“An Analysis of Regulatory Environment of Medical Devices in India”

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COMPANY PROFILE

•SPAG is an award-winning, independent communications conglomerate operating across key Asian markets, with a focus on life-sciences and development sector.

•Being a specialist in media advocacy, healthcare communications and offering expert driven integrated solutions, SPAG understands the need to adopt a multi-stakeholder and multi-channel communication strategy.

CORE EXPERTISE

- Media Relations
- Issue Advocacy
- Policy Research & Analysis
- Policy Issue Management

•Their deep industry expertise in media relations, digital and social media allows us to gauge the playground beforehand, so that they are well armed with all equations at play in our communications plan.

INTRODUCTION

- Medical devices are very essential components for patient care. They can also be uncomplicated devices employed during medical examinations, like tongue depressors and thermometers, or sophisticated life-saving implants like cardiac stents, knee implants and hip Implants.
- 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 2016 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.

LITERATURE REVIEW

- SKP business group in their report The medical device industry in India 2017. available from https://www.skpgroup.com/data/resource/skp_advamed_medical_device_industry_in_india_executive_summary_.pdf mentioned about the medical device industry in India including the challenges and the adoption process of medical devices rules in 2017, they have also mentioned about some loop holes in the medical device rules which are creating problems and restricting companies from entering in India.
- Meher BR in his article Materiovigilance: An Indian perspective has explained about the Materiovigilance program of India which was started in 2015 at Indian Pharmacopoeia commission. He also talked about the objectives of Materiovigilance program as well as explained about the process of reporting and working of the Materiovigilance program 2015.

LITERATURE REVIEW

- Bansal A, Shukla V.K, Chauhan S, Yamini Kanti SP, Kumar S, katrolia A. in their research article Drug regulatory paradigm and challenges for Medical devices in India published in International Journal of Drug Regulatory Affairs 7(1):25-33 on 15 Mar 2019. Available from: http://ijdra.com/index.php/journal/article/view/299 stated in their research article about the current scenario of regulatory framework of India where the classification and the current issues which Indian medical devices industry is facing including the issues related to price capping and approvals of medical devices.
- 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. Available from: http://www.cdsco.nic.in/writereaddata/Classificationwiselistof MD and IVDs17.pdf mentioned about the current medical device rules and regulations along with the documents and approval process of medical devices in India.

STUDY RATIONALE

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

- American Medical Device companies had a huge role to play in the termination of GSP benefits of India, this research was carried out to know the perception of these medical device companies on current regulatory tensions so this project could help the regulatory authorities to understand the perception as well as takes the voice of medical device industry to the authorities

RESEARCH QUESTIONS AND OBJECTIVES

❑ **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 Regulatory 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

DESIGN SAMPLING AND METHODS

- **STUDY DESIGN:** Observational Descriptive study design
- **SETTING:** It would be a primary research which would focus on gathering information from existing reports, legal documents, regulatory documents and guidelines and surveys and FGD's
- **STUDY POPULATION:** Doctors and Industry Experts
- **DURATION OF STUDY:** 6th February 2019 to 6th May 2019
- **SAMPLE SIZE:** 100 Doctors and 13 Industry Regulatory Experts
- **SAMPLING TECHNIQUE:** Non Probability Convenience Sampling
- **DATA COLLECTION PROCEDURE:** Data from doctors was collected by the Questionnaires and data from Industry Regulatory Experts was collected with the help of a Focused Group Discussion
- **STUDY AREA:** Gurgaon, Haryana

COMPANY PARTICIPANT

- ❑ AMCHAM, India (American Chamber for Commerce in India)
- ❑ Medtronic(2)
- ❑ Abbott Laboratories(2)
- ❑ Philips
- ❑ Edwards Life Sciences
- ❑ Stryker India (2)
- ❑ Boston Scientific
- ❑ GE Healthcare
- ❑ Baxter India Private Limited
- ❑ Bio-Rad Laboratories

ADOPTION OF MEDICAL DEVICE RULES IN 2017

- 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.
- 22 medical devices had been notified by the MoHFW and were 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 separated 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
- Going forward ideally the government should pursue a full separation of medical devices and drugs with each having distinct and separate regulations.

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

HIGHLIGHTS

PREVIOUS SCENARIO

MARKET OVERVIEW

- No rules and regulations for devices, regulated as drug under drug and cosmetics act1940 and rules 1945.

REGULATORY

- Device classified under notified medical device into 15 categories.
- No online e procedure

REGISTRATION

- No audit for manufacturing facility
- Quality documents are not up to standard.
- Form 40-application form
- Form 41- registration certificate issued

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.

HIGHLIGHTS

RECENT SCENARIO POST 2017

MARKET OVERVIEW

- 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

- 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

- Audit required for manufacturing facility
- Quality documents required to meet the new rules
- Approval and registration certificate is valid for five years.

