



HEALTHCARE, PHARMACEUTICAL, MEDICAL DEVICES, HR EXCHANGE  
SEMINAR: BUSINESS OPPORTUNITIES IN INDIA

23 APRIL 2019, OSAKA

INDIAN LEGAL AND REGULATORY REGIME  
FOR  
MEDICAL DEVICES AND HOSPITALS

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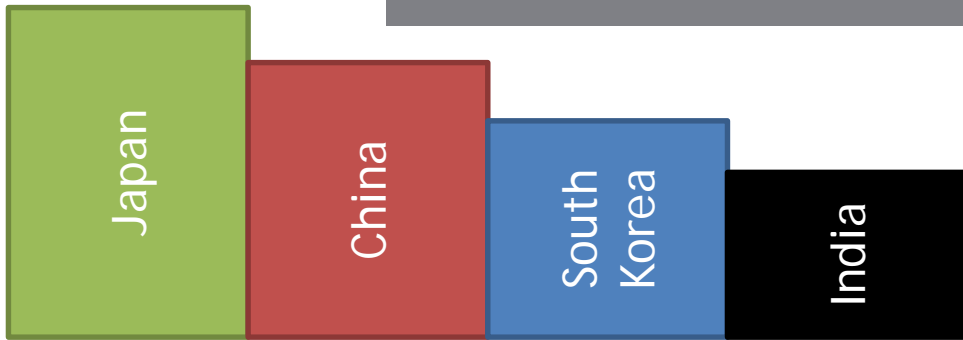
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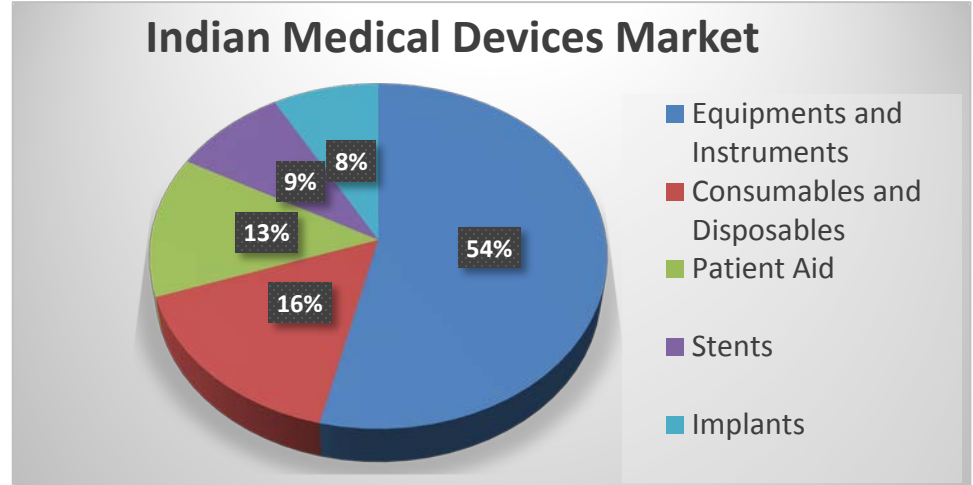


# MEDICAL DEVICES

# STATE OF MARKET



Growing @15.8% CAGR. Global industry @4.1%  
(Source: DIPP)



(Source: WHO, World Bank)

- 4<sup>th</sup> largest in Asia after Japan, China and South Korea; Top 20 globally (Source: Department of Industrial Policy & Promotion, Government of India ("DIPP"))

- Estimated size: \$5.2 billion; Expected to reach \$50 billion by 2025 (Source: Makeinindia)
- \$1.57 Billion FDI inflow in Medical and Surgical Appliances from Apr 2000 to Mar 2017 (Source: DIPP)
- Indian companies specialize in low-price / high-volume segment e.g. consumables and disposables; MNCs focus on sophisticated, high-end devices (Source: DIPP)
- Import dependency: 80%; particularly - higher end products that include cancer diagnostics, medical imaging, ultrasonic scans, and PCR technologies (Source: DIPP)

