An Analysis of Regulatory Environment of Medical Devices in India

Dissertation Submitted to

IIHMR UNIVERSITY

For the partial fulfillment for the award of the degree of Master of Business Administration (MBA)
In
Pharmaceutical Management
By

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Under the Supervision and Guidance of

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2023

Declaration by Student

By signing here, I certify that this dissertation, **An Analysis of Regulatory Environment of Medical Devices in India**, is an accurate account of my original research. I certify that it has not been applied for a degree or certificate from any other university or institution. Information that was taken from other people's published or unpublished work has been properly acknowledged in the text.

(Signature)

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This is to certify that Mr. Mayansh's dissertation, entitled "**An Analysis of Regulatory Environment of Medical Devices in India**," was written under my guidance and supervision and is a record of the research work he/she conducted in part fulfilment of the requirements for the award of the degree of MBA in Pharmaceutical Management from the IIHMR University, Jaipur.

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Abstract:

It was chosen to perform this research to benefit the medical device business aftertaking into account the present industry environment, where many medical device companies are dissatisfied with the current medical device rules. This study's primary goal was to extensively review India's medical device legislation and identify any gaps before making recommendations based on the opinions of doctors and industry experts. To accomplish this, we used a semi-structured questionnaire and focus group discussions (FGDs), which addressed a variety of factors including the current environment, patient awareness, and industry scenario.

Due to factors like price limiting and trade margin rationalization, it was discovered that the current framework did not encourage innovation and was instead overly concerned with affordability. Additionally, it was observed that patient awareness of several topics, such as price caps and the significance of new technologies, was not adequate and required improvement. The MNCs' decision to discontinue some of their most cutting-edge goods has a negative impact on the standard of medical care, medical tourism, investments in the creation of medical devices, etc. However, things are improving day by day now.

The conversation in the focused group began with a discussion of the problems with the current regulatory framework.

Almost all the experts had the same concern about the correct classification of medical devices and their distinct identities. It was also noted that several regulatory experts had emphasized the requirement for a distinct medical device law in India as well as the separation of medical devices from the D and C act. Many experts believed that even while patient comprehension of new technologies and the myriad pricing issues with medical devices is poor, there is an incredibly high need for awareness when the FGD turned its emphasis to patient awareness.

Acknowledgements:

It gives me great pleasure to publicly express my sincere appreciation for my mentor, **Dr. Surya Prakash**, an associate professor at the IIHMR University in Jaipur's School of Pharmaceutical Management. My work had been completed entirely and mostly as a result of his commitment, great attention, and most importantly, his outstanding attitude towards helping his pupils. His guidance, careful consideration, and intellectual suggestions greatly aided me in completing my work.

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Chapter-1: Introduction

An Overview of Medical Devices

The utilization of medical devices is a crucial aspect of patient care. There are now stricter requirements and safety measures for medical devices because of their complexity and the fact that most of them involve power factors. This article, An Introduction to Medical Devices, is the first in a series on advancements in the design of medical isolation transformers.

What exactly is a medical device?

Any device that is intended to be used by people for the purposes of diagnosing a disease, preventing it from occurring, treating it, or reducing its symptoms. This includes any appliance, tool, material, apparatus, or other item that can be used independently or in conjunction with other tools or devices. It also includes any software needed for its intended use by the manufacturer.

- Disability compensation or diagnosis, monitoring, therapy, or pain relief
- a physiological or anatomical evaluation, replacement, or modification
- the regulation of conception, which despite potential functional support from pharmacological, immunological, or metabolic processes doesn't have the main intended impact on our body.

The World Harmonization Task Force describes a "medical device" as "any instrument, apparatus, implement, machine, appliance, implant, in vitro chemical agent or calibrator, software, material or other similar or connected article supposed by the manufacturer to be used, alone or together, for kinfolk for one or many of the precise purposes(s) of designation, prevention, monitoring, treatment, or alleviation of sickness or deficiency."

The devices that make up the inside organs themselves are only growing at a 20% rate. Between 10% and 15% of the market is expected to grow in India. It is obvious that penetration rates are higher within the country. This might be the outcome of lower cost of care for patients, greater public knowledge of health issues, improved hospital infrastructure, and subsequently, more prevalent illness patterns.

Utilizing medical technology is a crucial component of patient care. The word "medical devices" covers a very broad and complex range of technologies, from tongue depressors to dialysis apparatus. The intricacy is increased by the fact that most medical equipment has power considerations. As a result, in addition to the performance of the device, important factors pertaining to patient and healthcare provider safety are also taken into consideration. To meet all safety requirements, several international standards and norms have been established. Adherence to these standards and norms ensures the proper delivery of technology. Testing is a means to ensure that the devices adhere to the appropriate requirements. Therefore, product testing generates the first level of assessment of the suitability of a gadget.

Because of developing economies and increased awareness, people are more worried about their health. Even if they are more expensive, people are willing to adopt cutting-edge tools and techniques for bettering their health. Because of this, the market for medical devices in the

healthcare industry has experienced remarkable growth. The medical device industry also contains subsectors for equipment used in cardiology, surgery, and orthopedics.

