An Analysis of Regulatory Environment of Medical Devices in India

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Overview

- This research study was chosen to perform to see the current rules and regulations in Medical Device sector in India.
- Both Primary and secondary data are being used in this research.
- A survey was conducted on 20 Doctors and 30 Industry Experts from Delhi and Sirsa.
- The main Objective of this research was to find the gap in current rules and regulations of medical device (if any).

Abstract

- A questionnaire and focus group discussion was used which addressed a variety of factors including current environment, patient awareness and industry scenario.
- It was noted that current framework is not encouraging the innovation.
- The patient awareness on several topics was not adequate.
- Almost all the experts had the same concern about the distinct identity of medical device and separation of medical device from Drug and Cosmetic Act.

INTRODUCTION

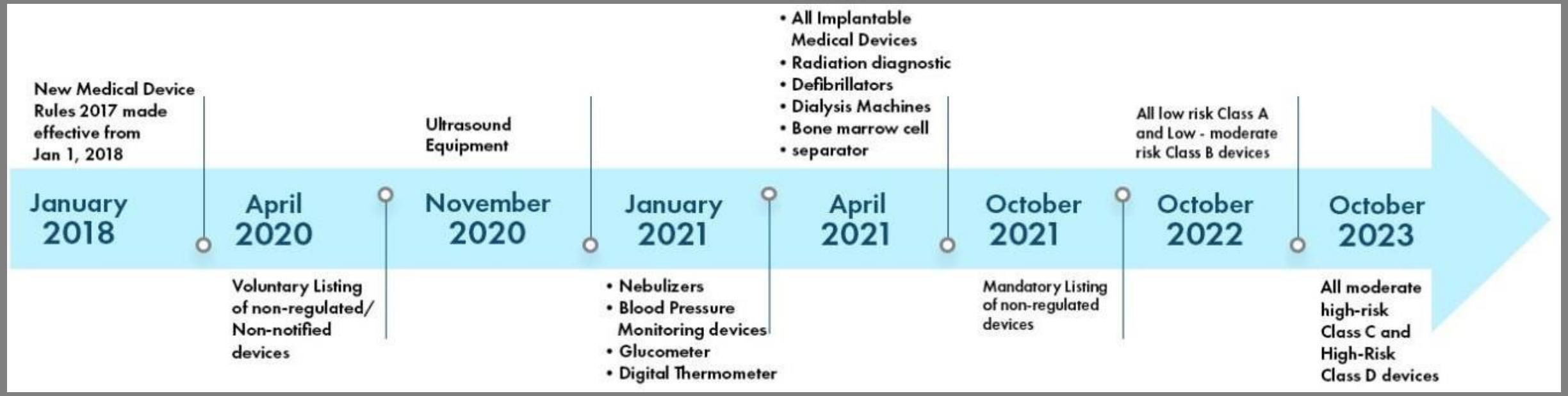
MEDICAL DEVICE:-

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.

CLASSIFICATION OF MEDICAL DEVICE

Class	Example
1. Class A	Thermometers/tongue depressors
2. Class B	Hypodermic needles/suction equipment
3. Class C	Lung ventilator/bone fixation plate
4. Class D	Heart valves/ implantable defibrillator