# GROWTH DRIVERS

## Demographics

- Ageing population: >60 years - 200 million by 2025
- Rise in non-communicable and chronic diseases
- Health infrastructure - inadequate and uneven
- Will require home-based healthcare devices

- Increasing insurance coverage
- Under-penetration of medical devices in India: current per capita spending lowest in the world
- Growth of world-class hospitals with high-end equipment infrastructure
- Growth in medical tourism; expected to reach \$9 billion by 2020 (*Source: IBEF*)

## Policy Push for Manufacturing

- 100% FDI under the automatic route
- Focus sector of Make in India Program
- Favoured treatment under the GST regime
- Dedicated Medical Devices Parks set up

# Laws and Regulatory Bodies

## LAW

- Drugs and Cosmetics Act, 1940
- Medical Devices Rules, 2017 (MD Rules)

## REGULATORY BODIES

Central Drugs Standards Control Organization (CDSCO) - national regulatory authority

Drugs Controller General of India (DCGI)

- Manufacture of Class C and D devices
- Imports
- Clinical investigations
- Clinical performance evaluations

State Drugs Controllers

- Manufacture/sale of Class A and B devices
- Sale, stocking, exhibiting, distribution of all classes of devices

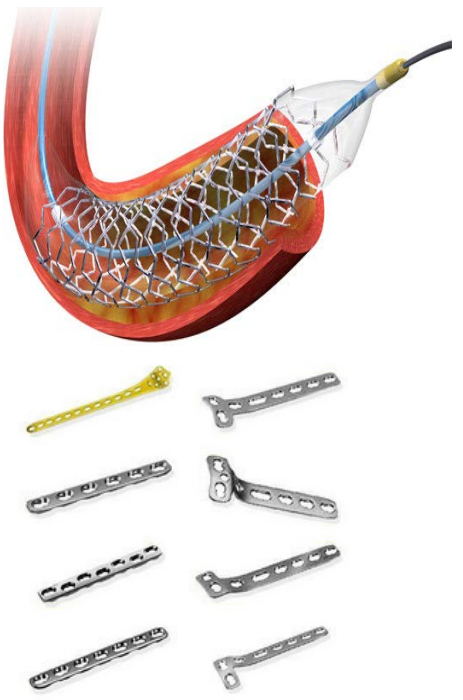
## Definition - What is a Medical Device?

- Part of definition of “Drugs” under the Drugs & Cosmetics Act – S. 3(b)(iv)
  - Devices for internal / external use
  - For diagnosis, treatment, mitigation or prevention of disease or disorder
  - As notified by the Central Government
  
- 15 Devices presently being regulated: Cardiac Stents, Heart Valves, Catheters, Bone Cements, etc
  
- 4 Devices Notified (3<sup>rd</sup> December 2018) - to be regulated with effect from 1<sup>st</sup> January 2020:
  - Nebulizers
  - Blood Pressure Monitoring Devices
  - Digital Thermometers
  - Glucometers

