI	Sale of Medical Devices
XII	Miscellaneous

The rules include definitions to avoid the confusion between various types of terminologies, such as active medical device, active diagnostic device, invasive device, investigational device, and predicate device.

Medical Device Classification Rules

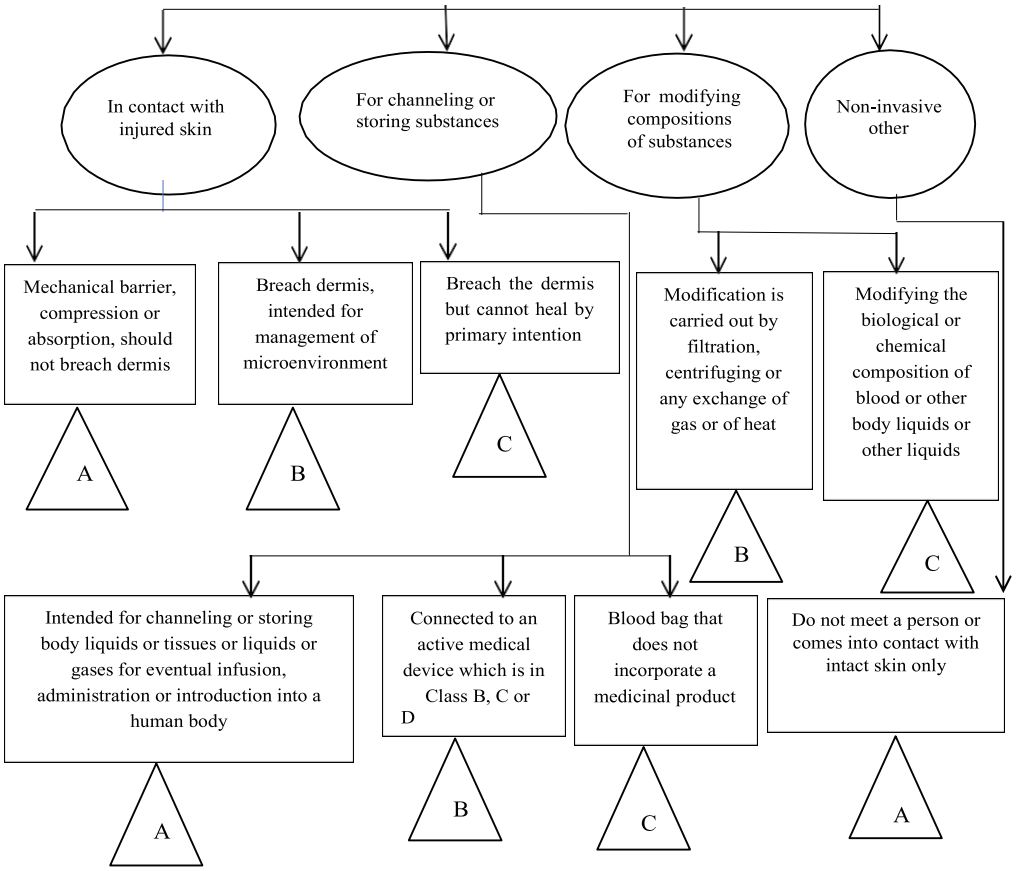
The well-defined classification system, based on the GHTF, is intended to help manufacturers determine a device category and regulatory requirements for gaining marketing authorization. The system includes "medical devices other than in vitro and in vitro diagnostic device categories classified into categories as A, B, C, and D based on their low, moderate and high risks associated with them.

Table 3: Risk based classification of medical devices



Medical devices other than in vitro diagnostic devices are classified further classified as invasive medical devices, non-invasive medical devices, surgically invasive devices and miscellaneous.

Figure 1: Classification of Non-Invasive devices



Examples of devices within each risk class are presented below:

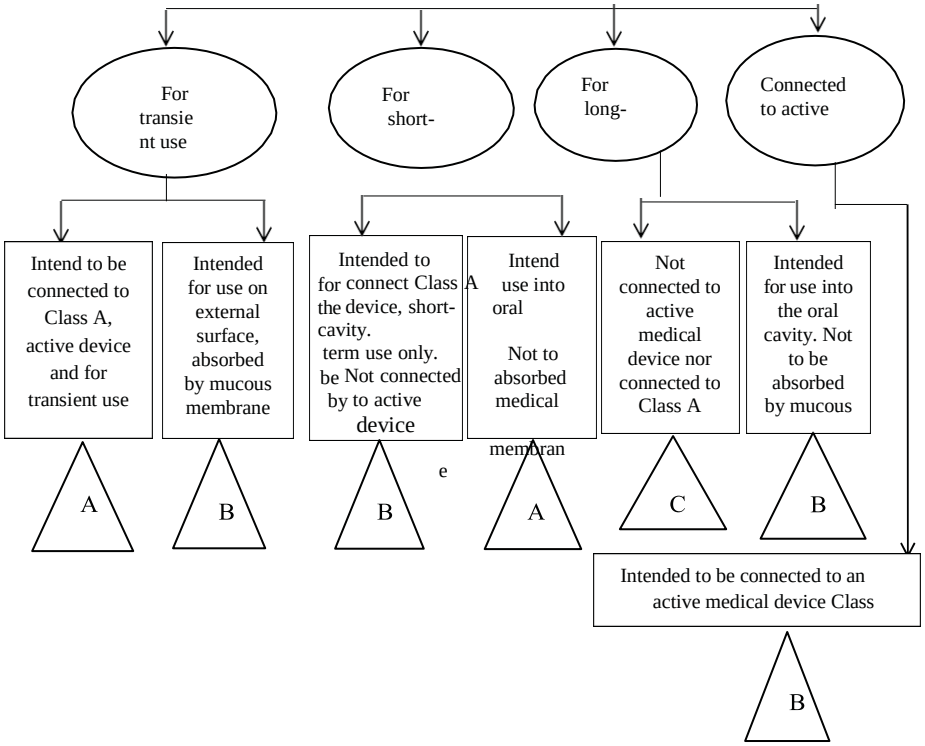
Class A: syringes for infusion pumps, wound dressings, absorbent pads, island dressings, cotton wool, adhesive bandages, anti-static tubing for anesthesia, anesthesia breathing circuits, pressure indicator, pressure limiting device, wound strips.