List of notified medical device

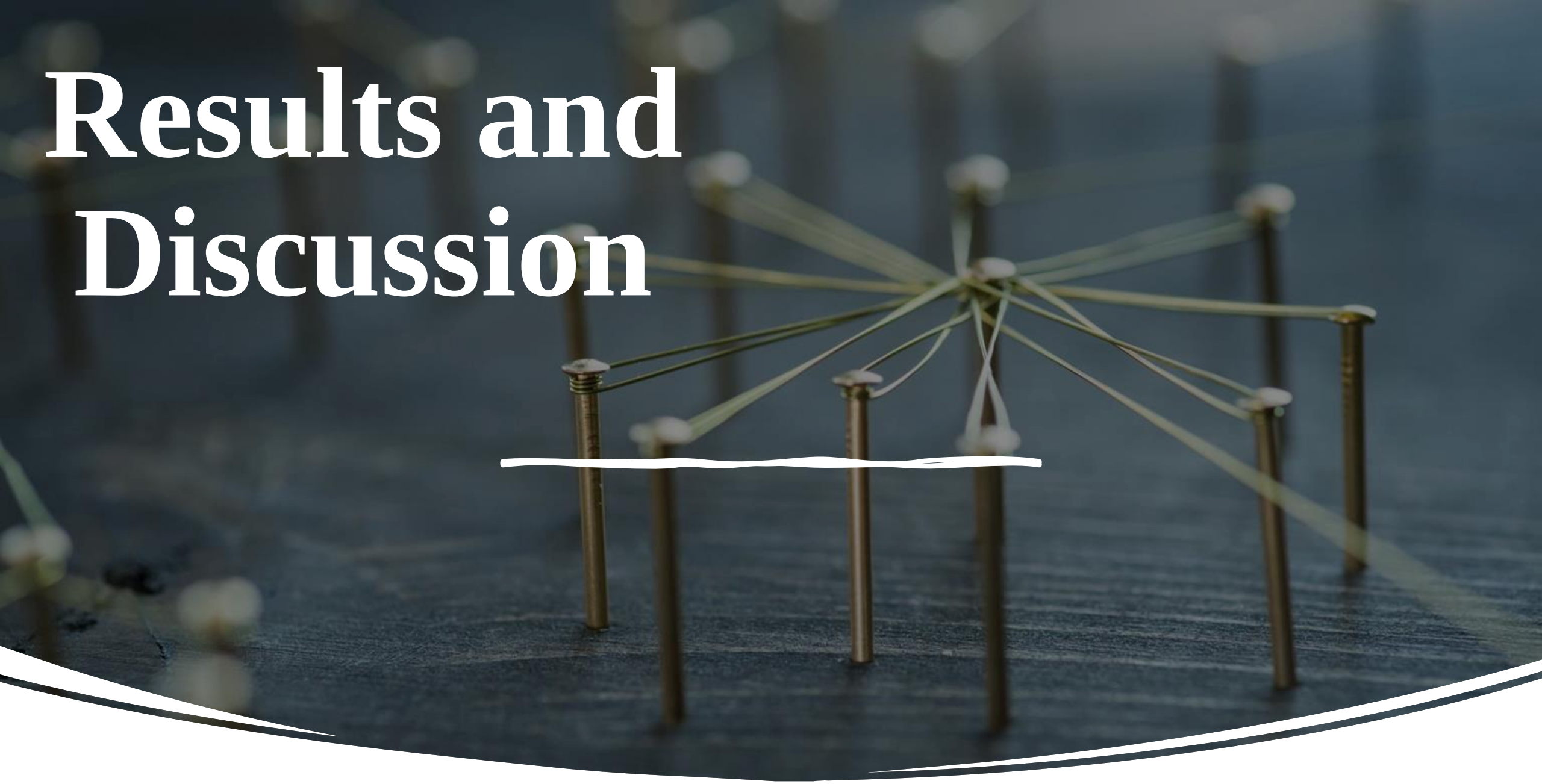