# Definition - What is a Medical Device?

8 Devices Notified (8<sup>th</sup> February 2019) - to be regulated with effect from 1<sup>st</sup> April 2020:

All implantable medical devices



Defibrillators



X-ray machines



bone marrow cell separator



dialysis machines



CT scan equipment



MRI equipment



PET equipment



# Latest Development - April 2, 2019 - All Unregulated Medical Devices to be Regulated soon

Will become effective once Government of India issues relevant notification

## 1<sup>st</sup> Phase: Registration

- voluntary registration requirements - for 18 months
- mandatory thereafter

## 2<sup>nd</sup> Phase: Licensing

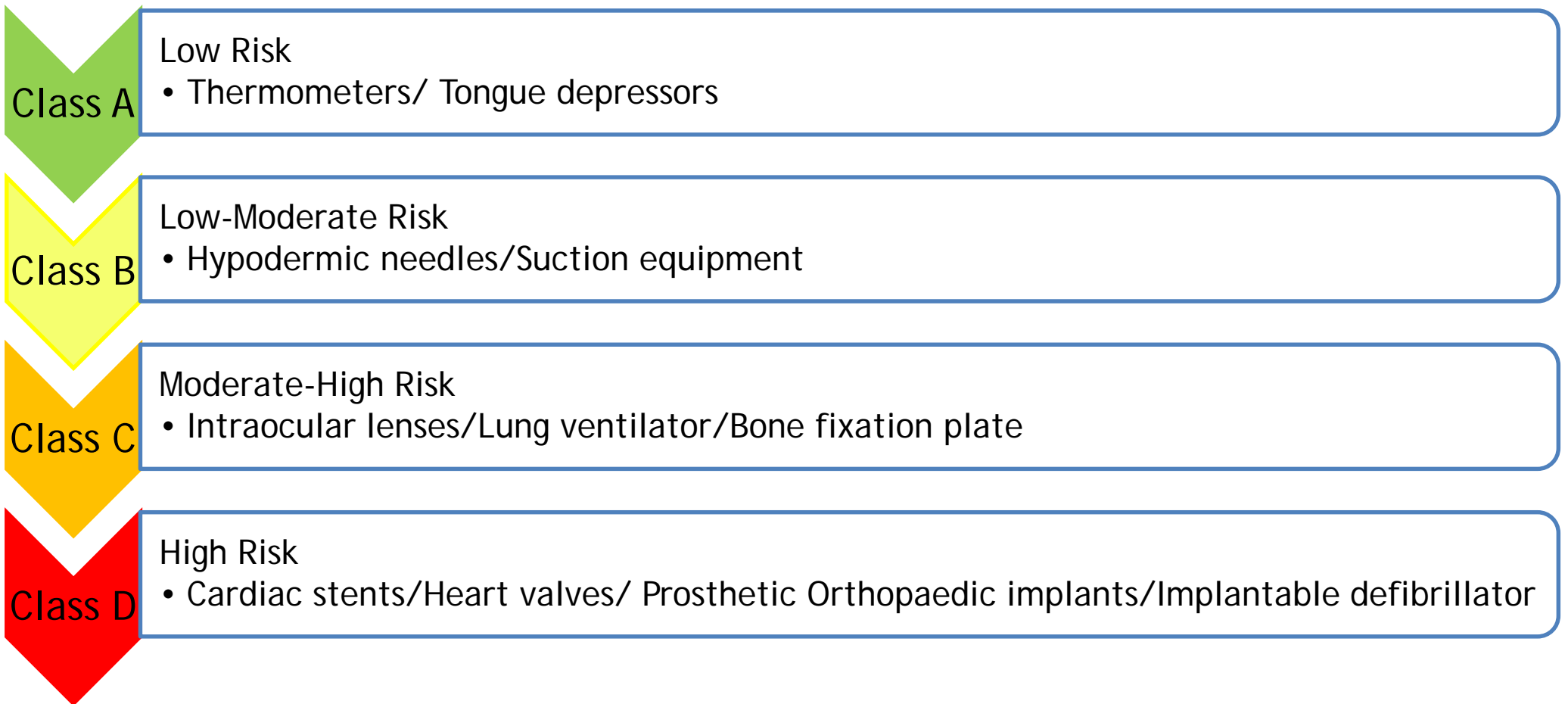
- Classes A & B - within 12 months of Government notification
- Classes C & D - within 24 months

Interim period reporting requirement - of all serious adverse event



# Classification System

- Risk Based
- Decided by DCGI; No discretion to Manufacturers/Importers



# Licensing - Manufacturing and Import

| Device Category | Manufacturing License Requirements     | Import License Requirements   |
|-----------------|--|---|
| Class A         | No pre audit of manufacturing facility | <ul style="list-style-type: none"> <li>▪ Free sale certificate in country of origin</li> <li>▪ Established safety and performance               <ul style="list-style-type: none"> <li>➤ through published safety/performance data <u>or</u></li> <li>➤ through clinical investigation</li> </ul> </li> </ul> |
| Class B         | Pre audit                              |   |
| Class C         | Pre audit + Prior Official inspection  | <ul style="list-style-type: none"> <li>▪ Clinical investigation in India</li> <li>▪ Establishing safety and effectiveness</li> </ul>  |
| Class D         |  |   |

