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## Medical Devices In India

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### Introduction

- ❑ Medical device industry- a unique blend of engineering and medicine.
  - Involves creation of machines that are used to support life within the human body.
- ❑ Medical devices include **Surgical, Diagnostic and Life Support equipments; Implants; and Disposables.**

### Medical Devices Sector in India

- ❑ India is one of the top twenty markets for medical devices in the world
  - 4<sup>th</sup> largest market in Asia after Japan, China and South Korea
- ❑ 80-90% of medical devices imported by India, the vast majority are unregulated for quality and safety
- ❑ Growing population, ageing, income base and associated disposable income, changing disease prevalence, etc. provide potential for high growth of the medical device industry in India

### Issues Regarding Medical Devices Sector in India

- ❑ **Underdevelopment**
- ❑ **Regulatory Loopholes/deficit:** lack of harmonized standards, accreditation, legal requirements, proper guidance on quality and best practices
- ❑ No legal provisions in India to compensate patients facing health problems due to implants or use of faulty medical devices
- ❑ Less investment due to predictable, incomplete and incorrect regulatory environment
- ❑ Regulated under the **Drugs and Cosmetics Act**

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1940 that puts drugs and medical devices under the same basket, which brings several regulatory challenges

### Major Recommendations of the Task Force on the Medical Devices Sector (2015)

- ❑ Formulate “Medical Device Regulatory Act” as a separate law
- ❑ Set up an independent body with a permanent office and support staff to promote and facilitate the medical device industry
- ❑ Preferential treatment in government procurement
- ❑ Separate price control order for medical devices
- ❑ Setting up of Medical devices Park
- ❑ Set up a Skill development committee with representatives from Medical devices industry, academia (NIPERs) and Healthcare Sector Skill Council (HSSC) under National Skill Development Council (NSDC)
- ❑ Department of Pharmaceuticals should be strengthened and rechristened as Department of Pharmaceuticals and Medical Devices

### Recent Government Steps

- ❑ **4 medical device parks set up** in Andhra Pradesh, Telangana, Tamil Nadu and Kerala
- ❑ In Nov 2018, govt. approved formula for determination of **compensation for those patients who had received faulty hip implants** manufactured by **Johnson & Johnson**

### Conclusion

- ❑ A targeted and separate provision is needed to regulate medical devices other than drugs
- ❑ Medical devices sector needs to be made effective and transparent to make healthcare devices affordable and accessible



For TTP