



A STUDY ON NEW MEDICAL DEVICE POLICY AT SMT

Presented By: **Shubham Soni**, Roll No. 0443

Under the guidance of **Dr. Ashok Peepliwal** (University Mentor) &
Dr. Rajiv Chhibber (Industry Mentor)



ABOUT SAHAJANAND MEDICAL TECHNOLOGIES (SMT)

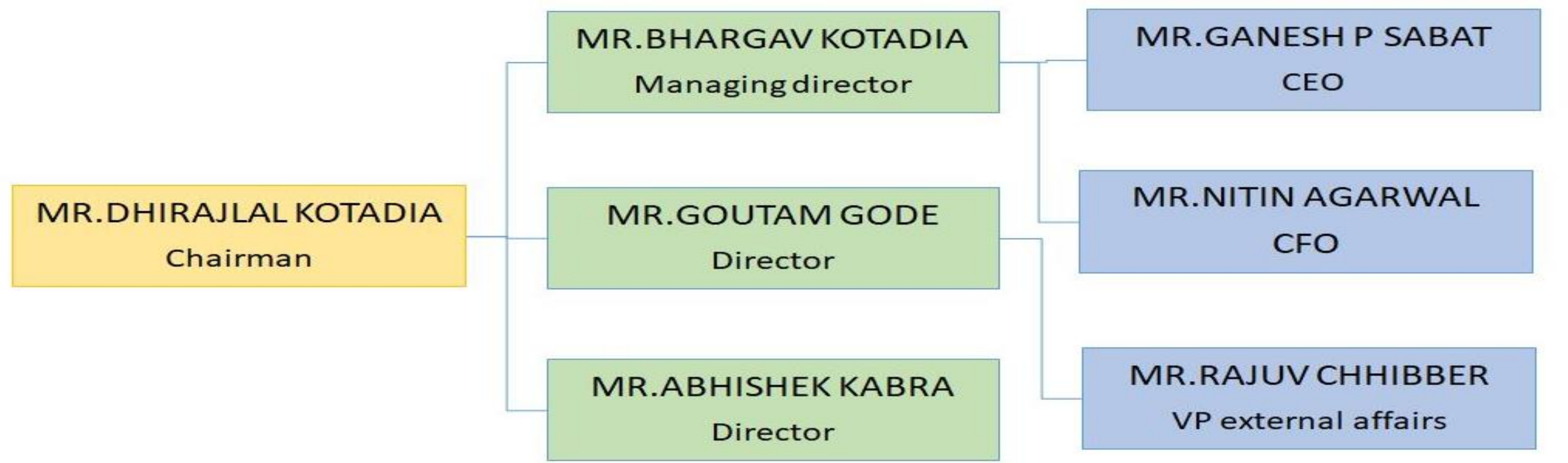
SMT is a global medical device company committed to make advanced medical technologies accessible to everyone around the world. With presence in 69 countries, SMT has achieved recognitions from the Ministry of Health Sciences & Technologies for its tremendous contributions in the field of Coronary healthcare. SMT also pioneered the introduction of biodegradable polymer in the cardiovascular segment. SMT will continue the journey to heal hearts around the world by creating healthcare future promising for everyone.

VISION & MISSION

Vision: A world where life-saving healthcare technologies & products are accessible to all.

Mission: We are “Pledged to Save Millions” by making critical healthcare affordable for millions of people around the world.

ORGANIZATION STRUCTURE



PRACTICAL VS THEORETICAL EXPOSURE

- Theoretical understanding is important for understanding the regulatory landscape and the various laws and regulations that govern the development, testing, and marketing of medical devices. Practical understanding, on the other hand, is critical for implementing those laws and regulations in a way that ensures compliance and the development of safe and effective products.
- This practical understanding of how these laws and regulations are implemented in the real world. This includes understanding the processes and procedures used to review and approve medical devices, as well as the challenges and obstacles that can arise during the development and regulatory review process.
- As an intern in the regulatory department of a medical device organization, it is important to have a strong theoretical understanding of the regulatory landscape and the various laws and regulations that apply to medical devices. This helped me to understand the requirements for product development, testing, and marketing, as well as the role that regulatory affairs professionals play in ensuring compliance with these requirements.

SWOT Analysis (of organization)

STRENGTH

- SMT is a key player coronary stent market in Asia
- Strong distribution network and partnerships with leading healthcare providers.
- SMT has collaborations with leading research institutions to develop innovative medical technologies.

WEAKNESS

- SMT faces stiff competition from established players in the medical devices market.
- The company may face challenges in maintaining its market share due to increasing regulations and pricing pressures.

SWOT ANALYSIS

OPPORTUNITY

- Global market growth in the coronary stent market.
- Expansion into the Electrophysiology (EP) Ablation Catheters market..