India is one of the top 20 markets worldwide for medical equipment, ranking fourth in Asia with a market value of EUR 4.6 billion (about $5.4 billion). In India alone, medical device sales are anticipated to reach EUR 8.6 billion ($10.1 billion) in 2020, with a projected compound annual growth rate (CAGR) of 15% over the next ten years and a reported CAGR of 11% between 2008 and 2015. Implants, consumables and disposables, equipment and instruments, and patient support are the primary industries expanding. Instruments and diagnostic imaging equipment make up 66% of the market in India, which is now 70% reliant on imports.

Several multinational corporations (MNCs) are expected to open medical device manufacturing facilities in Asian countries because of the changes made by the Medical Devices Rules, 2017, which will speed up the delivery of new treatments to patients in those countries. These rules can considerably improve the domestic market's friendliness to the medical device industry when combined with the Global Harmonization Task Force's (GHTF) suggestions. Certifications from the International Standards Organization (ISO) and the Bureau of Indian Customary (BIS), which are recognized by the Asian government, can promote domestic production, guarantee adherence to quality standards, and require product testing and certification. Most of the foundations concentrate on clinical research, device classification, and the conditions and procedures for registration and post-marketing licenses.

Due to the lack of a distinction between pharmaceuticals and devices, foreign corporations have encountered difficulties in the medical device industry. There isn't a single list of regulated devices with uniform regulations for all devices (you should combine several lists), and some gadgets aren't even subject to regulations at all. In some cases, manufacturing specifications meant for drugs also apply to the creation of device

GOVERNING AND ALLOWING AUTHORITY:

The 1940 Drugs and Cosmetics Act no longer regulates any medical devices; only those that have been specifically notified are. According to their intended use and risk class, the CDSCO published a list of 31 oncology medical devices in 2020. By October 2022, CDSCO licencing will be required for any medical devices that fall within Risk Classes A or B. A CDSCO licence is required for importers of oncology medical devices in order to sell their goods in India. The CDSCO website provides access to the whole list.

A recent notification states that starting on 1st April 2020, medical devices that fit the following definition will be governed by the "DCA and MDR" and be subject to the same regulations as drugs. This includes "all devices, including an instrument, apparatus, appliance, implant, material, or other article, whether used alone or in combination, including software or an accessory, intended by their manufacturer to be used especially for human beings or animals, which does not a) contain a drug or a biological product;"

(i) Any sickness or disorder detection, monitoring, alleviation, or assistance.

(ii) Diagnosis, follow-up, care, assistance, or monitoring of any injury or handicap.

(iii) Analyzing, replacing, modifying, or assisting the physiology or a process;

(iv) sustaining or ensuring life.

(v) sanitizing medical gear; and

(vi) Reproductive management

The MDR Amendment (effective April 2020) modifies MDR in two significant ways.

1. The creation of a new chapter that will let the makers and importers mentioned above to register recently updated medical equipment.

2. The registration requirement does not apply to the 37 categories of presently regulated or notified medical devices that were formed under the new chapter.

PROCESS OF REGISTRATION:

The Drugs Controller General of India ("DCGI") demands that makers and the one who exports freshly approved medical devices register with them before to 1st October 2021. Some medical devices, such as the 37 goods in Table 2 that have been on the market for some time and are already controlled or have been reported to be regulated, are exempt from the registration requirement. It is no longer essential to engage in a registration for or authorization of full-service marketing representative because the government has simplified the registration process. By providing the below mentioned information, any importer or manufacturer of recently disclosed medical devices may register online.

- The organization's, partnerships, or the name of that legal entity.
- The manufacturing facility's brand and address (for made in India devices only)
- The standards and requirements for medical equipment (applicable only to imported items).
- Specific details about medical devices may include their generic name, model number, intended use, class of medical equipment, construction material, measurements (if required), shelf life, sterility or non-sterility status, and brand name, but only if those details have been registered in accordance with Indian trademark laws.
- A document attesting that the medical equipment in issue conforms with ISO 13485 standards, such as one from the International Accreditation Forum or the National Accreditation Board for Certification Bodies.
- An origin-country-free selling certificate (only for imported equipment).
- A legally binding declaration confirming the completeness and authenticity of the applicant's information.

