



**CHALLENGES AND ISSUES TO
REGULATE AN INNOVATIVE
MEDICAL DEVICES: BARRIERS
AND ENABLERS TO
DEVELOPMENT**

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Medical Device Market-India

Fastest growing market

- Around 6 US billion \$

Growth Rate

- 15%

Market Segments –

1. Equipment: 50-55%

2. Medical disposables: 25-30%

3. Implants: 20-25%

Medical device industry contd...

Medical Technologies/Devices:

1. Medical Equipments/Instruments

Eg. CT Scan, MRI, X-Ray machines etc

2. Medical Implants

Eg. Cardiac Stents, IOL, Orthopedic Implants

3. Medical Disposables

Eg. Syringes, Needles, Catheters

4. Medical Furniture

Eg. Hospital Beds, Wheel Chair etc.

Products – Mostly depend on imports

- **Cardiovascular & Diabetes**

Pacemakers, Defibrillators, Drug-eluting stents, Catheters, Valves

- **Orthopaedics:** Joint replacement

- **Ophthalmology:** Intra ocular lens (IOL), Viscoelastics

- **Oncology:** Newer range of genetic diagnostic kits

- **Neurology**

Treatment of stroke. Coiling of aneurysms; angioplasty and stenting of carotid

- **Diagnostics and Imaging**

Radiology, Ultrasound, CT, MRI, X-ray etc.

Challenges and issues- Innovative MD

- Lack of regulatory knowledge to the R&D Institutions
- Inadequate regulatory support to Innovators
- No Standards for such devices
- Approval of Clinical Investigation protocol
- Inadequate in-house expertise in the agency
- Potential risk and benefit analysis (with limited data)
- Monitoring of Adverse Events
- How to use the new device (Training)
- Pressure on the regulator

Market Entry Barriers

- Lack of complete Eco system
- Inadequate Regulatory system
- Lack of training facilities
- Price control
- Lack of social security system
- High interest rates
- No integration of institutions
- No financial incentives
- Non availability of trained staff
- Service and Maintenance?

Steps Taken

- Make in India
- MD specific regulations
- FDI policy
- Medical devices Parks
- Custom duty exemptions
- Establishment of MD testing centres
- Incentives for R & D
- Regulator support for innovation
- NIPER – Ahmedabad, Centre for Excellency
- Draft Medical Devices Policy

Thank you