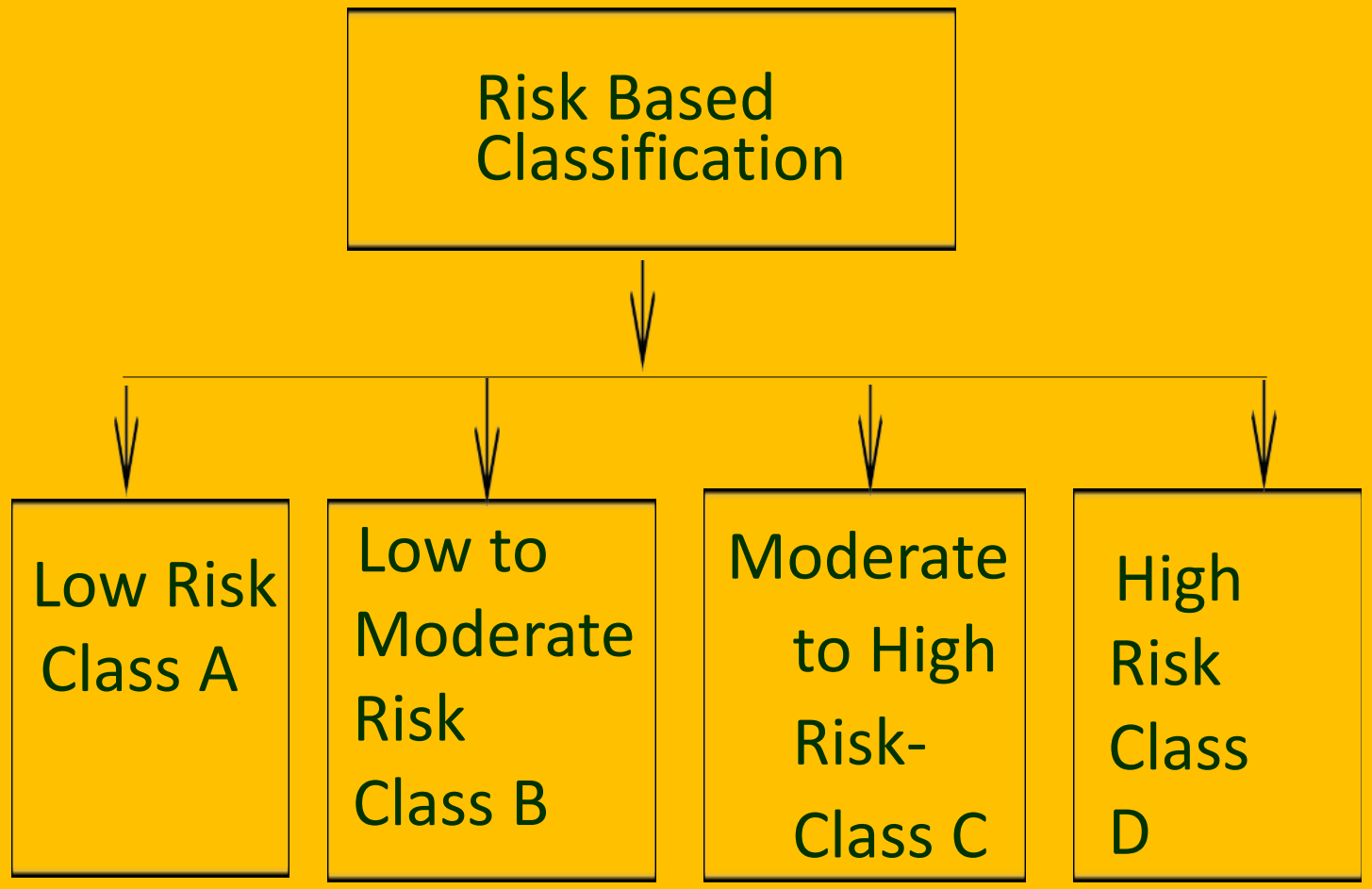
Bansal A, Shukla V.K, Chauhan S, Yamini Kanti SP, Kumar S, katrolia A. Drug regulatory paradigm and challenges for Medical devices in India. International Journal of Drug Regulatory Affairs [Internet]. 15 Mar 2019; 7(1):25-33.

HIGHLIGHTS FROM MEDICAL DEVICE RULES 2017

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

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]. Availablefrom- http://www.cdsco.nic.in/writereaddata/Classificationwiselistof MD and IVDs17.pdf

HIGHLIGHTS MEDICAL DEVICE CLASSIFICAT-ION RULES



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.