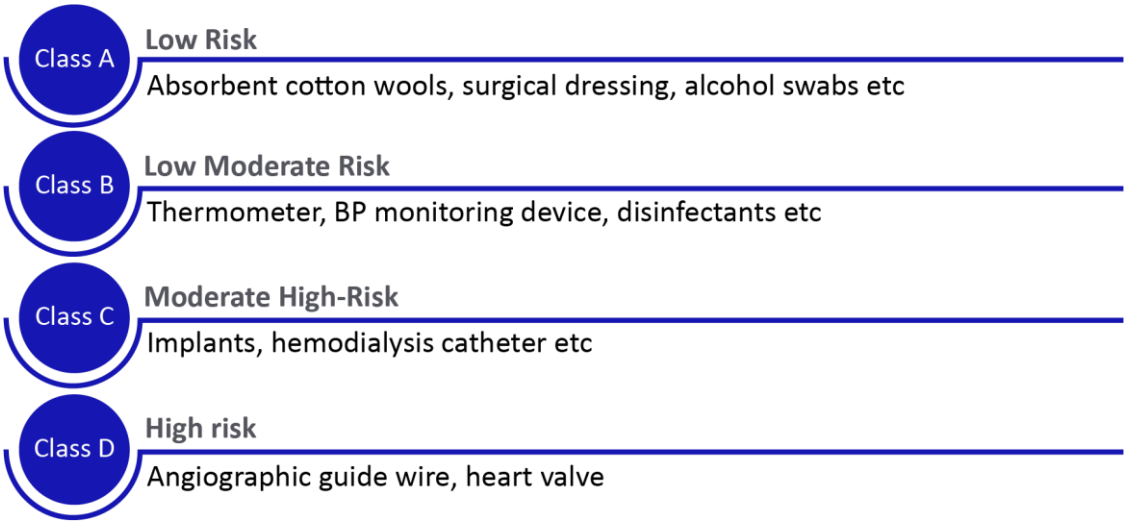

Fig. 1 Classification of medical device

Notified medical device:

The CDSCO, the health organisation in charge of regulating the regulation of medical devices in India, has compiled a list of the devices that are subject to the Medical Devices Rules (MDR), 2017, known as the "Notified Devices." The Medical Devices (Amendment) Rules, 2020, one of two notifications issued by the CDSCO in February 2020, took effect on April 1, 2020. New guidelines for medical devices were included of the other announcement. All devices are now governed by the CDSCO in accordance with the revision and the new definition. The only device and IVD categories that were regulated in India prior to these announcements were 37. "Newly Notified Devices" refers to the newly brought within the CDSCO's jurisdiction devices.

Fig. 2 List of Notified Medical Devices

Comparison between outdated and Revised medical device rules:

Parameters	Outdated	Revised
Analysis of Market	• Uncontrolled marketspace provide obstacles to market acceptance. • Medical devices can be certified if they meet certain requirements (conformity). • Devices are not subject to rules and regulations since they are governed by the Drug and Cosmetics Act of 1940 and laws from 1945 as drugs.	• Highly controlled, easily approved for the market Each nation has its own method of approval. The manufacturer does not need clearance from international regulatory bodies. • Various medical device regulations were released in 2017.
Legislative	• Devices are divided into 15 categories of under-recognised medical devices. • No online procedure • No audit, no renewal criteria, no list of defined/required documents, and no clear approval process.	• Classification of medical devices based on risk associated as A, B, C, or D. • Online applications, licence grants process • Detailed document list and renewal specifications
Regulation And Renewal	• The manufacturing site was not audited. • Document quality is not that good. • Form 40: Application form • Form 41: Issuance of registration certificate	• An audit is necessary for the production plant. • High quality documents must comply with the new regulations. • The certificate of approval and registration is good for five years.
Production distribution, retail	• There is no mention of the QMS (Quality Management System).	• Clinical trials for medical devices are conducted in accordance with separate norms

	• CDSCO managed all the tasks. • There are no such guidelines and procedures for conducting medical device clinical trials.	and regulations that fall within the purview of the quality control system and are covered by ISO 13485.
Labelling and shelf life	• There is no such demand	• There are new labelling recommendations given. There should be a five-year maximum shelf life.

Table-1

Chapter-2: Literature review

The procedure for selecting medical devices required for diagnostic, therapeutic, or rehabilitative reasons owing to disease or clinical intervention was devised by the WHO Priority Medical Devices initiative beginning in 2011. Over time, there have been more diseases and medical conditions added to the list. The ultimate objective of the priority medical equipment lists is to serve as a reference for Member States in the preparation or revision of their national lists for the purpose of ensuring patient access, procurement, availability in healthcare institutions, and appropriate use. Depending on their infrastructure, health workforce, financial resources, and local goals, countries and environments should alter these lists. This book contains the priority medical devices that WHO has developed over the past five years for the current epidemic. (WHO, 2020) (1)

Over the past ten years, India's healthcare industry has grown significantly. In many parts of the nation, access to high-quality, affordable healthcare is still a challenge, and the distribution of healthcare services is still uneven.
Over this time, the market for medical devices has grown tremendously and is now necessary for all phases of the healthcare continuum. Although it has contributed to the accessibility and affordability of healthcare services, several ecosystem limitations have made it challenging to meet domestic demand domestically, leading to a significant reliance on imports.

The current dynamics of supply and demand support the potential and justification of medical device production in India. The Indian government's "Make in India" effort offers a chance for the market to assess its guiding principles, pinpoint key growth drivers, and consider potential routes for bringing about a sea change in the medical devices market.