Research Methodology

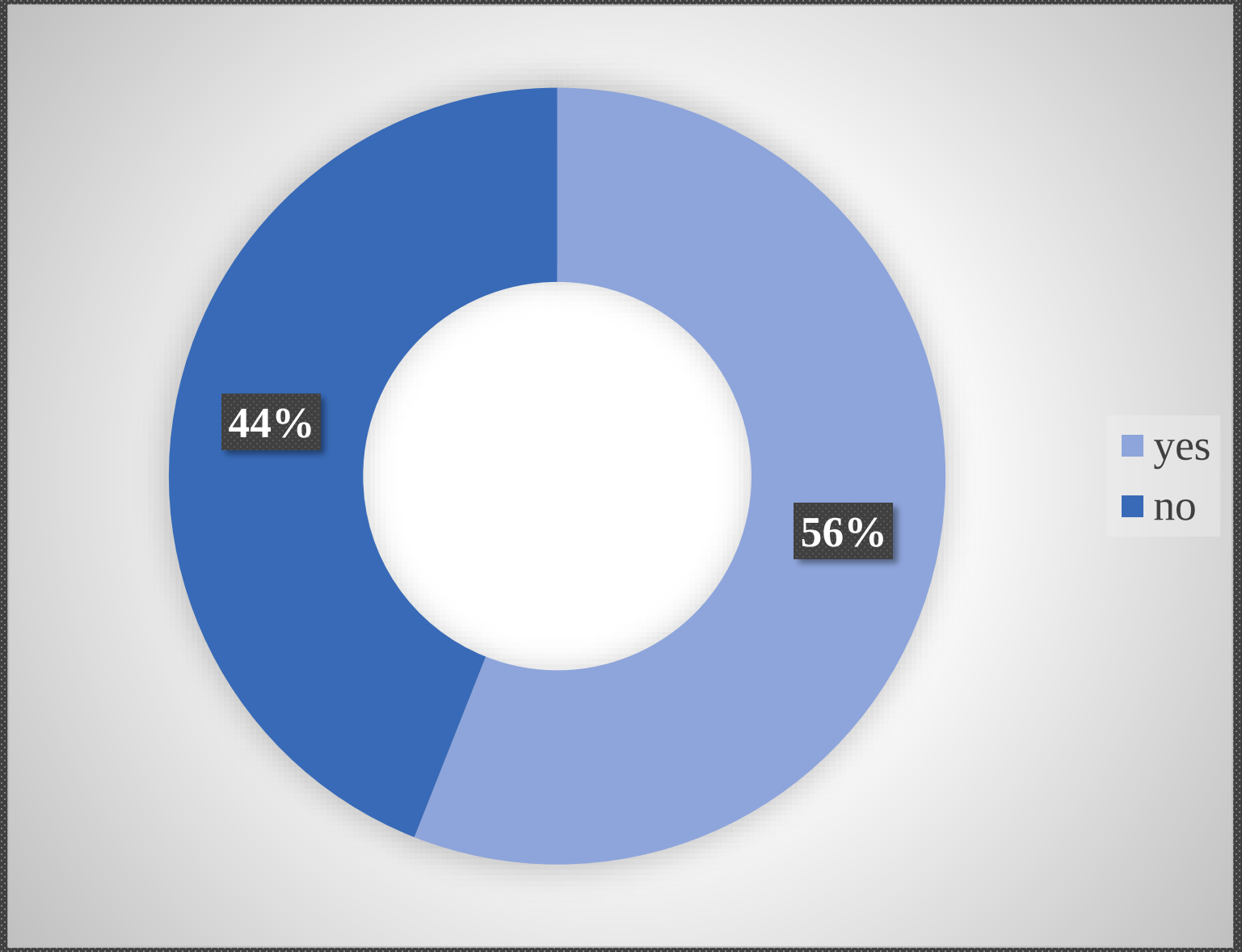
Material and Methods:

- **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

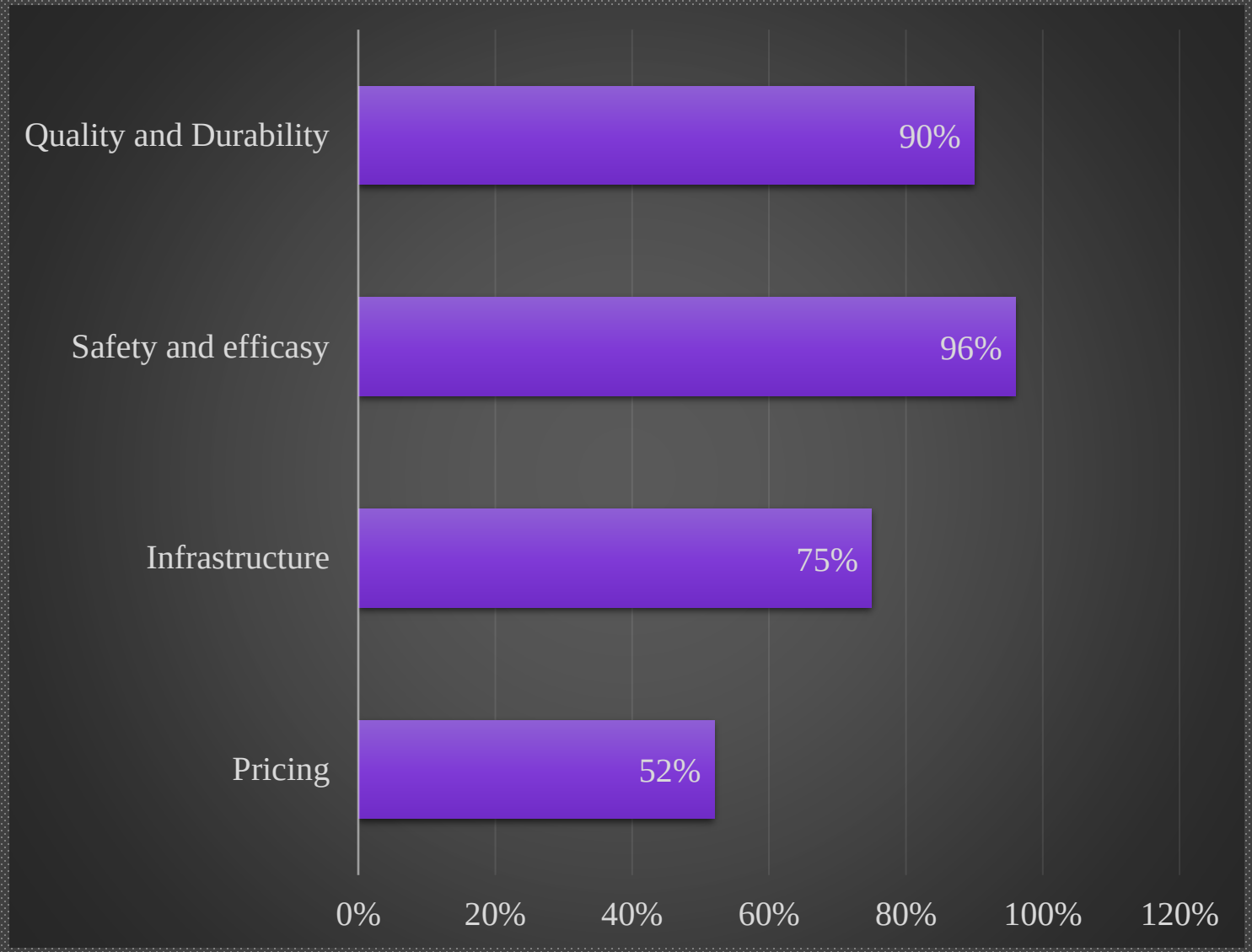
Results and Discussion