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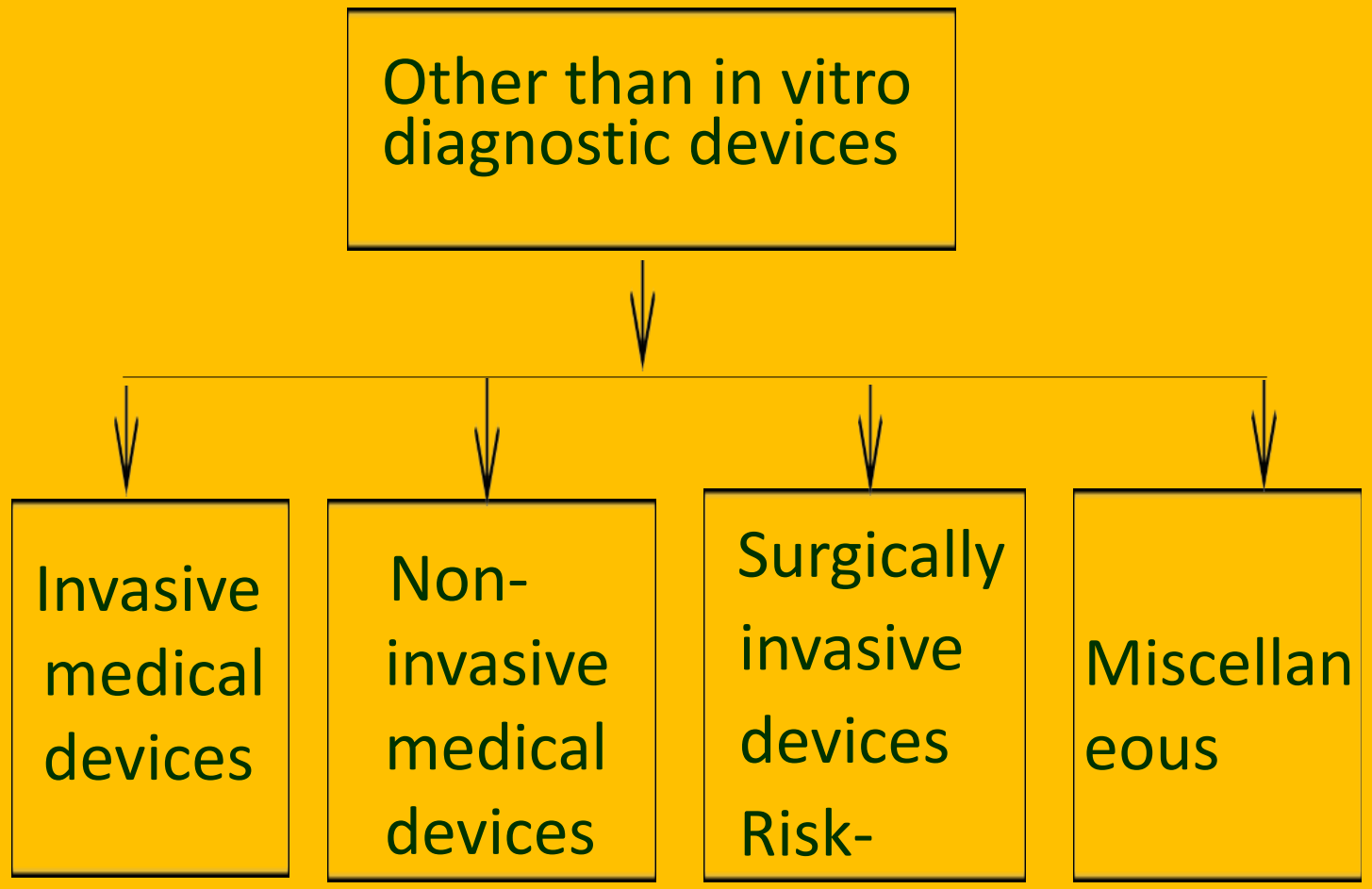

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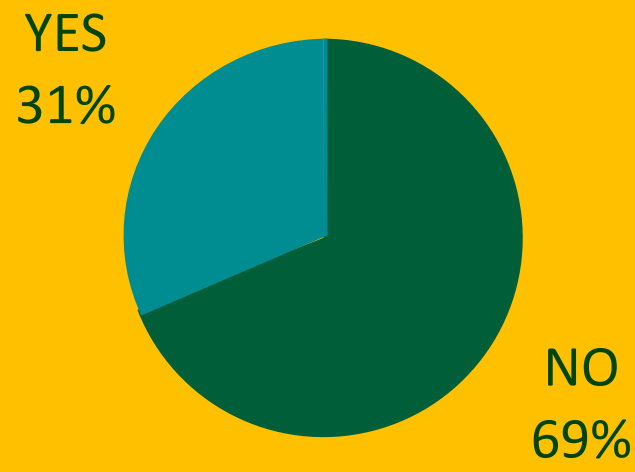
RESULT AND DISCUSSION

