All India Institute of Medical Sciences Rajkot

PHARMACOLOGY OF MEDICAL DEVICES

e – Bulletin

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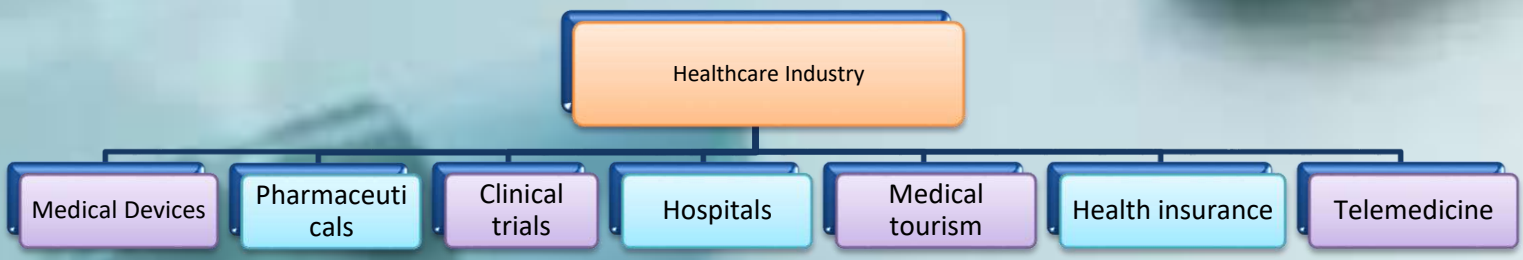
Contents

*INTRODUCTION [1]

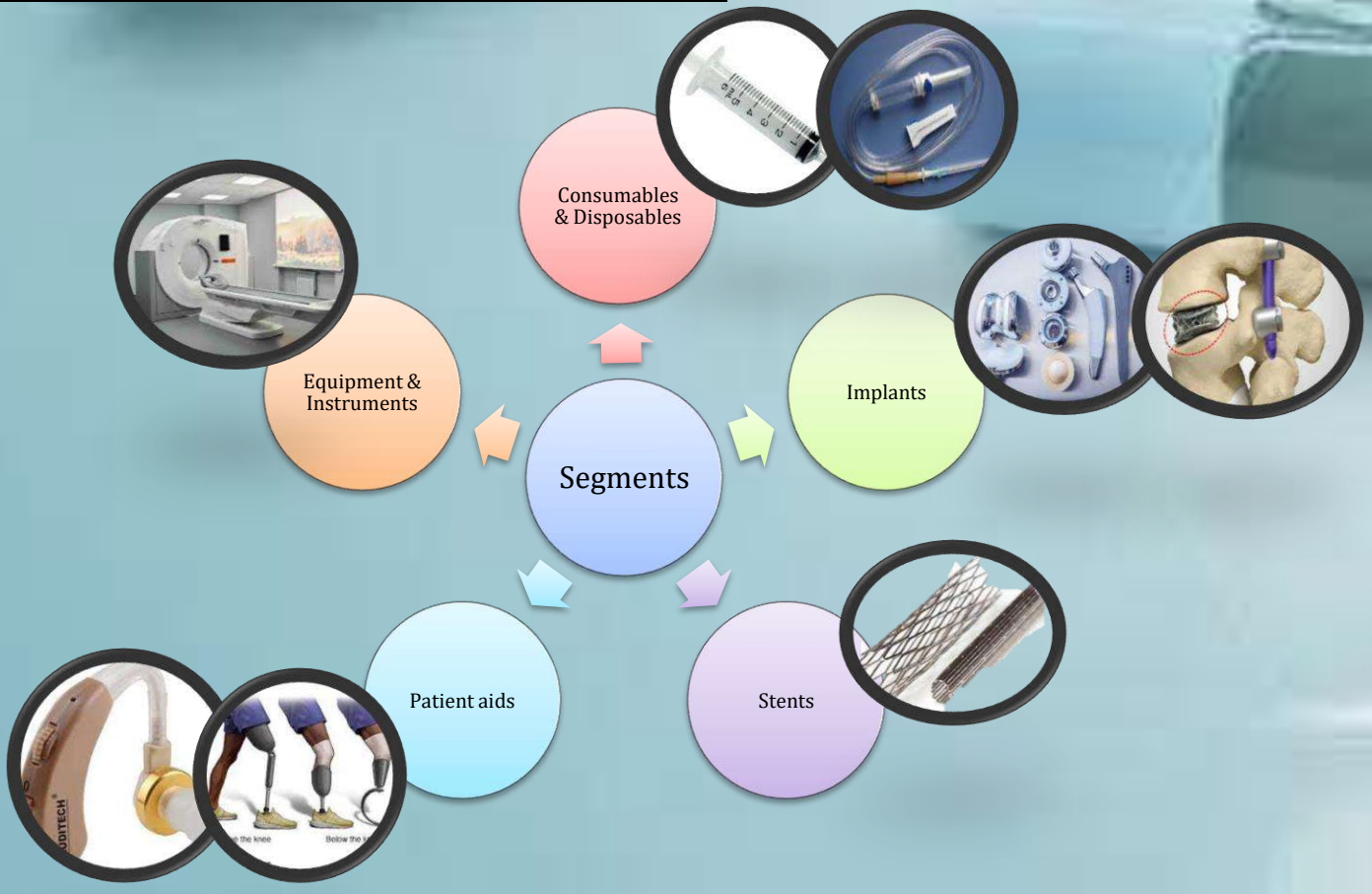
WHAT IS A MEDICAL DEVICE?