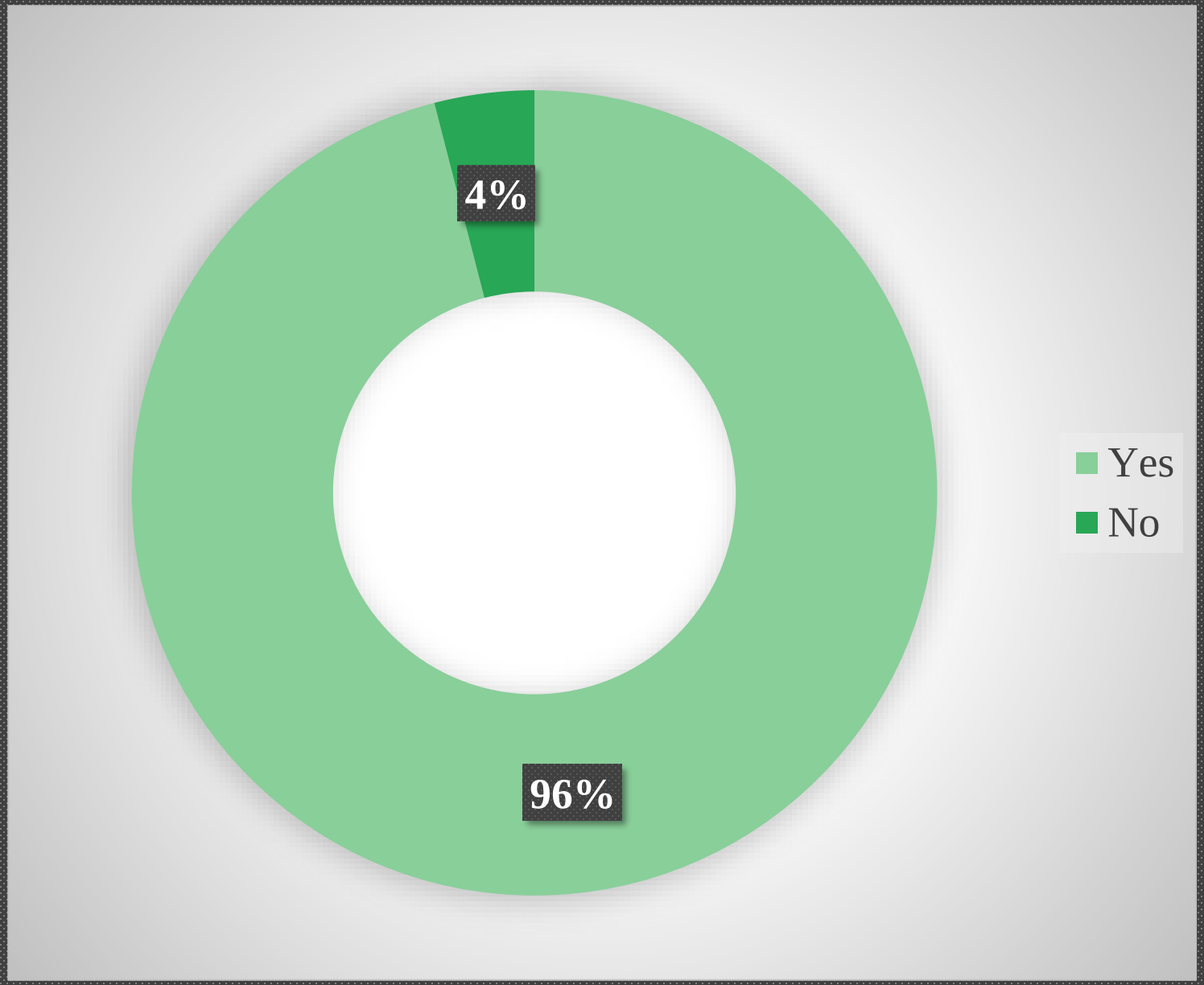
Is the distinction between medicines and medical devices clear in the regulatory framework?