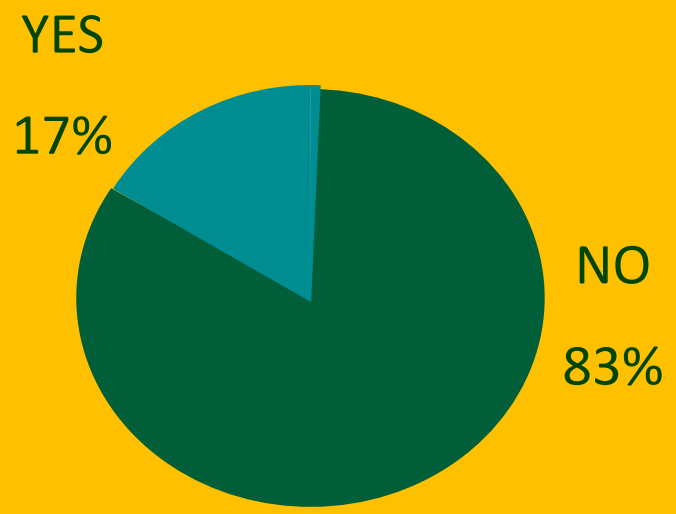
DOCTOR'S SURVEY

- 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.

- 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.

Difference between Medical Devices and Pharmaceuticals





Classification of Medical Devices

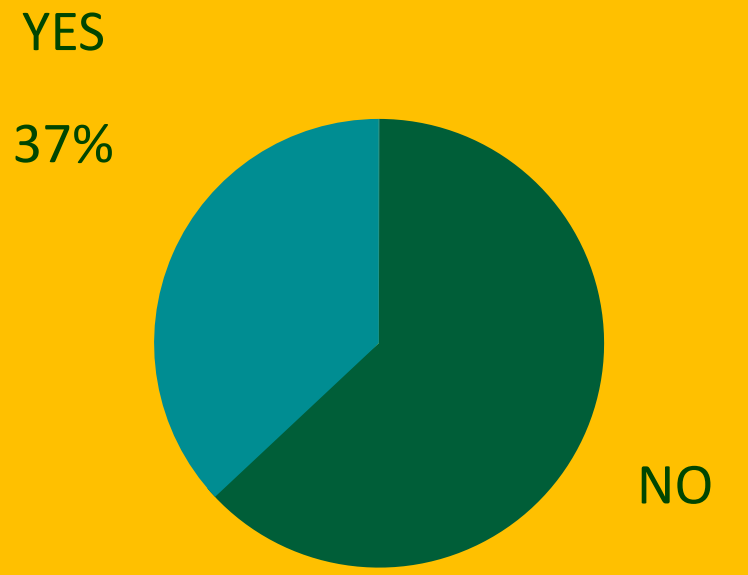
RESULT AND DISCUSSION

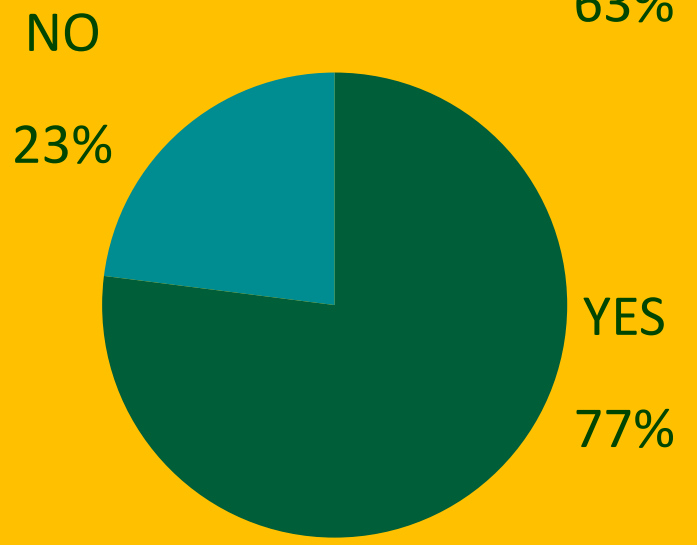
DOCTOR'S SURVEY

- As the data shows majority of the doctors feel that Indian policies do not favor 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.

- Majority of the doctors felt that Indian healthcare policies have stringent regulations while 23% of the doctors do not feel Indian healthcare polices are stringent.