Class B: polymer film dressings, hydrogel dressings, non-medicated impregnated gauze dressings, adhesive for topical use.

Class C: dressings for severe decubitus wounds, dressings for chronic extensive ulcerated wounds, dressings for severe burns.

Figure 2 : Classification of Invasive Devices

Examples of devices within each risk class are presented below:

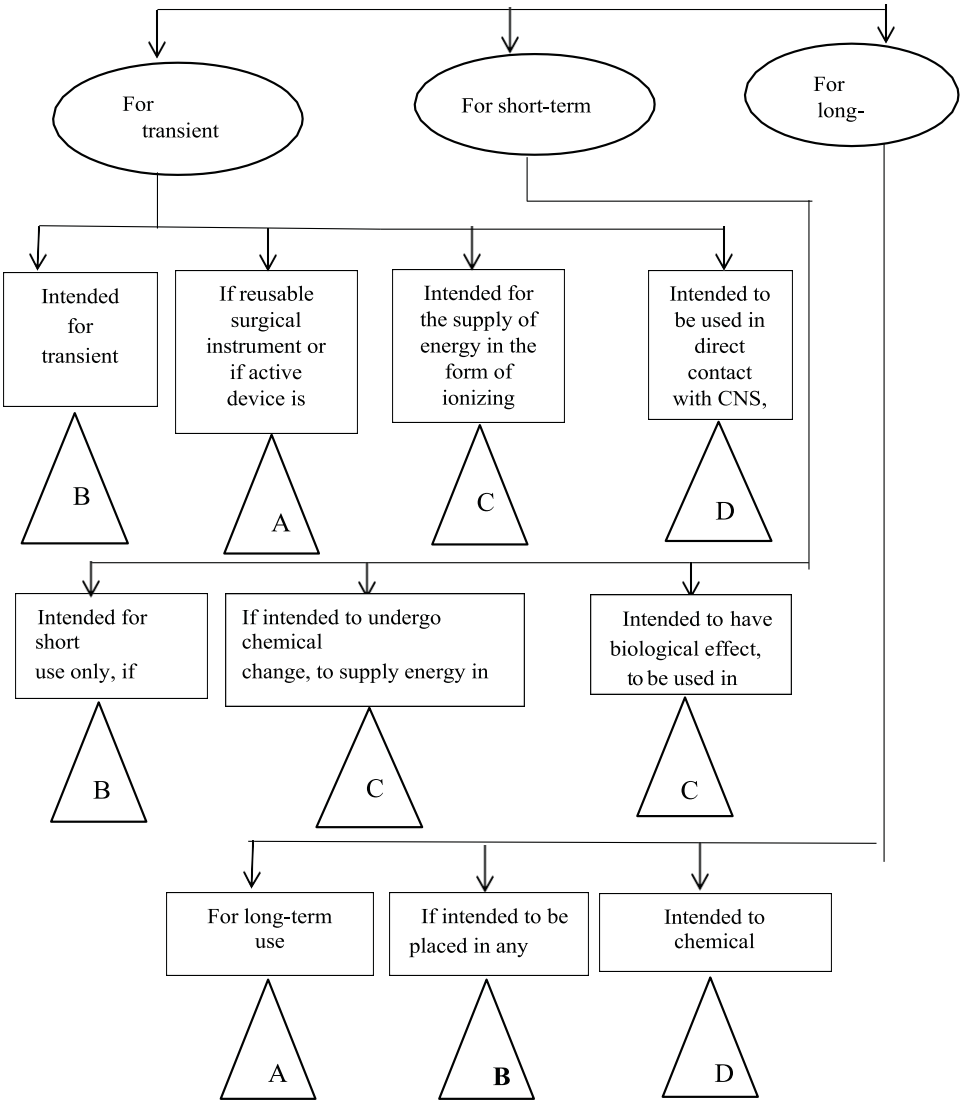


Class A: handheld mirrors used in dentistry to aid in dental diagnosis and surgery, dental impression materials, impression trays, enema devices, examination gloves, urinary catheters intended for transient use, materials for manufacturing dentures.