To identify the main challenges and conditions needed to take advantage of the "Make in India." opportunity, NATHEALTH and Deloitte worked together to study the present environment and role of the medical devices industry. The findings of this study are the result of an in-depth investigation and numerous interviews with influential figures in the public and commercial healthcare sectors. 2016 Deloitte report (2)

The healthcare industry has developed into one of the largest in India in terms of revenue and jobs. It has added 4.7 million new direct jobs since 2016, growing at a CAG of 22%.
Over 500,000 new jobs each year, or 2.7 million new jobs between 2017 and 22 in India, might be added by this sector.

Over the past two decades, the Indian healthcare sector has grown as a result of the prevalence of lifestyle diseases, an ageing population, a growing middle class, a focus on public-private partnerships, the quick adoption of digital technologies like telemedicine, as well as increased investor interest and increased FDI inflows. NitiAyog for 2016. (3)

In the 21st century, India's healthcare system has undergone substantial development. By continually increasing by 10%, this industry in India is expected to reach $280 billion by 2025. India only spent $75 per person on healthcare in 2016, compared to $9403, $3613, $420, and $1061 in the US, EU, China, and the global average. The $128 billion Indian healthcare industry is expected to expand at a 12 per cent yearly rate over the next four years.

Medical technology must now be a part of any emerging nation's healthcare system that is concerned with patient quality. These have a range of uses in the healthcare industry, including but not limited to screening and diagnosis, treatment and care, recovery, and monitoring. One of the top 20 markets in the world for medical devices is India. (4] Given that it is expanding quickly—at a rate of 15% yearly—by 2025, it is predicted to reach $50 billion. In India, different items supplied in distinct market segments have varying market shares. The market is dominated by medical equipment and devices (34%) followed by diagnostic imaging equipment (31%), patient assistance and other non-medical items (19%). (4)

Vital sign monitoring is provided by a wearable medical device. To monitor fitness and perform medical diagnostics, it is necessary to monitor one or more of the physiological vitals listed below as well as any others, including blood sugar level, blood pressure, pulse rate, electrocardiogram (ECG) patterns, respiration rate, and respiration efficiency (such as blood oxygen saturation). wearable medical technologies is a very helpful preventative technology as a result. Similar gadgets are now commonly accessible. They are not generally known in India despite their worth. Given that metropolitan areas have the biggest markets for these devices, this may be a result of insufficient knowledge. (Nanda, 2018) (5)

Essential materials needed for the prevention, detection, and treatment of COVID-19 are in low supply worldwide, and price speculation and increases may have had a detrimental impact on availability. This study found that the pricing of items acquired under government-driven contracts varied during the first pandemic reaction in Ecuador, which had the greatest fatality rates ever recorded in single 24 hours.

In order to determine the pertinent metrics for frequently purchased items, medical equipment, prescription medications, and other products, a statistical descriptive analysis was carried out. The three items with the biggest spending were face masks ($4.5 million), paracetamol ($2.2 million), and RTPCR kits. 2019 Ortiz-Parado (6)

For the advancement of universal health care, the management of medical emergencies, and the promotion of healthier communities, access to high-quality, reasonably priced, and suitable health items is essential.

A broken ankle can be bandaged, HIV/AIDS can be identified, an artificial hip can be implanted, and any operation may be performed without the need of medical equipment, would not be conceivable. In addition to optometrists, dentists, and other healthcare professionals working in state-of-the-art medical facilities, laypeople at home, paramedics and clinicians in remote clinics, and patients receiving palliative care all use medical devices. These medical technologies are used to diagnose and treat both acute and long-term diseases, as well as to help people with impairments.

Approximately 2 million distinct types of medical devices and 7000 generic device grouping are available on the current global market.
A medical device is any piece of equipment that the maker intended to be used for a medical purpose, either by itself or in conjunction with other items. This covers devices such as tools, implements, machineries, appliances, implants, reagents for use in vitro, software, materials, and other similar or related objects. (7)

India's current regulatory framework for medical devices is insufficient for a $6 billion industry. In India, there was no legislation governing medical equipment until recently. 22

medical devices are currently classified as "drugs" under the Drugs & Cosmetics Act (DCA), 1940 & Rules, and are handled accordingly.

In July 2016, the MoHFW published the first draughts of the Medical Device Rules. The second draught was made public in October 2016 following discussions with stakeholders and the industry. The industry was given time to adjust to the new Rules when the Medical Devices Rules, 2017—which were released by the MoHFW—indicatively stated that they will go into effect on January 1, 2018. The Rules make a clear distinction between medical devices and pharmaceuticals, which helps the business overcome some challenges. Even while the DCA still sees medical devices as drugs, the government need to work towards a total separation of medical devices and medicines, with each having its own set of laws.

The Global Harmonization Task Force (GHTF) rules for medical devices are generally followed by the Rules, which are following international standards. The Rules also address procedural issues, such as the necessity of routine renewal of manufacturing licenses and the elimination of the requirement for simultaneous submission of import permits and registrations. Monitoring the progress of license application processes is made easier by online technologies. Even while the new Rules are meant to fill in some of the gaps in the existing framework, they have caused confusion among medical device businesses. Consumer perception of electronics created in India is expected to change as the Indian market and manufacturers grow, and these rules should help to elevate product quality. (8)

Chapter-3: Research Methodology

3.1 Research Question:

- What is India's system for regulating medical devices?
- Is it necessary to alter India's regulations governing medical devices?