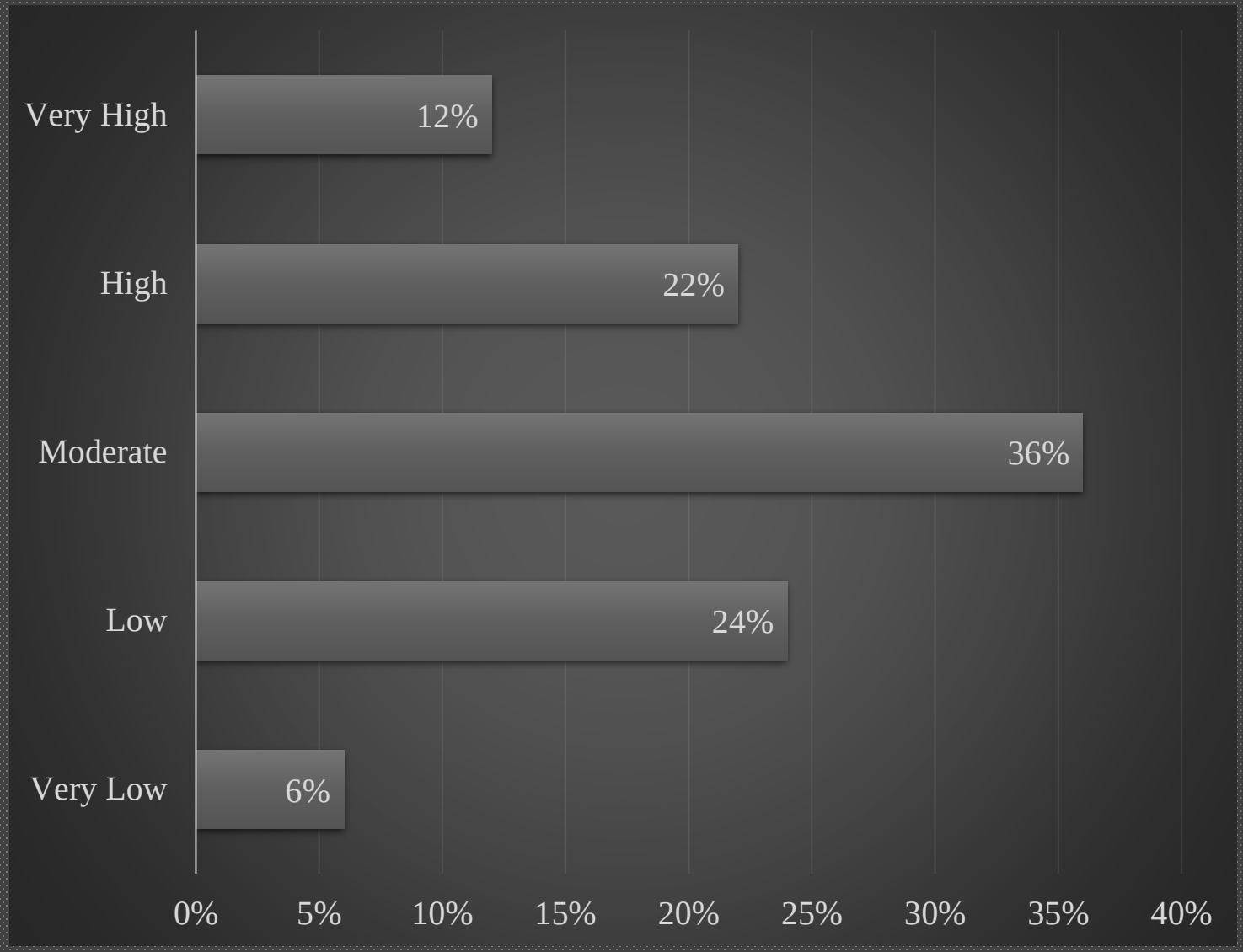
What factors should be considered by the regulatory agencies when drafting the new medical device legislation or policy?