Class B: urinary catheters, orthodontic materials, removable dental prosthesis.

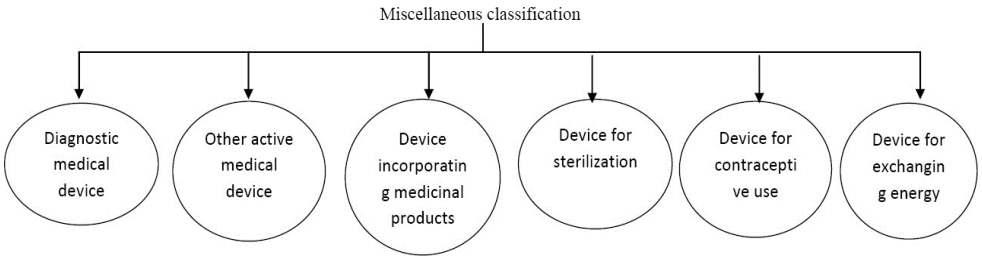
Class C: urethral stents, lenses, tracheal cannula, urinary catheters intended for long term use, short term corrective contact lenses, stents, vaginal pessaries, indwelling urinary catheters intended for short term use, orthodontic wires, fixed dental prostheses, tracheostomy or tracheal tubes connected to a ventilator, blood oxygen analyzers placed under the eye- lid, powered nasal irrigators, some enteral feeding tubes, fiber optics in endoscopes connected to surgical lasers, suction catheters or tubes for stomach drainage, dental aspirator tips.

Figure 3 : Classification of Surgical Invasive Devices



Class A: scalpels, retractors forceps and sternum retractors.
Class B: needles, lancets, suckers, scalpels, staplers, drill bits, surgical gloves, etchants, heart valve, swabs, single use aortic punches, clamps, dental filling materials, dental alloys.
Class C: catheters, radioisotopes, insulin pens, nails and plates, shunts, intraocular lens, internal closures, penile implants.
Class D: neuro endoscopes, brain spatula, catheters, distal protection device, absorbable sutures, cortical electrodes, spinal stents, Cochlear Nerve Deficiency (CND) electrodes.

Figure 4 : Classification of Miscellaneous Devices



Class A: Surgical instruments (reusable)

Class B: Electrical acupuncture, cryosurgery equipment, eye electromagnets, pulp testers.

Class C: Electrosurgical generators, kinetic energy, blood warmers

Class D: Central nervous system instruments (CNS), and heart defects

Bansal A, Shukla V.K, Chauhan S, Yamini Kanti SP, Kumar S, katrolia A. Drug regulatory paradigm and challenges for Medical devices in India. International Journal of Drug Regulatory Affairs [Internet]. 15 Mar 2019; 7(1):25-33.

These new medical device rules published on 31st January 2017 and implemented from 1 January 2018.

Table 1- Difference between old medical device rules and new medical device rules

Parameters	Old medical device rules	New medical device rules 2017
Market overview	Unregulated market, Pose challenges for market approval USFDA and CE (European Conformity) approved medical devices are allowed for approval. No rules and regulations for devices,regulated as drug under drug and cosmetics act1940 and rules 1945.	• Highly regulated , ease in market approval Country has its own approval procedure. Manufacturer doesn't need foreign regulatory approval. Separate medical devices rules published in 2017.
Regulatory	Device classified under notified medical device into 15 categories. No online e procedure No list of defined /required documents, no audit, no renewal requirements, undefined approval procedure.	Medical device classified based on risk as A, B, C, D. Online procedure for application and grants of license Defined documents list, renewal requirements
Registration and renewal	No audit for manufacturing facility Quality documents are not up to standard. Form 40 – application form Form 41- registration certificate issued	Audit required for manufacturing facility Quality documents required to meet the new rules Approval and registration certificate is valid for five years.
manufact-ure , distribution and sale	QMS (Quality Management System) is not covered. CDSCO handled all the activities No such rules and provisions for the conduction of clinical trials of medical device.	Quality management system is covered and obey the ISO 13485 Separate rules and guidelines for the conduction of clinical trials for medical device.
Shelf life and labeling	No such requirement	New labeling guidelines are provided. The shelf life should not exceed five years.

Research Methodology

- **Research Questions:**

❖ What is the regulatory framework for Medical devices in India?
❖ Is there a need for change in regulatory framework of medical devices in India?
❖ What are the ambiguities in the current frame work of medical devices in India?
❖ What is the perspective of Doctors and Industry Experts on the current frame work in India?

- **Objectives:**

❖ To understand the current regulatory framework of medical devices in India
❖ To find ambiguities and suggest the needful alterations in the existing framework
❖ To understand the perspective of doctors and Industry Experts on the regulatory framework of medical devices in India

- **Materials and Methods**:

❖ **STUDY DESIGN:**
Descriptive study in which observational study was done to defined as a method of viewing and recording the participants.