3.2 Objectives: to comprehend India's current medical device regulation system.

3.3 Hypotheses: A continuum of care approach that provides a framework for the deliveryof appropriate healthcare to population groups by way of an evidence-based,comprehensive, measurable, and patient-centric survey is required to address the rising burden of diabetes.

3.4 Material and Methods:

Study Design: Descriptive Type

Setting: It would be primary research, with the goal of compiling data from surveys, legal documents, regulatory documents, and reports that are already inexistence.

Study Population: doctors and business professionals.

Sampling Technique: Non-Probability Convenient Sampling.

Sample source: Primary and Secondary research

3.5 Data Analysis Plan: if necessary, analyze surveys and reports using MS Excel.

3.6 Ethical Considerations: The required research standards will be followed during the conduct of the research. To ensure the use of respondents' information, theirconsent will be requested, and appropriate authorization will also be carried out. The respondent's consent is required before their identity can be revealed.

3.7 Implications of Research: Understanding medical device marketing and being aware of current trends in the business are both aided by this research.

3.8 Operational Definition: "Medical device" refers to "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 purposes(s) of diagnosis, prevention, monitoring, treatment, or alleviation of disease or diagnosis, monitoring, alleviation of, or compensation for an injury." (9)

- CDSCO: Central Drug Standards Control Organization.
- MHFW: Ministry of Health and Family Welfare.
- MDRA: the Indian Medical Device Regulatory Authority.

Chapter-4: Results and discussions

1. **Is the distinction between medicines and medical devices clear in the regulatory framework?**

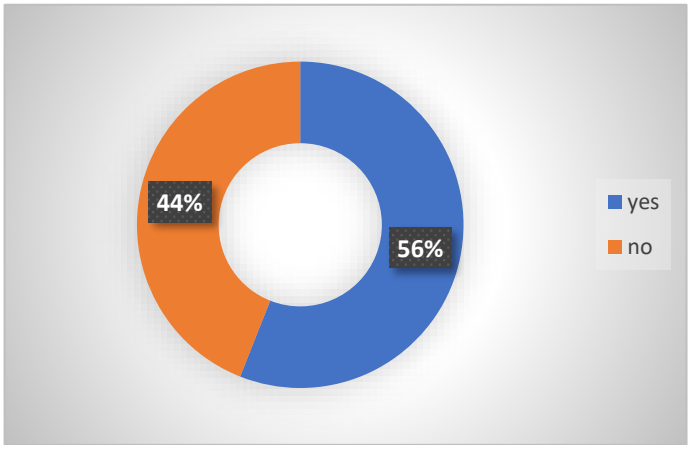

Fig. 3.1

The opinions of 50 individuals were collected, and 22 of them believed that the regulatory framework in India did not adequately distinguish between pharmaceuticals and medical devices because many of those devices are also regarded as medications.

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

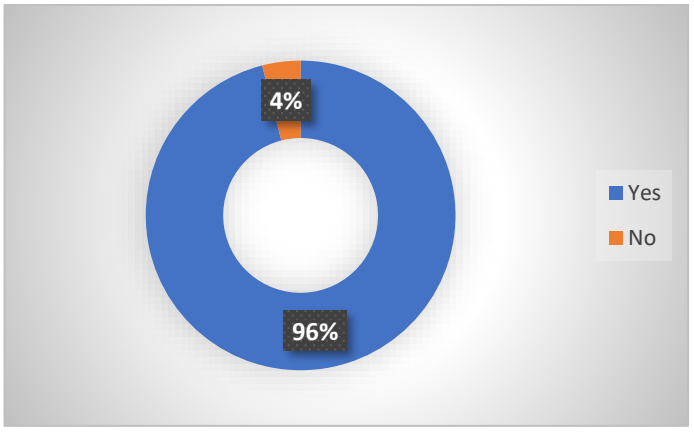

Fig. 3.2

96% of physicians agreed that the current framework for classifying medical devices.

3. **Do our policies support a healthcare environment that is innovative?**

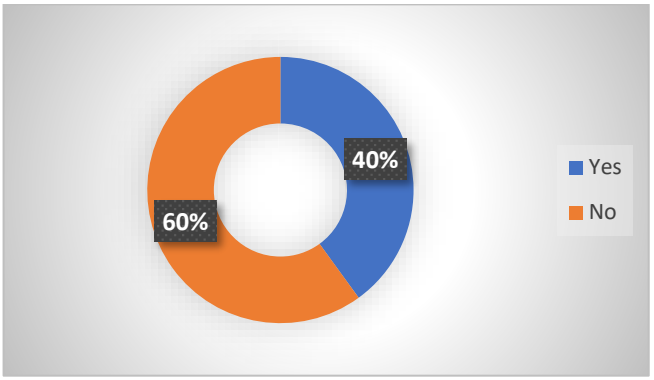

Fig. 3.3

The majority of doctors, as evidenced by the data, believe that Indian policies do not support the development of innovative healthcare environments. To support their claim, they provided an example of price caps on various devices, which prevent research-based companies from introducing new technologies into India due to insufficient returns on investment.