Encouragement of Innovative Healthcare Environment



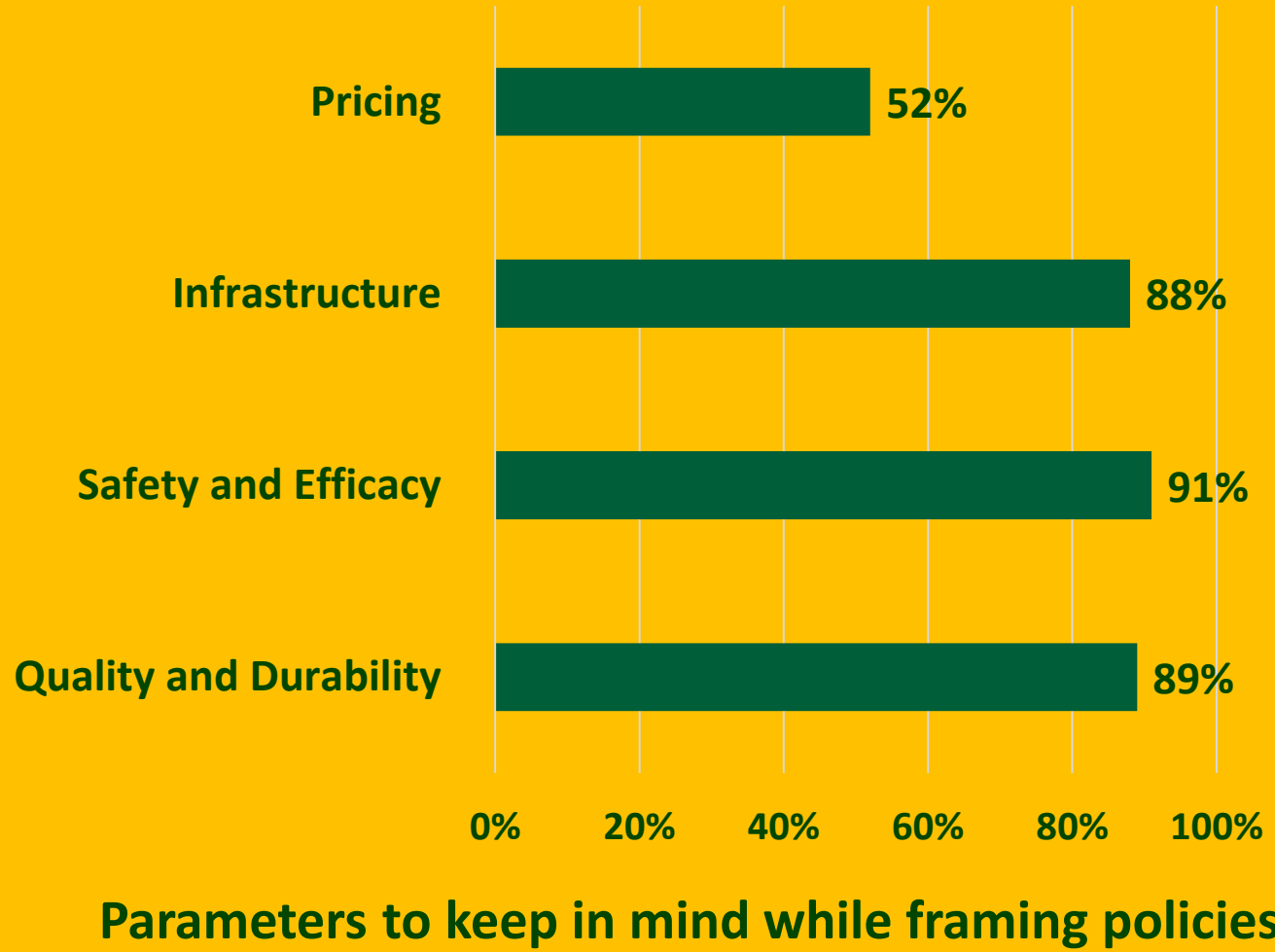


Stringency of Indian Regulations

RESULT AND DISCUSSION

DOCTOR'S SURVEY

- 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.