❖ **SETTING:** It would be a primary research which would focus on gathering information from existing reports, legal documents, regulatory documents and guidelines and surveys

❖ **STUDY POPULATION:** Doctors and Industry Experts

❖ **DURATION OF STUDY:** 6th February 2019 to 6th May 2019

❖ **SAMPLE SIZE:** 100 Doctors (Specialists) and 12 Industry Regulatory

❖ **SAMPLING TECHNIQUE:** Non Probability Convenience Sampling

❖ **DATA COLLECTION PROCEDURE:** Data from doctors was collected by the Questionnaires and data from Industry Regulaotry Experts was collected with the help of a Focused Group Dicsusssion

❖ **STUDY AREA:** Delhi

❖ **DATA ANALYSIS PLAN**: Using MS Excel if needed for analysis of Surveys

❖ **OPERATIONAL DEFINITIONS:**

- Medical Device- "medical device" means "any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of diagnosis, prevention, monitoring, treatment or alleviation of disease or diagnosis, monitoring, treatment, alleviation of or compensation for an injury or investigation, replacement, modification, or support of the anatomy or of a physiological process or supporting or sustaining life or control of conception or disinfection of medical devices

or providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function"

- CDSCO- Central Drug Standards Control Organization
- MHFW- Ministry of Health and Family Welfare
- MDRA- Medical Device Regulatory Authority of India
- Regulatory- Serving or intended to regulate something.

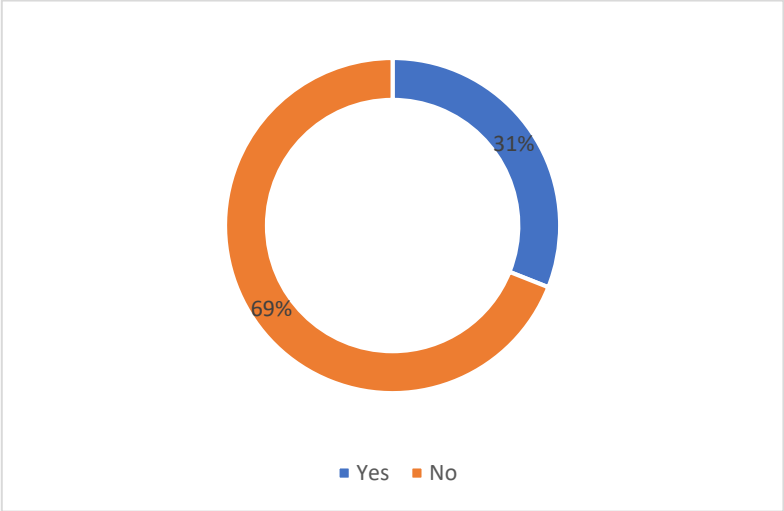
Results and Discussion

Primary research dara was collected from survey of 100 doctors and a Focused Group Discussion of 12 Industry Regulatory Experts and further it was analysed.

Doctor Survey-

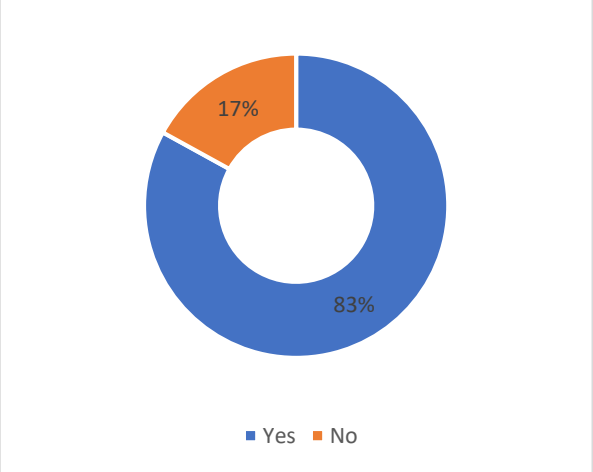
The doctor survey consisted of 12 questions which dealt with several parameters like government and regulatory affairs, Industry and patients

1. **Is the difference between medical devices and pharmaceuticals is well defined in the regulatory frame work?**



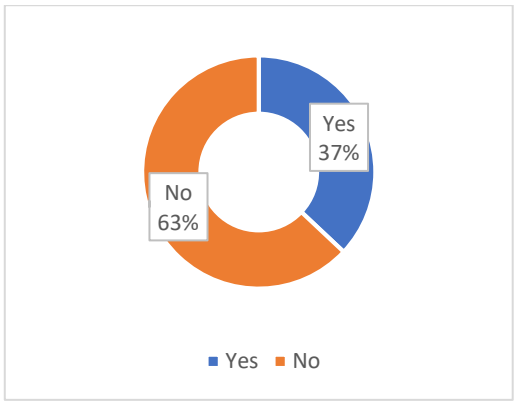
A total of 100 doctors were surveyed out of which 69 doctors felt that the difference between pharmaceuticals and Medical devices was not well defined in the Indian regulatory framework, because the current frame work do not have definition of medical device and also it has been a part of Drugs and Cosmetics act. There are several medical devices who are considered as drugs.