4. **What factors should be considered by the regulatory agencies when drafting the new medical device legislation or policy? (Factors include things like pricing, quality, microbial vigilance, and infrastructure accessibility.)**

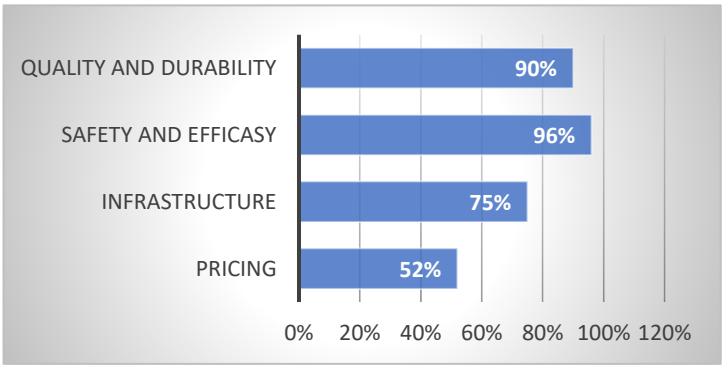

Fig. 3.4

Among 50 doctors most physicians emphasized the significance of factors like safety, infrastructure, and quality when developing India's regulatory framework. Some doctors did not value price because they believed it prevented businesses from bringing cutting-edge technology to India.

5. **Are there strict control rules missing from Indian Healthcare Policies?**

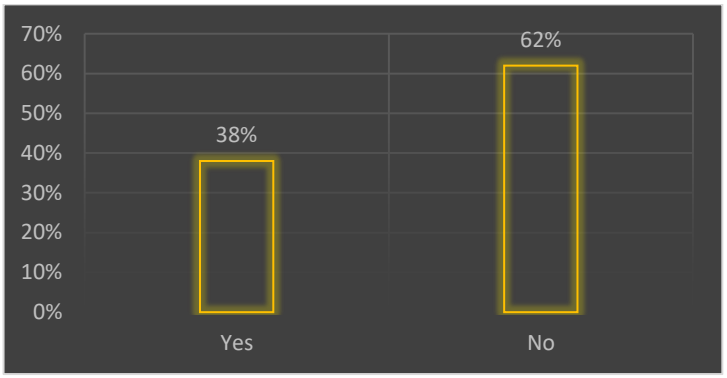

Fig. 3.5

Most doctors believe that the high-quality standards in Indian healthcare policies were enough.

6. Do you support the government strategy for price capping?

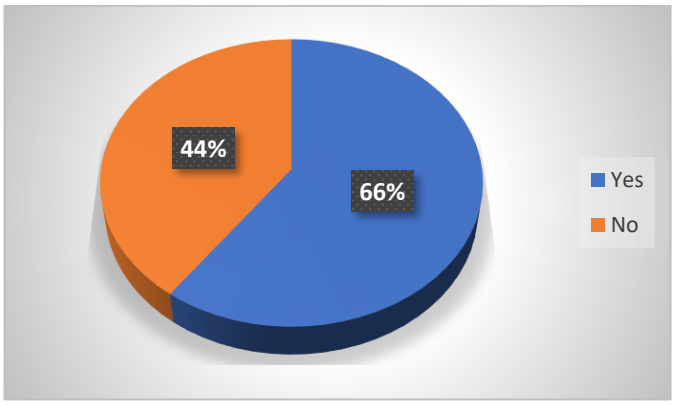

Fig. 3.6

In response, 44% of physicians said they disagreed with the government's strategy of price limiting, while 66% of physicians said they did.

7. Do you believe that domestic business can produce breakthrough medical devices?

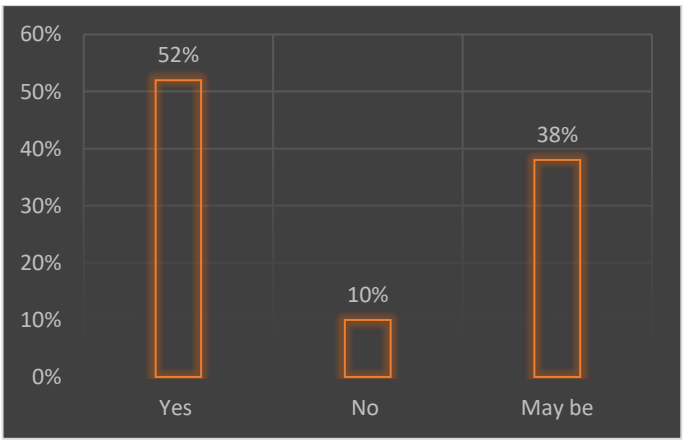

Fig. 3.7

Most doctors said that the domestic industry is currently focusing on innovation and will

soon be able to meet the need for manufacturing novel medical gadgets.

8. Do you believe that the medical device industry, through CMEs, is important in educating doctors about new technology?