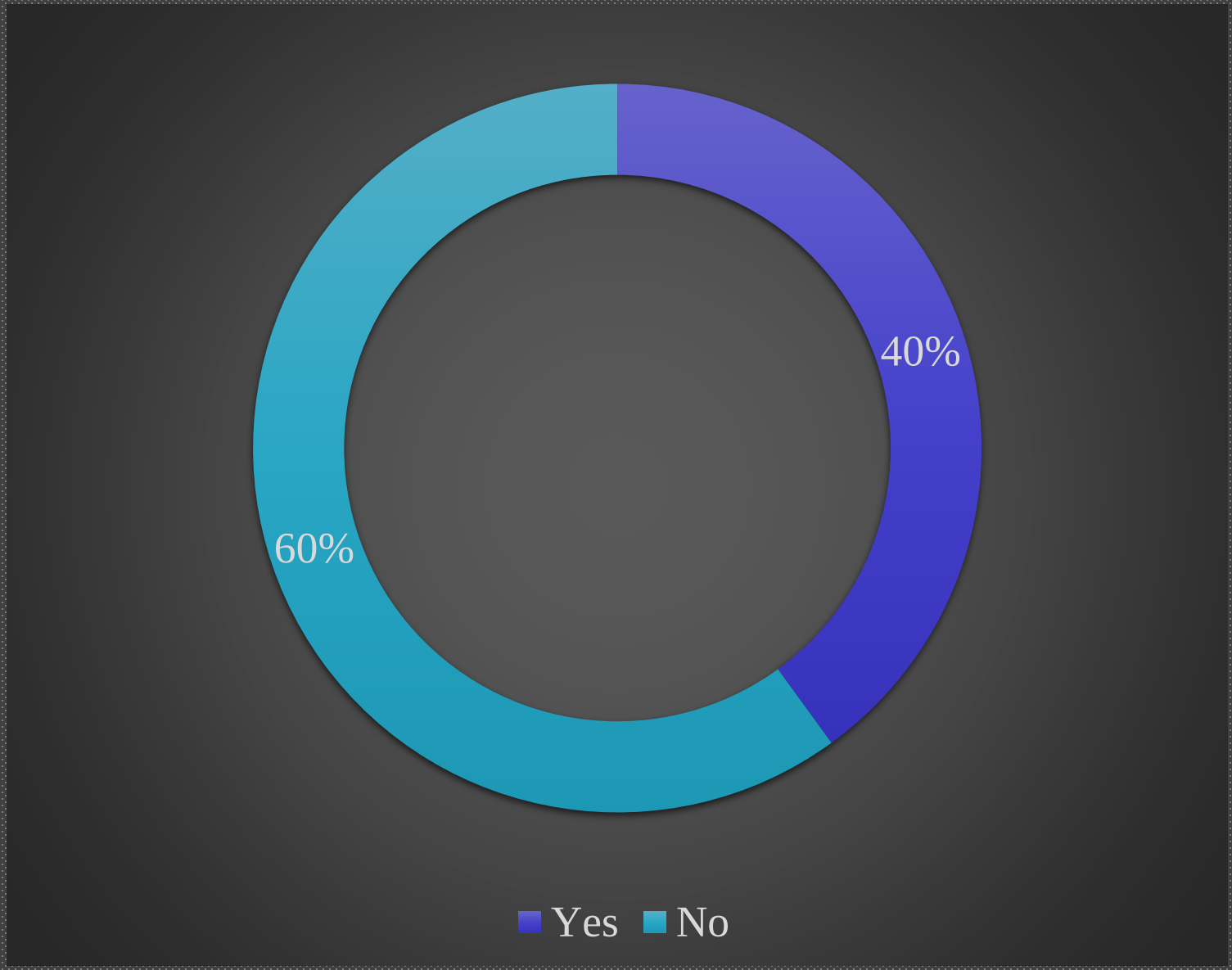
Is the Indian regulatory framework's classification of medical devices well defined?