2. **Is the classification of medical devices well defined in the Indian regulatory framework?**



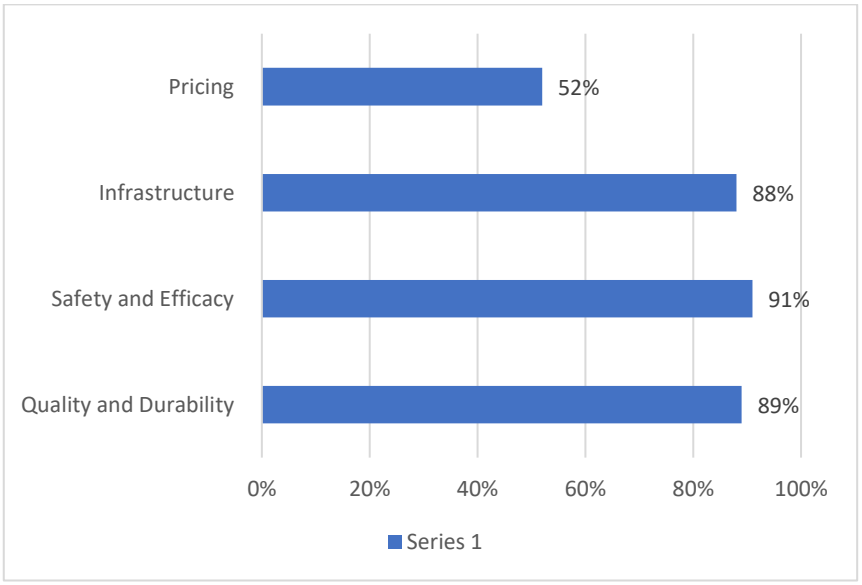
83% of the doctors had said that the classification of medical devices was appropriate in the current frame work as they are classified into types on the basis of risk as Class A, Class B, Class C, Class D.

3. **Do our policies encourage an innovative healthcare environment?**



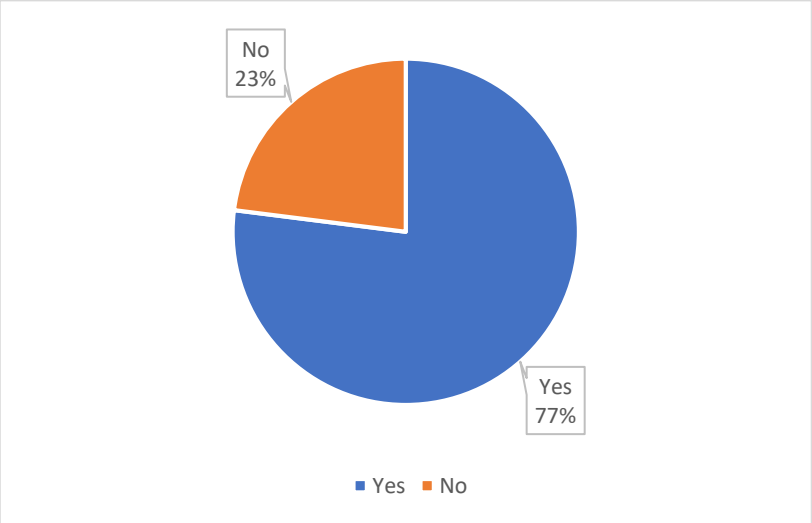
As the data shows tmaority of the doctors feel that Indian policies do not favour innovative healthcare environment, they also explained this by giving example of price capping on various devices which stop the research based companies to sell their new technologies in India due to insufficient return of investment.

4. **What considerations should the regulatory bodies keep in mind while framing the new medical device act/policy. (Factors can be like- Quality, Materiovigilance, infrastructure accessibility and Pricing)**



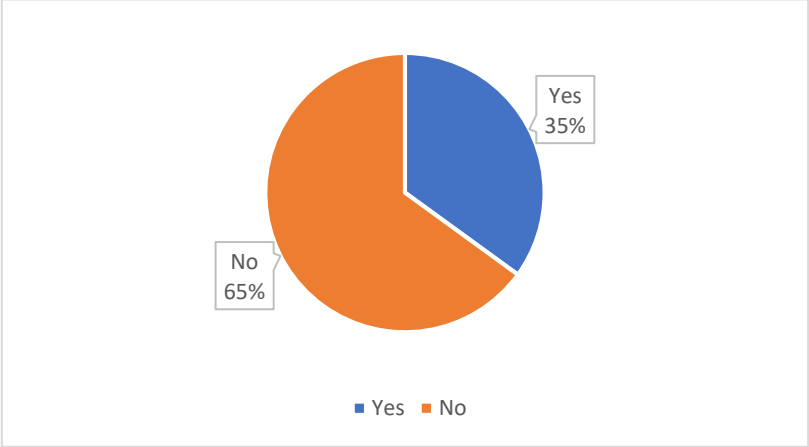
Out of 100 Doctors Majority of doctors emphasized on the importance of parameters like Safety, Infrastructure and Quality for making the regulatory framework of India. Certain doctors did not feel the importance of pricing because they thought this stops the companies from bringing the innovative devices to India.