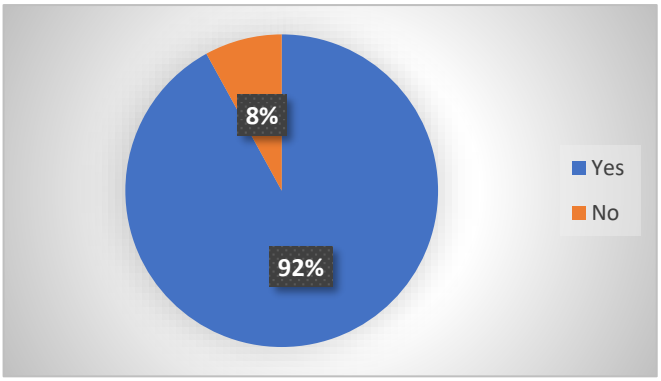

Fig. 3.8

92% of doctors agreed that the medical device business is important in educating doctors about new technologies through CME or other means, as opposed to 8% who disagreed.

9. Can business and medical professionals work together to guarantee that the government takes a comprehensive approach to the medical device industry?

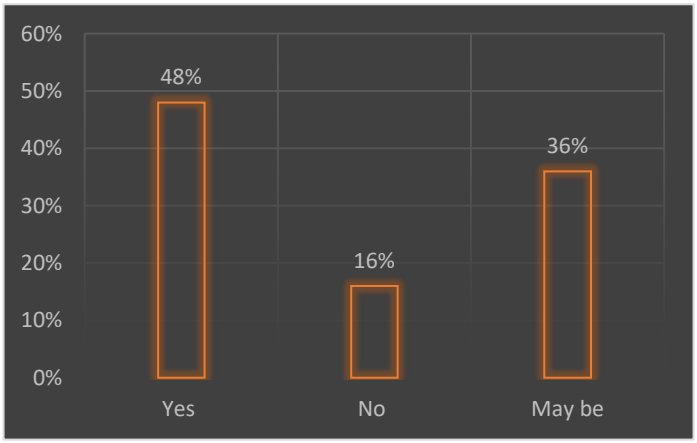

Fig 3.9

In order to shape the medical device business holistically, 36% of doctors believed industry, physician, and government collaboration may be viable. In contrast, 48% of doctors were sufficiently confidence in this possibility, while 16% disagreed.

10. To what extent are patients aware of the benefits of technology? Do you believe price controls will affect how patients are treated?

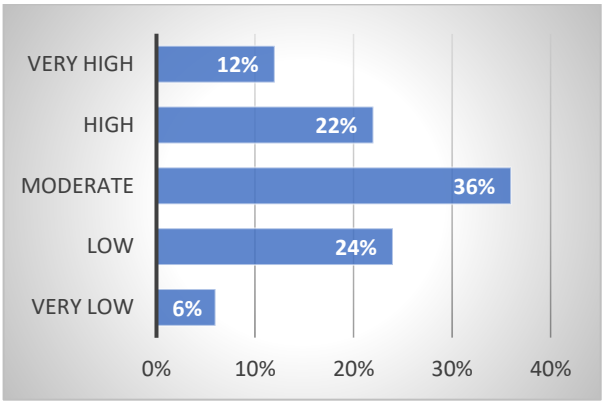

Fig. 3.10

Most doctors said that patients have a moderate level of technology awareness, whereas the second-most common response was that patients have a low level of knowledge.

11. Do you believe price controls will affect how well a patient does?

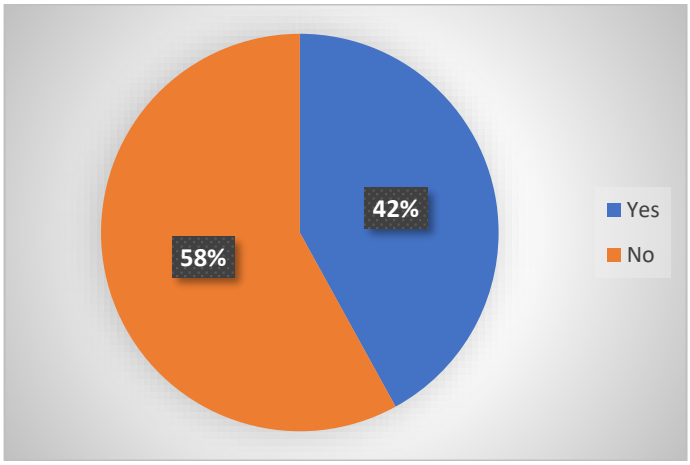

Fig. 3.11

Most physicians believed that price regulation had little impact on patient outcomes.