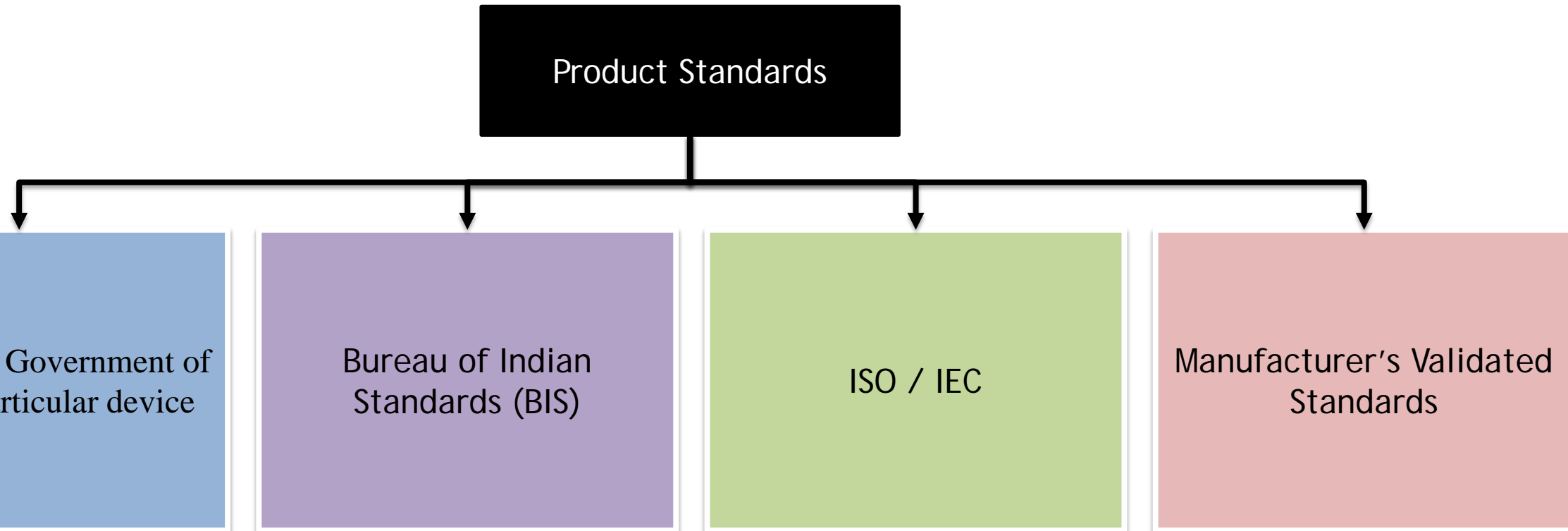
**Foreign manufacturer must appoint authorized agent in India**

# LIBERAL IMPORT REGIME FOR REGULATED MARKETS' PRODUCTS

- Regulated Markets: Australia, Canada, EU, **Japan**, U.K., U.S.
- No clinical investigation in India required for import in India of devices granted free sale certificate in Japan
- Exceptions:
  - For Investigational Medical Devices
    - 2 years marketing history
    - Same expected performance on Indian population
    - Only post marketing clinical investigation required in India
  - For new InVitro Diagnostic devices
    - Clinical performance evaluation in India required

# Standards, Safety and Performance

Design & manufacturing - must conform to the “essential principles of safety and performance” - described in the Guidance Document



# Pricing

- Prices subject to control:
  - Devices listed in National List of Essential Medicines and/or
  - Any device – in public interest
  
- Prices capped for :
  - Bare Metal Stents – Rs. 7,000
  - Drug Eluting Stents – Rs. 29,000
  - Knee Implants – Rs. 54,270 to Rs. 113,950
  
- Government examining proposal to cap trade margins i.e.  $MRP = \text{Price at First Point of Sale} + \text{Trade Margin}$
  
- Issue: First point of sale – Importer or Distributor?