5. **Does Indian healthcare policies lack in stringent regulations on quality?**



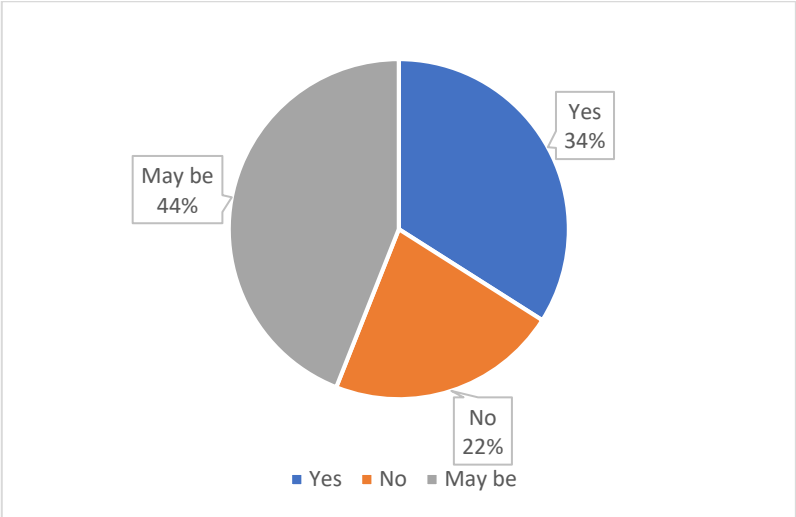
Majotiy of the doctors felt that Indian healthcare policies have strinent regulations while 23% of the doctors do not feel Indian healthcare polcies are stringent.

6. **Do you agree with government's approach towards price-capping?**



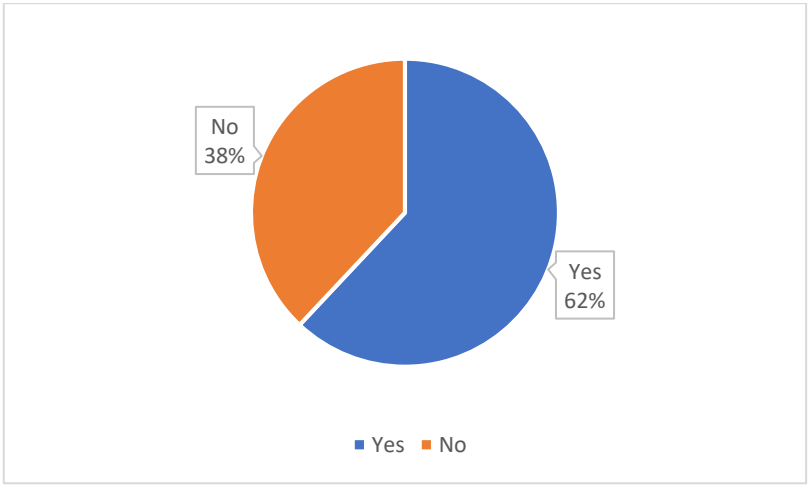
65% of doctors had responded that they do not agree with government's approach of price capping while 35% doctors agreed with the governments approach of price capping.

7. **Do your think domestic industry is capable or meeting the needs and manufacturing innovative medical devices?**



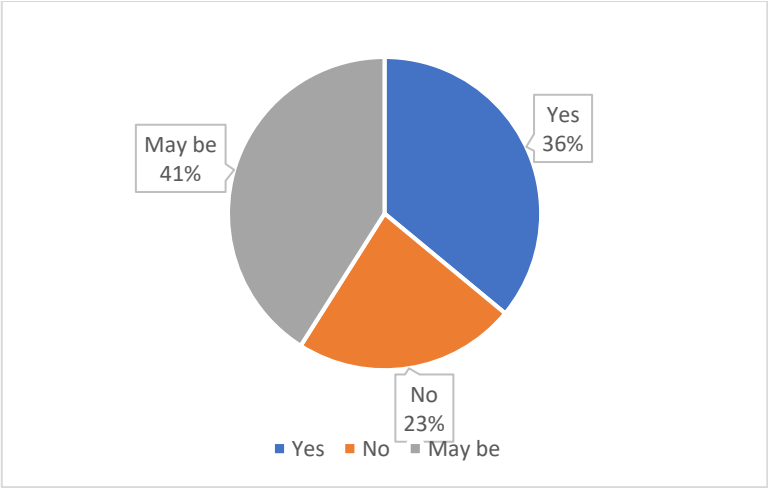
Majority of the doctor's thought that right now domestic industry is increasing it's focus on innovation and withing couple of years it will be meet the needs of manufacturing innovative medical devices where as 34% of the doctors think it is capable of meeting the needs right now and 22% of the doctors denied the fact that domestic industry is capable of manufacturing innovative medical devices.

8. **Do you think medical device industry plays a key role in educating doctors about the new technology in form of CME's?**