12. To what extent are patients aware of price capping, in your opinion?

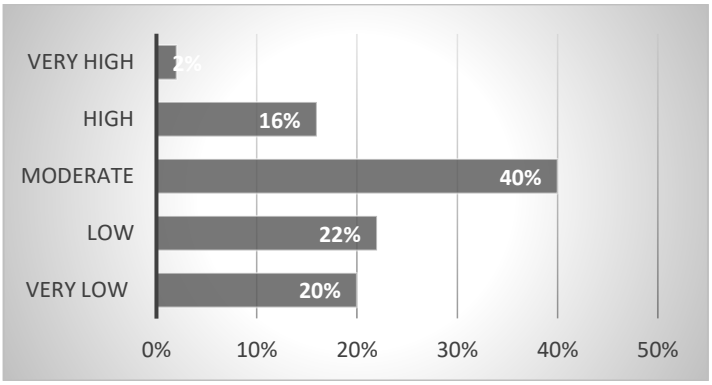

Fig. 3.12

A moderate level of patient awareness of price capping was reported by 40% of doctors, while a low level of awareness that can be raised was reported by 22% of doctors.

Focused Group Discussion

Twelve industry regulatory specialists were requested to address current difficulties with the Indian regulatory framework as well as problems in their sectors during a concentrated group discussion. The results of the FGD are outlined below:

The current regulatory framework issues debate served as the focus group discussion's starting point. Nearly all the experts expressed worry regarding the proper classification of medical devices and their distinctive identities. Also it was seen that many experts want separate medical device act which stressed more clear difference between medical device and Drug and Cosmetics in India. A number of regulatory experts also discussed how the creation and use of medical devices differ from those of drugs, and they came to the conclusion that while drugs are chemicals or chemical entities, which are very different from medical devices, medical devices are machines that lean towards engineering. Therefore, it is not possible to apply the drug screening method, which evaluates the safety and effectiveness of pharmaceuticals, to medical devices. (10)

Many experts believed that even while patient comprehension of new technologies and the myriad cost issues with medical devices is low, there is a strong need for awareness when the FDG changed its emphasis to patient awareness. They also found that patients frequently use subpar medical devices since they are unaware of the main, reliable producers of those items.

When discussing price limiting, the experts shown their concern with the method employed by Indian Government to produce medical equipment affordable because it discourages MNCs from bringing in newer technology and promoting the usage of inferior medical devices. The group believed that the Trade Margin Rationalization method should be used by the government to ‘rationalize medical device prices’.

Conclusion

Most medical professionals and industry experts surveyed think that the current medical device regulations need to be improved and that there should be distinct legislation or set of rules for medical devices that are created exclusively for them. (11) Additionally, the clearance and testing procedures for medical devices should be distinct from those for drugs because they are mostly made of machines rather than chemical products.

Additionally, it was stated that the current framework did not stimulate innovation and was instead overly focused on affordability for factors like price cap and trade margin rationalization and that this approach was opposed by doctors and other professionals.

The level of patient comprehension of topics like price caps and the significance of new technology was also recognized as an area for development. (12)

The significance of the medical device sector to healthcare and patient welfare was emphasised by several medical specialists.

The government should employ the trade margin rationalisation technique, according to the FGDs of industry experts, as the trade device industry is now grappling with several price concerns. It was also said that the industry is not pleased with how medical devices are currently governed.

Recommendations and suggestions

- Lower and higher limits for safety and quality criteria are absent.
  It was discovered that the new document lacked upper limit and lower limit limitations aswell as safety and quality criteria for medical devices. (13)

- Describe the medical and paramedical staff's training.
  The government must update the medical course curriculum and make accommodationssince there is a shortage of training on new technologies and medical equipment.

- Give the Medical Technology Advisory Board (MTAB) the authority to specify the method and top-priority medical equipment that are necessary considering the prevalence of illnesses.

- When measured as a proportion of GDP, India behind other industrialized nations in healthcare spending.

- It is noted that the current policy's enforcement is not up to par, which is something thatmust be prioritized.

- The medical device sector needs a specific legislation that will help to regulate the medical device industry accurately and precisely.

Limitations of Study

- There is a chance that the replies provided by the respondents may be biased.
- The analysis uses actual data, not projections.
- There was a limited amount of time which affected the accuracy.
- Only 20 doctors and 30 industry experts were involved in the study.
- The study was conducted in 2 places: Sirsa, Delhi.

Annexure

Government and Regulatory framework

1. Is the regulatory framework clear about how medical devices and drugs differ from one another? Yes/No
2. Is the Indian regulatory framework's classification of medical devices clearly stated? Yes/No
3. Do our policies support a cutting-edge healthcare setting? Yes/No
4. What factors ought to be considered by the regulatory agencies while drafting the new medical device act or policy. (Factors include things like quality, microbial vigilance, and accessibility of infrastructure.) (Open-ended) Does the quality of Indian healthcare policy not have strict regulations? Yes/No
5. Do you support the government's strategy for price capping? Yes/No
6. Do you believe that the domestic industry can produce revolutionary medical devices?
7. Do you believe that the medical device business is important in educating doctors about new technology through CMEs?
8. Can business and medical professionals work together to guarantee that the government takes a comprehensive approach to the medical device industry?
9. How well-informed are patients about the benefits of technology?
10. Do you believe price controls will affect how patients are treated?
11. What effects do pricing controls have on patient care?
12. What level of patient knowledge do you think there is about price caps?
    Very high, High, Moderate, Low, very low

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