# Adverse Event Reporting and Recall

- **Mandatory recall requirement**
  - By manufacturer / importer
  - Reason to believe that use of device likely to pose risk to health of user
  
- **Power to DCGI to order recall**
  - Manufacturer - obligation to inform DCGI of any suspected unexpected serious adverse event and action taken within 15 days
  - Importer – must inform DCGI of any administrative action taken by regulator in country of origin
  - DCGI – may order recall after examination of facts
  - DCGI – may also order recall on account of non-conformity of device with provisions of the Act and Rules

# Easing of Process

- Prescribed Quality Management System for manufacturing
- Single window clearance – through single online portal of Government of India
- Time bound audit and approval/rejection process
- Import application – 9 months from application date
- Deemed approval – if no decision taken by licensing authority within stipulated time
- Perpetual license – with 5-year retention fee



# HOSPITALS

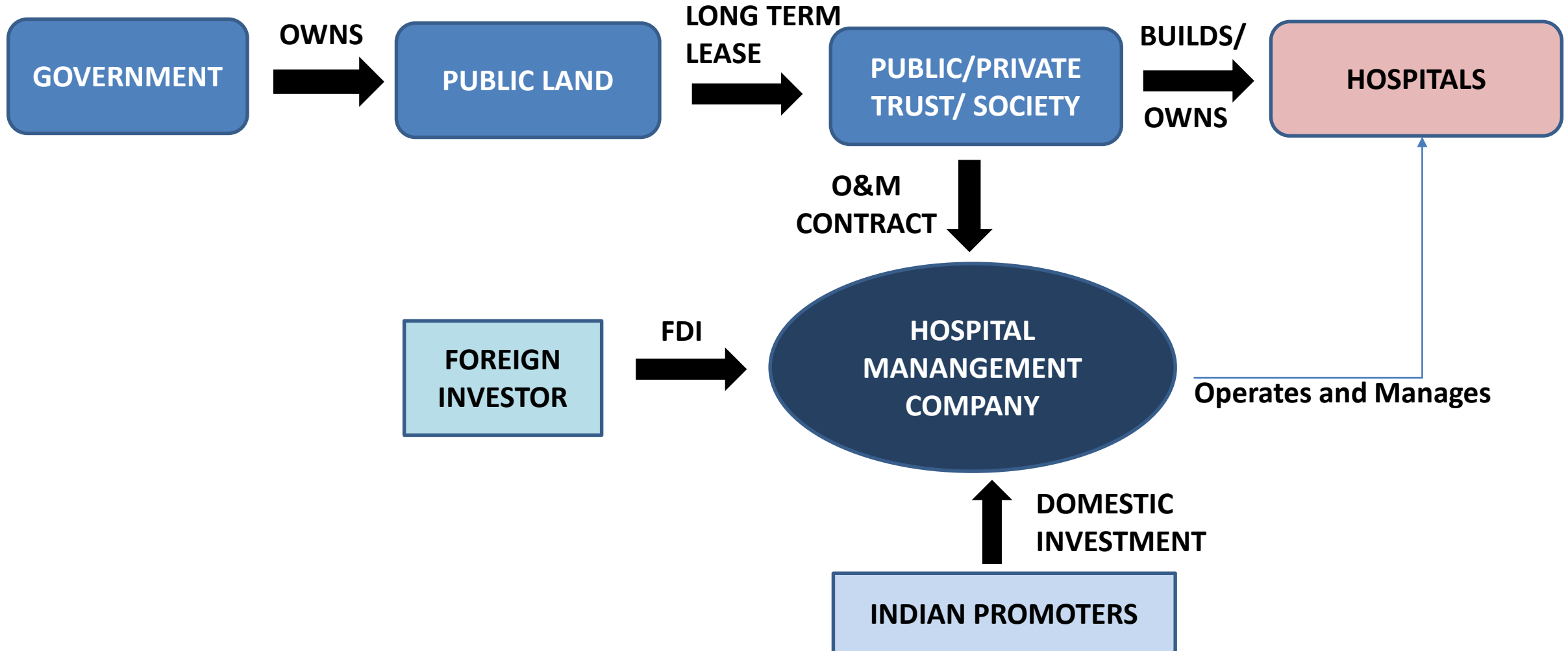


# STATE OF MARKET

- Growth – 15% CAGR; \$280 billion by 2020 (*Source: IBEF*)
- Additional 600,000 to 700,000 beds needed over the next three to four years (*Source: IBEF*)
- Growth areas: multi-speciality, single-speciality, and super-speciality hospitals in Tier 1 and Tier 2 cities
- 100% FDI under automatic route in Hospitals sector
- FDI of \$5,419.08 million between April 2000 and December 2018 (*Source: DIPP*)