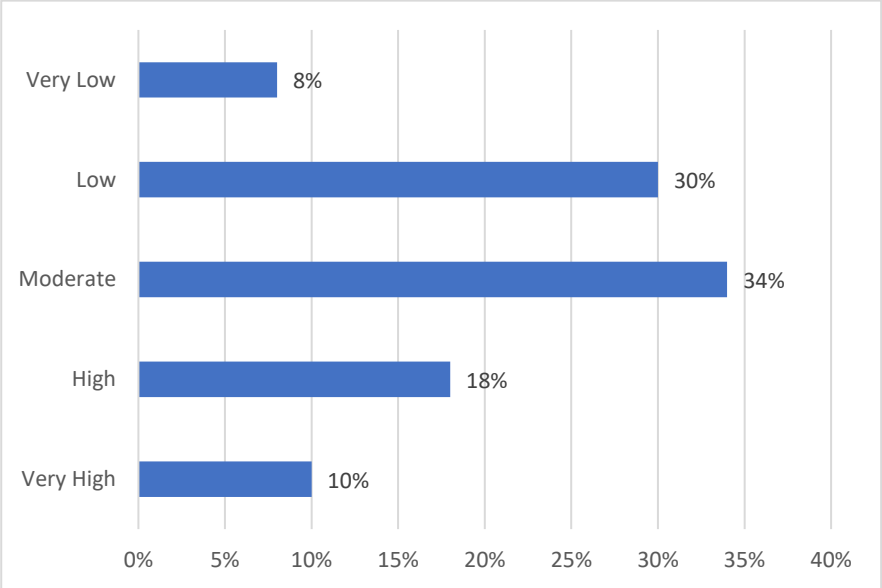
62% of doctors felt that medical device industry plays a key role in educating the doctors about the new technology in form of CME or in other ways where as 38% of doctors responded NO.

9. **Can industry and physicians collaborate to ensure government take a holistic approach regarding medical device industry?**



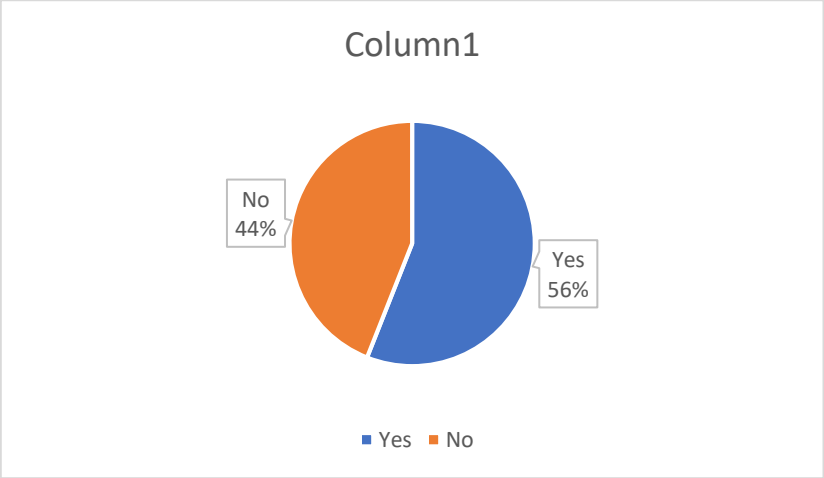
41% of doctors felt mmay be industry and physician collaboration with government is possible for taking a holistic approach regarding shaping medical device industry where as 36% were confident enough and 23% denied that industry, government and physician collaboration is possible.

10. **What is the level of awareness among patients on the value of technology?**



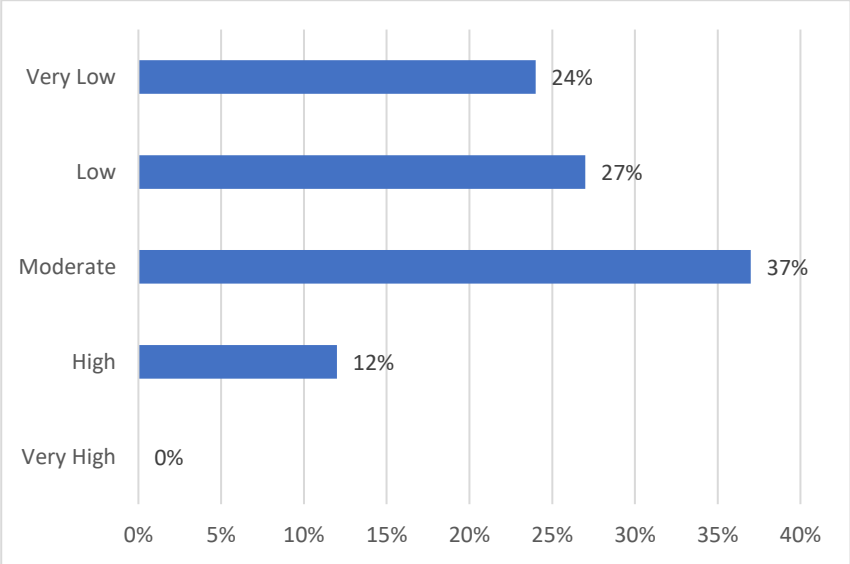
Maority of doctors felt that the awareness of patients regarding technology is at moderate level while, second most responses were seen for low level of awareness among patients.

11. Do you think price regulations will have an impact on the patient outcome?



Majority of doctors felt that price regulation does impact on patient out come and footfall while the opinion of all the doctors was quite mixed and quite close.