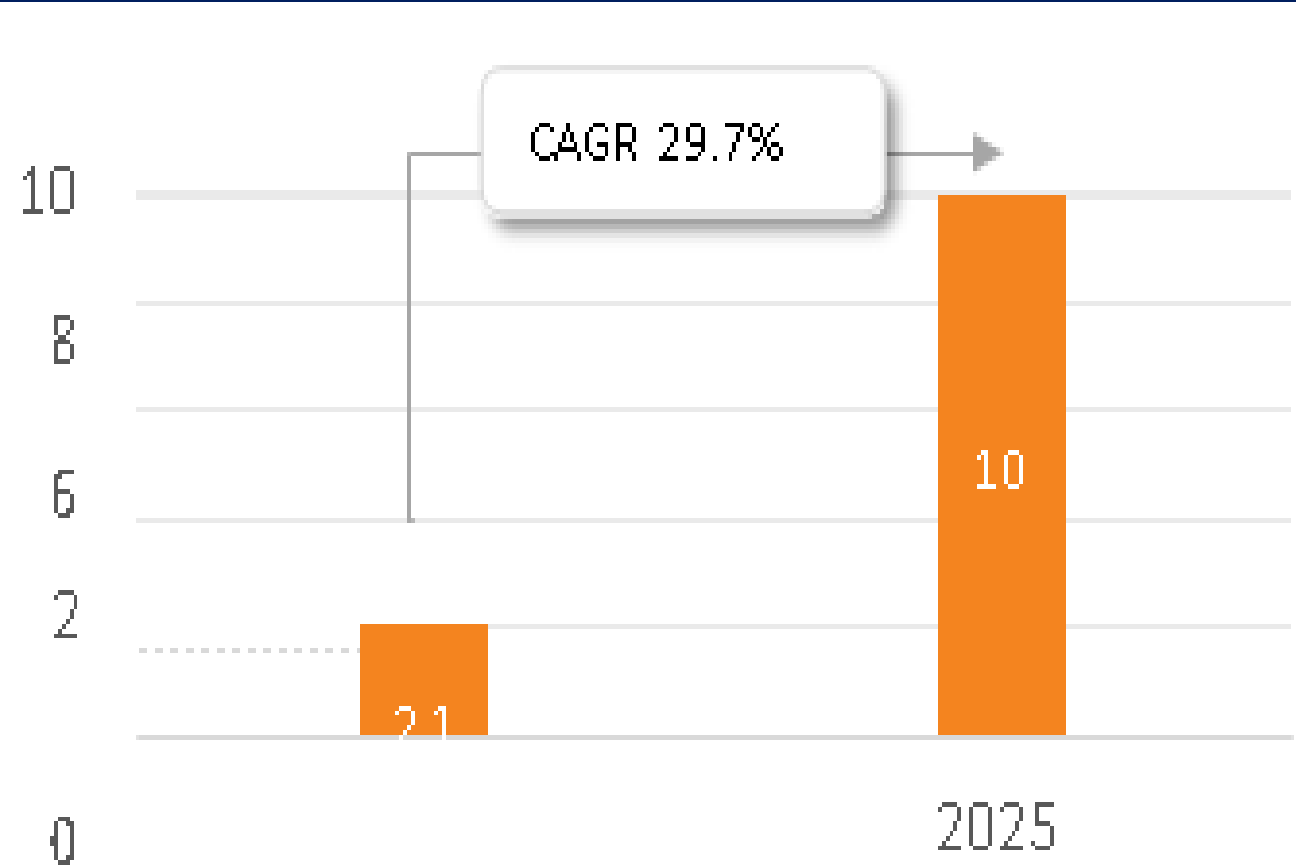
THREATS

- Competition from other market players.
- Regulatory hurdles in some markets.