Parameters to keep in mind while framing policies

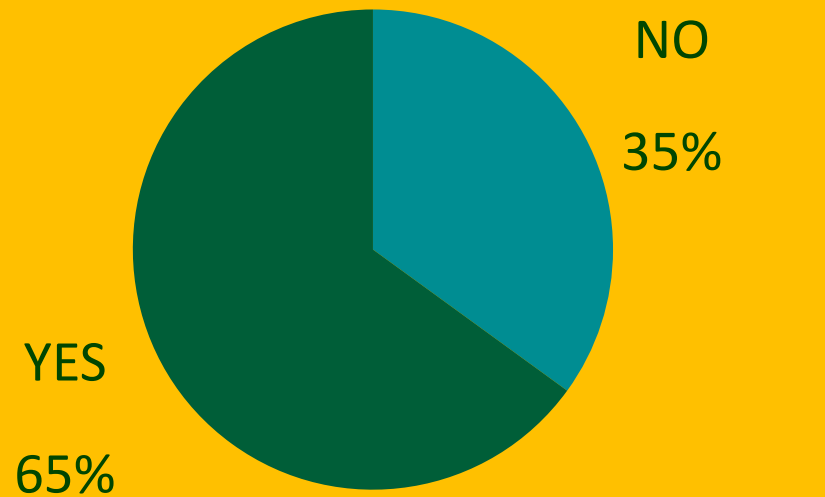
RESULT AND DISCUSSION

DOCTOR'S SURVEY

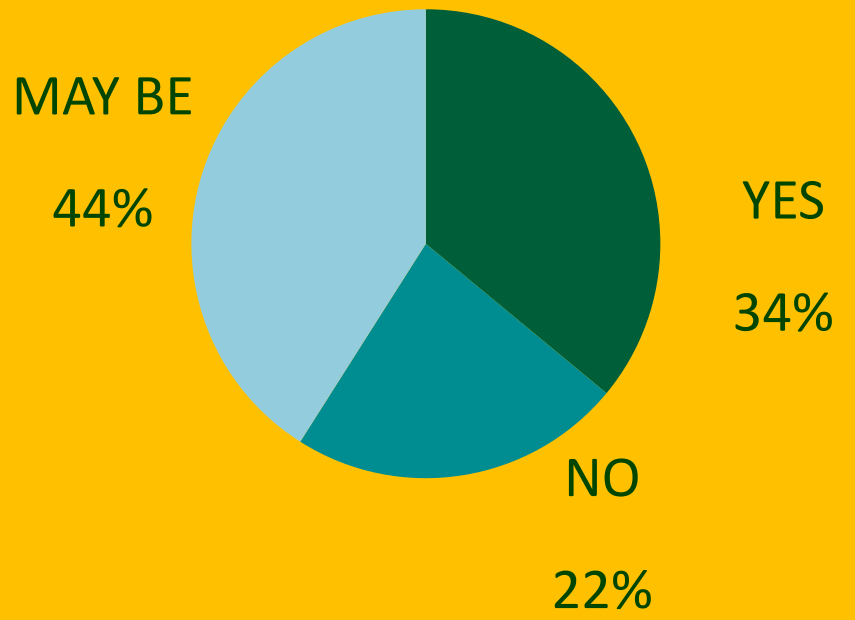
- 65% of doctors had responded that they do not agree with government’s approach of price capping while 35% doctors agreed with the governments approach of price capping.

- Majority of the doctor’s thought that right now domestic industry is increasing it’s focus on innovation and within 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.