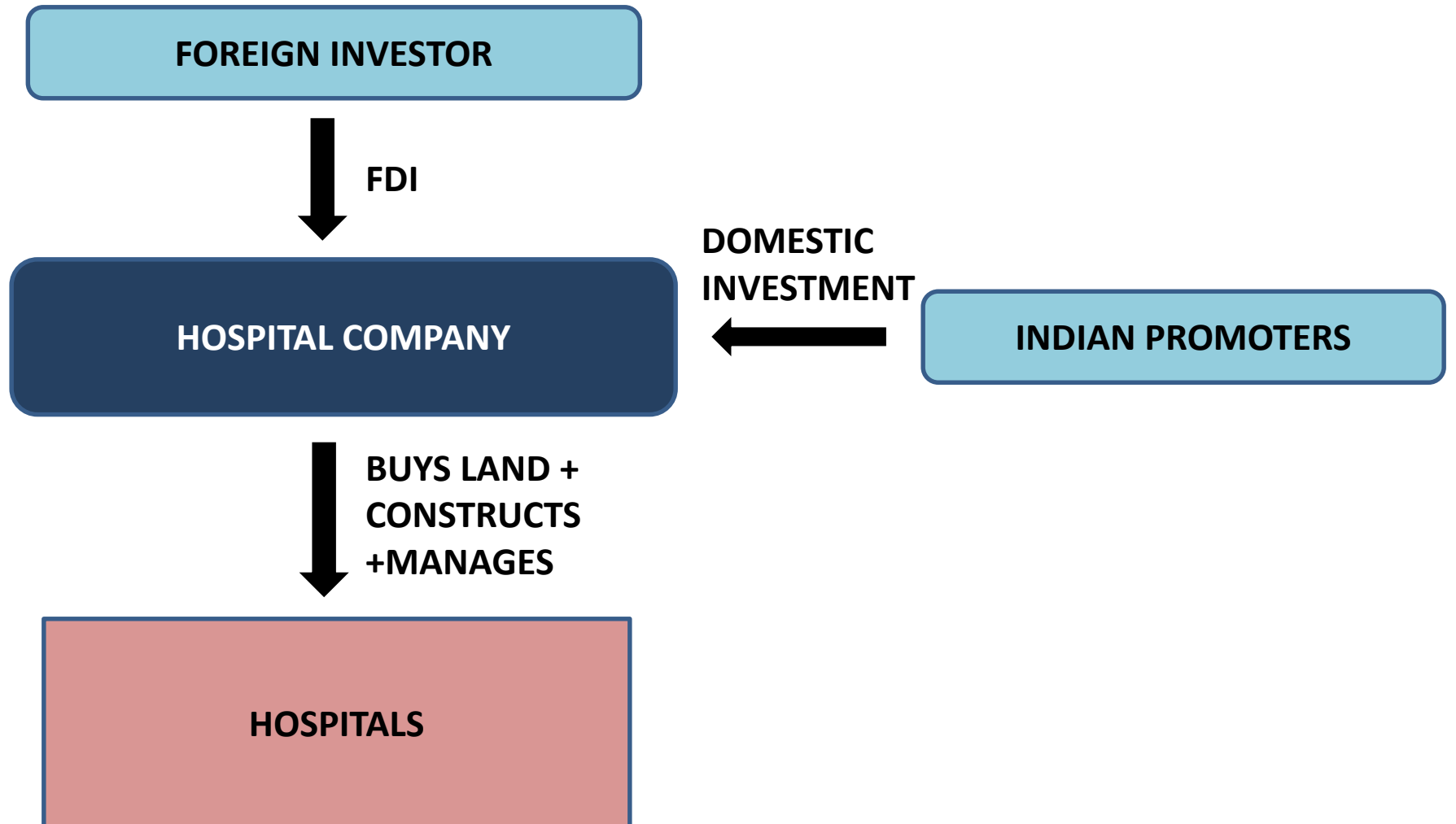
# Typical Operational Models

## TRUST MODEL



# Typical Operational Models

## CORPORATE HOSPITAL MODEL



# Issues for Foreign Investors

- Highly regulated
- Multitude of laws
  - The Clinical Establishment (Registration and Regulation) Act, 2010
    - Registration and regulation of all clinical establishments
    - Minimum standards
  - Biomedical Waste Disposal
  - Drugs and Cosmetics Acts
  - Environmental consents
  - Clinical trials – law regarding compensation to human subjects in clinical trials
- Need for proper due diligence before investing

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# **DISPUTES IN RELATION TO MEDICAL DEVICES & HOSPITALS**



# MEDICAL DEVICES

# Prosecution under Drugs & Cosmetics Act, 1940

- The definition of 'drugs' under the D&C Act includes certain medical devices (as specified by the Government).
- D&C Act prescribes penalty for violation of provisions relating to -
  - Import into India
  - Manufacture, Sale and Distribution in India
- D&C Act provides for the following penalties :
  - Imprisonment
  - Fine
  - Confiscation of the device

# Remedies in Civil law

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- Civil Suit
- Complaint under the Consumer Protection Act, 1986 (CPA)
- Public Interest Litigation



# General Remedies in Civil law

## Civil Suit

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- In case of a faulty medical device, a civil suit for damages can be filed by the affected party
- The basis of the civil suit would be that the manufacturer was negligent (did not exercise its duty of care)
- As a result of such negligence, the affected party suffered loss

# General Remedies in Civil law

## Complaint under CPA

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- CPA is a welfare legislation which provides remedy to a consumer against any defect in goods supplied to it
- CPA also provides for initiation of class action litigation by one or more consumers, where a number of consumers have the same interest
- If there is any defect in a medical device, the consumer can file a complaint under the CPA

## Complaint under CPA (2)

- Under the CPA, the Consumer Forums have the power to pass directions against the manufacturer to :
  - Remove the defects from the devices
  - Replace the defective devices
  - Return to the complainant price and charges