12. In your opinion what is level of awareness among patient regarding price capping?



51% of doctors responded for low level of awareness among patients regarding price capping where as 37% also responded that the level of awareness is at moderate level and can be improved

Focused Group Discussion

A Focused group discussion was conducted within 12 Industry Regulatory Experts where they were asked to discuss about the current issues in the Regulatory Framework of India and also on the current industry issues. The conclusion from the FGD is given below:

The Focused group discussion started with discussion on current regulatory framework issues where almost all the experts had a common stance of issue with the proper definition of the Medical Devices and a separate identity of medical devices. It was also seen that several regulatory experts emphasized on the need of a separate medical device act and differentiation of medical devices from D and C act in India.Several regulatory experts also discussed on how medical devices differ in the making process and functioning process then of drugs and concluded that medical devices are machines and incline towards engineering where as drugs are chemicals or chemical entities which are variedly different from the medical device. So the screening process of drugs which is used to test the safety and efficacy of drugs cannot be applied on medical devices. However it was also seen that the medical device industry was satisfied with the current classification of medical device under Medical Device rules, 2017. All the experts believed that the regulatory authority should pay keen focus on the functioning, safery and quality assuarance part of medical devices while framing the policy rather then focusing on quality control. With addition to this majority of industry experts thought that Indian regulatory policies do not lack in stringent regulations and is self sufficient.

When the FGD changed it focus on patient awareness many experts took the stance that the awareness of patients regarding the new technology and various pricing issues of medical devices is low and the need for awareness is very high. They also found an issue with patient's knowledge on the maojor and reliable medical device companies is low which leads them to use low quality medical devices.

When discussing on the Price Capping the regulatory experts expressed their unhappiniess with the approach which Indian authorities are using to make medical devices affordable which leads to restrict the MNC's to bring newer technologies to India and also promote low quality medical devices. The group believed that the government should use the Trade Margin Rationlization approach for medical device rather then price capping.

Lastly when the group was moved forward to the discussion over Materiovigilance issue the group believed that the Materiovigilance framework is too recent and it would be unconventional to comment on the progress of Materiovigilance. However they feel that the programme should focus on casualty assessment in a proactive manner and the reporting of adverse events should be focused on at an greater extent. They also suggested that the current team should refer to the existing Materiovigilance programme around the globe to take key insights and apply them in the Indian Materiovigilance programme.

Conclusion

From conductng surveys of doctors and FGD's industry specialists

It was observed that majority of doctors and industry experts stance was that the medical device regulations currently follow has some loop holes they thought that the difference between medical devices and pharmaceutical was not well defined and medial device needs a separate act or policy, which was tailored made for itself. And the regulatory process for approval and testing of Medical Devices should defer from drugs as medical devices are majojrly machines and not chemical products..

It was also observed that the current frame work did not support innovation rather is over focused on affordability because of certain reasons like price capping and trade margin rationalization and doctors and specialists did not agree to this approach.

It was also seen that the level of patient awareness on certain areas like price capping and importance of new technology was not satisfactory and needed some work to be done.

Several doctors also had emphasized on the importance of medical device industry in the healthcare domain and in well-being of the patients.

Based on the FGD's of industry experts it was learned that the current medical device industry has been facing a lot of issues in the area of pricing whereas the industry believes that the government should use the Trade Margin Rationalization approach. It was also observed that the industry is not satisfied with the current framework of medical devices.

Recommendations and Suggestions

- Safety and quality guidelines are (lower and upper limits) are missing
  It was seen that safety and quality guidelines for medical device were missing from the new document along with upperlimit and lower limits
- Provide training received by medical and Para- medical staff.
  There is lack of training on new technology and medical devices from the government and in the medical course syllabus which has to be changed and provisions should be made
- Allow the MTAB (Medical Technology Advisory Board) to recognize the procedure and priority medical device that reveal the need from diseases burden.
- India lags behind other developed countries in term of healthcare spending as a percentage of GDP.
- The enforcement of the existing policy is observed to be below the satisfactory level which should be focused on
- There is the need of a separate act for Medical Devices which will help to govern medical device industry with precision and accuracy

Limitations of Research

- There was limited amount of time which affected the accuracy
- The sample was carried out in one region only (Delhi)
- The respondends of the survey were very busy to explain more about their perception

Annexure

Questionnaire for Doctors

Government and Regulatory framework

1. Is the difference between medical devices and pharmaceuticals is well defined in the regulatory frame work? Yes/No
2. Is the classification of medical devices well defined in the Indian regulatory framework? Yes/No
3. Do our policies encourage an innovative healthcare environment? Yes/No
4. What considerations should the regulatory bodies keep in mind while framing the new medical device act/policy. (Factors can be like- Quality, Materiovigilance, infrastructure accessibility) (Open-ended)
5. Does Indian healthcare policies lack in stringent regulations on quality? Yes/No
6. Do you agree with government's approach towards price-capping?

- Your opinion on the government's decision to extend price-capping of knee implants by a year.
- Your opinion on the government's decision to impose price-cap on stents.

Industry

7. Do your think domestic industry is capable or meeting the needs and manufacturing innovative medical devices?
8. Do you think medical device industry plays a key role in educating doctors about the new technology in form of CME's?
9. Can industry and physicians collaborate to ensure government take a holistic approach regarding medical device industry?

Patients

10. What is the level of awareness amongst patients on the value of technology?
11. Do you think price regulations will have an impact on the patient outcome? // How does price regulations impact while treating patients?
12. In your opinion what is level of awareness amongst patient regarding price capping

a) Very High
b) High
c) Moderate
d) Low
e) Very low

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