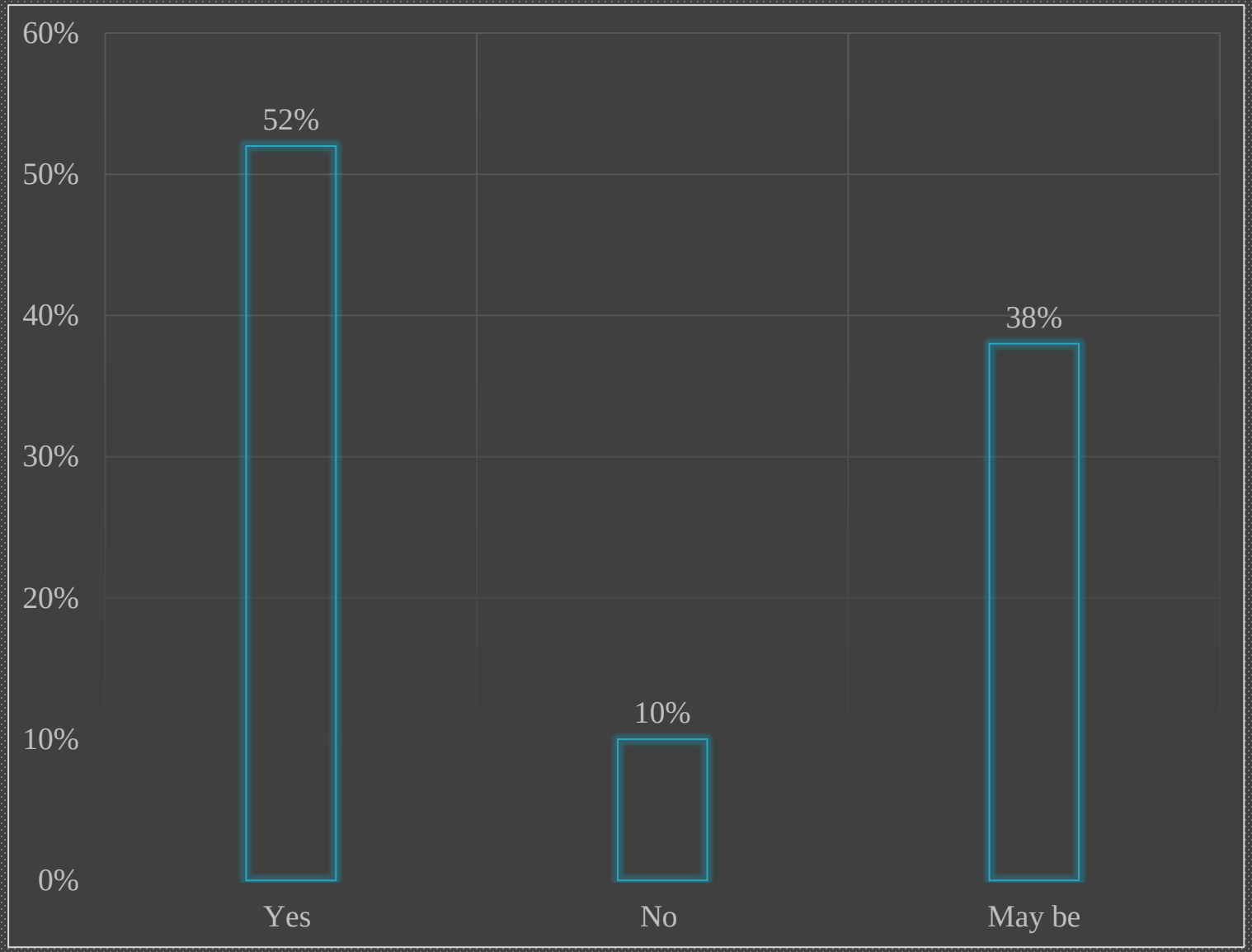
To what extent are patients aware of the benefits of technology?



Do our policies support a healthcare environment that is innovative?



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



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.
- 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.
- The significance of the medical device sector to healthcare and patient welfare was emphasized by several medical specialists.
- It was also said that the industry is not pleased with how medical devices are currently governed.

Recommendations and Suggestions

- The medical device sector needs a specific legislation that will help to regulate the medical device industry accurately and precisely.
- Describe the medical and paramedical staff’s training. (The government must update the medical course curriculum).
- 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 is behind from other industrialized nations in healthcare spending.

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.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