  - Award damages (including punitive damages) for any loss or injury suffered due to negligence

contd ...

## Complaint under CPA (3)

- Discontinue the unfair trade practice or restrictive trade practice or not to repeat them
- Not to offer hazardous devices for sale
- Withdraw hazardous devices from being offered for sale
- Cease manufacture of hazardous devices
- Award claims in a class action

# General Remedies in Civil law

## Public Interest Litigation (PIL)

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- In case of a faulty medical device, a PIL can also be filed by affected party or parties
- PIL can be filed on the basis that the fundamental right of a group of people was violated by use of the medical device
- The court has wide powers to grant relief to meet the ends of justice

# Compensation

Two kinds of compensation can be awarded in law :

- Compensatory Damages
  - Special damages : Out-of-pocket expenses, loss of earnings, compensation for future treatment etc.
  - General damages : Compensation for pain and suffering, compensation for loss of earning in future.
- Punitive/Exemplary Damages
  - CPA specifically empowers the Consumer Forum to grant punitive damages

# Recent Development

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Johnson & Johnson (J&J) faulty Articular Surface Replacement (ASR) hip implants

## Recent Development (2)

- In 2010, J&J globally recalled its faulty ASR hip implants
- The Indian Government set up an expert committee in 2017 to examine issues arising out of faulty hip implants in India
- Based on reports of expert committees, the Government fixed compensation payable to the parties affected by the faulty implants (ranging up to INR 1.23 crores)
- J&J has challenged the compensation fixed by the Government on the ground that the Government has no authority in law to fix any compensation. The challenge is presently pending adjudication before Court.





# HOSPITALS

# Hospitals

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- A hospital can be held to be vicariously liable for the acts of its doctors/nurses/employees or independent persons working under its supervision
- Liability of a hospital is based on the principle in common law that employers are liable for acts of their employees
- Hospitals can be held liable for compensation under civil law, Consumer Protection law, or even in a Public Interest Litigation

# THANK YOU

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