Government's approach towards price-capping



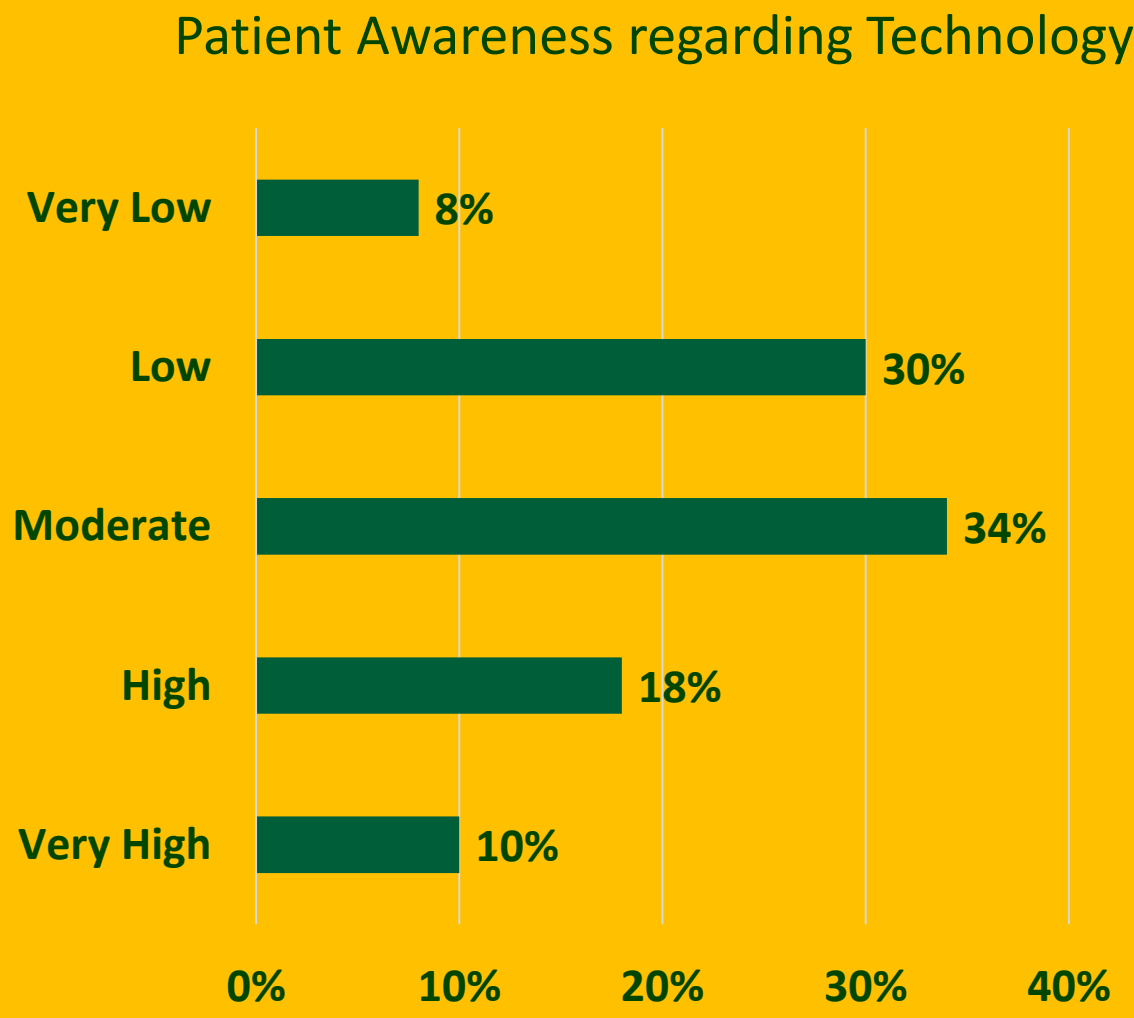
Ability of Domestic Industry



RESULT AND DISCUSSION

DOCTOR'S SURVEY

- Majority 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.



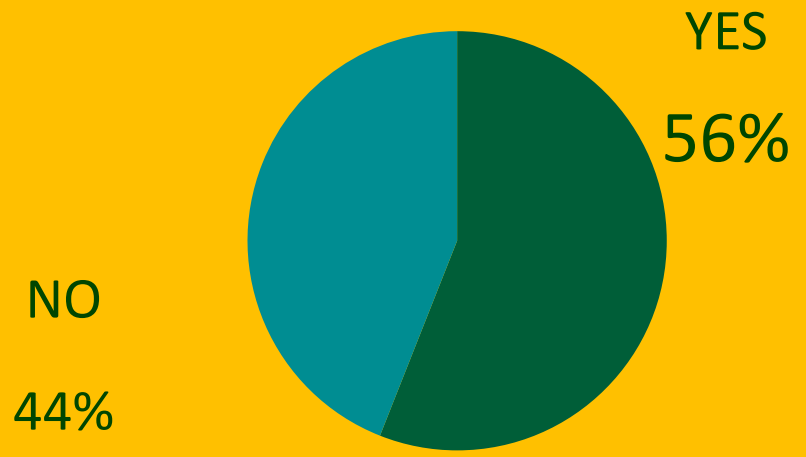
RESULT AND DISCUSSION

DOCTOR'S SURVEY

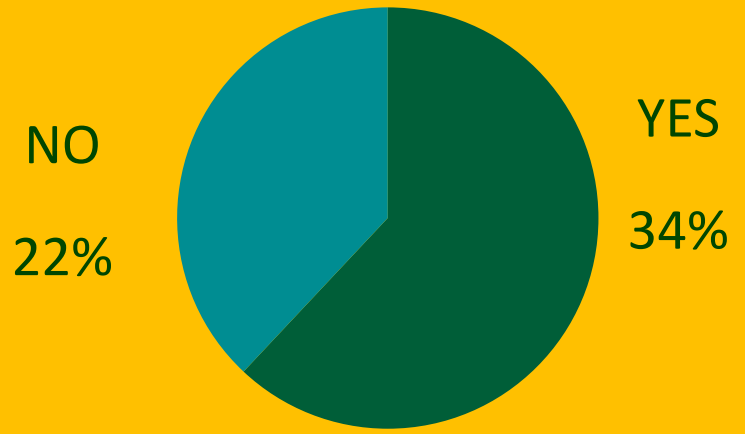
- Majority of doctors felt that price regulation does impact on patient out come and footfall while the opinion of all the doctors was quite mixed and quite close. Because doctors were confused between several factors like health insurance, awareness and price control

- 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 denied the statement. A well known example of medical education by medical device companies is Boston Scientific