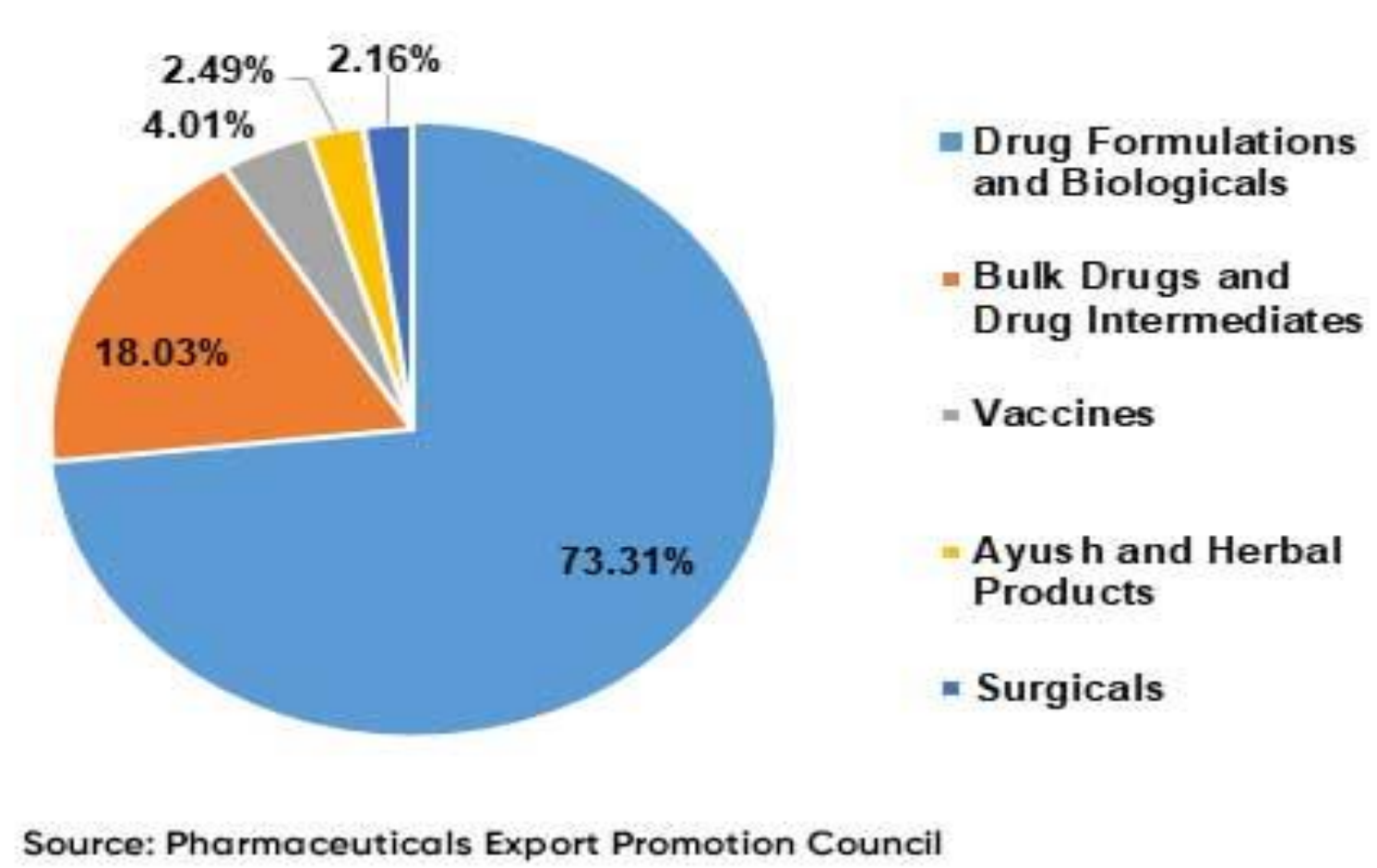
WORKING AT SMT

- Detailed go through study of SMT background and products.
- Read about Trade margin rationalization on medical devices.
- Completed report on new medical device policy.
- Attended virtual meetings on the strategies on a new policy which will reduce import of medical devices and critical components in India.
- Made a report on critical components of medical device which are imported and not manufactured in india and alternate medical device india can offer.
- Attended angioplasty operation in GIPMER hospital in cath lab.
- Register our organization in UNDRR Arise India.
- Attended two days international conference on pharma and medical device sector.
- Made a report on R&D financing policy wrt to the medtech industry under new medical device policy 2023.
- Made a report on public procurement orders of medical device under make in india.

Medical Devices Export Market in India (2019-25, in US\$ billion)



India's category wise export share (2021-22)



CHALLENGES FACED DURING INTERNSHIP

- Regulatory department of a medical device organization, I faced several challenges. One of the main challenges is keeping up with the constantly evolving regulations and guidelines set by drug and medical device regulatory authorities.
- Another challenge is ensuring compliance with these regulations while also meeting the organization's business objectives.
- SMT was facing new compliance challenges related to recent changes in medical device regulations, which can impact the bottom line.

LEARNINGS & USEFULNESS OF INTERNSHIP

- Learned about New Medical Device Policy 2023.
- Learned about TMR on medical devices.
- Learned about R&D policies and schemes that help the medical device industry.
- Learned about all the challenges and opportunities in public procurement order (PPO) of medical devices.
- Learned about the export promotion council (EPC-MD) under medical device policy 2023.
- Learned about how cardiac stents are placed in the heart in cath lab setting.

SUGGESTION

- Website rectification suggestion for correcting medical terminology.
- Should work actively on TRL as per GOI guidelines.
- Cross departmental communication barriers and did not close crucial information to the interns.
- Facilitate a hybrid mode of working by making the workspace more employee-friendly.