Impact of price regulation on patient outcome



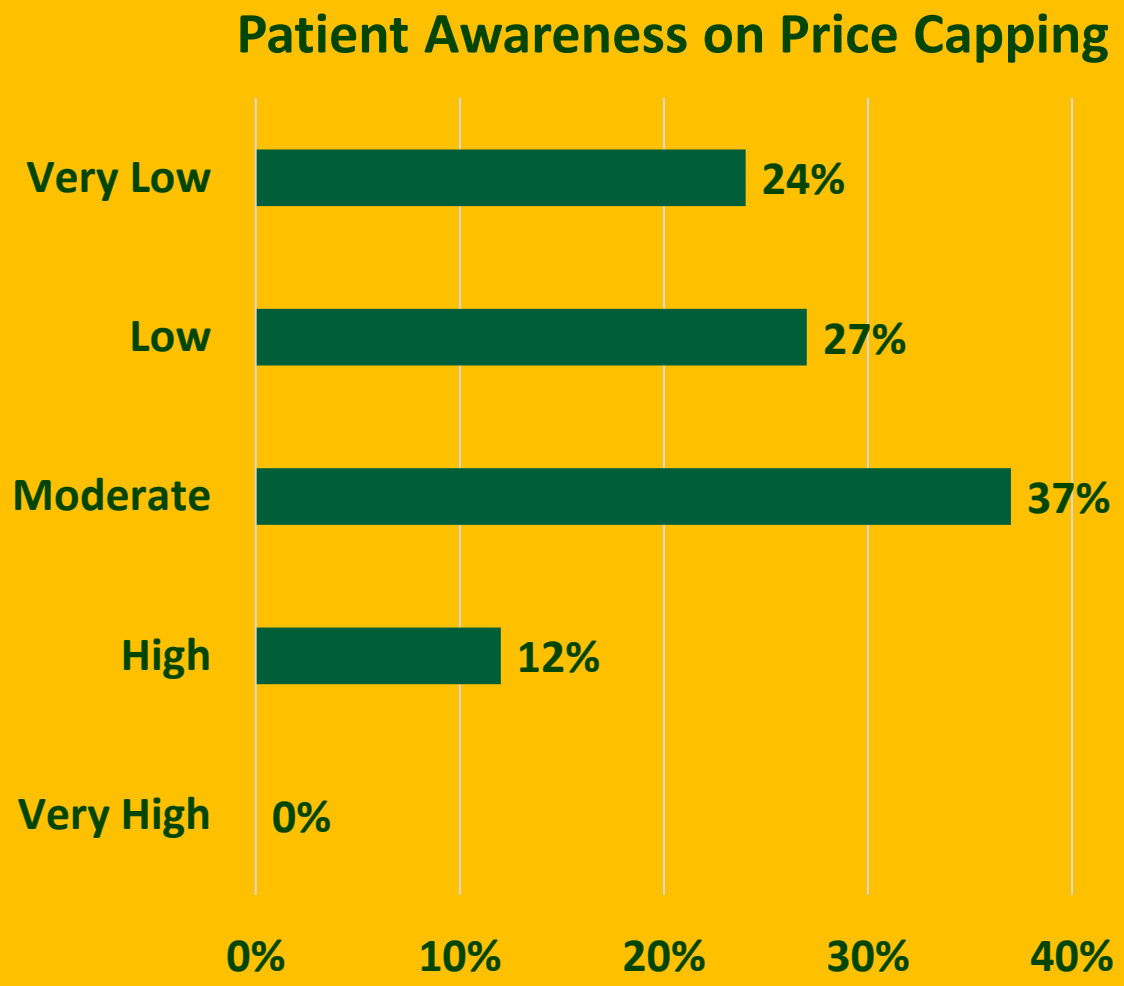
Education through CME by Medical Device companies



RESULT AND DISCUSSION

DOCTOR'S SURVEY

- 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



HIGHLIGHTS FROM FOCUSED GROUP DISCUSSION

- 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.

- All the experts believed that the regulatory authority should pay keen focus on the functioning, safety and quality assurance part of medical devices while framing the policy rather then focusing on quality control.

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

HIGHLIGHTS FROM FOCUSED GROUP DISCUSSION

- 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.

- When discussing on the Price Capping the regulatory experts expressed their unhappiness 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 Rationalization** approach for medical device rather then price capping.

- 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.

CONCLUSION

- From conducting surveys of doctors and FGD's industry specialists and referring to several literatures it was observed that:

- 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 is tailored made for itself.
- And the regulatory process for approval and testing of Medical Devices should defer from drugs as medical devices are majorly 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.

CONCLUSION

- 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, also level of awareness of patients on medical devices as whole isn’t satisfactory
- Several doctors also had emphasized on the importance of medical device industry in the healthcare domain and in well-being of the patients. They emphasized on how medical devices introduces new treatment frontiers and provides training and hands on to new technology
- 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

SUGGESTIONS AND RECOMMENDATIONS

- Differentiate between Pharmaceuticals and Medical Devices
- 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.
- Differentiate and define the testing procedures for medical devices
- 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
- Have only one regulatory body for Medical Devices instead of multiples
- Use TMR for affordability and not price capping

THANK YOU