- Any material, software, appliance, instrument, apparatus
  - Used for diagnosis and treatment
  - Helps in disease prevention and management
  - Helps improve the quality of life
  - E.g. Syringe, I/V set, UPT kits, Glucometers, hearing aids, and monitors, Stents etc.

*SEGMENTATION IN HEALTHCARE INDUSTRY

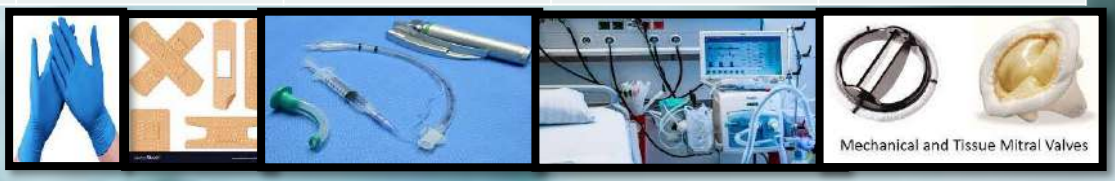


*SEGMENTATION WITHIN MEDICAL DEVICES[2]



*CLASSIFICATION OF MEDICAL DEVICES WITH RISK LEVEL[3]

	CLASS A	CLASS B	CLASS C	CLASS D
RISK LEVEL	LOW	LOW-MODERATE	MODERATE-HIGH	HIGH
EXAMPLES	MEDICAL GLOVES, BANDAGES	NEEDLES, TRACHEAL TUBES	VENTILATORS AND OTHER ICU EQUIPMENT	BALLOON CATHETERS, PACEMAKERS, PROSTHETIC HEART VALVES



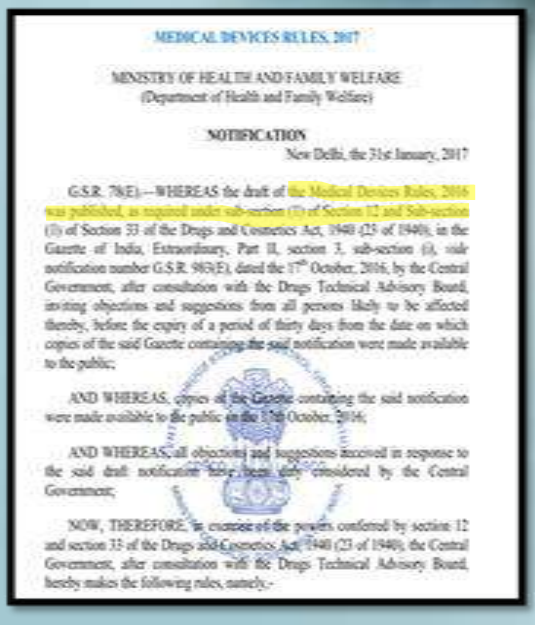
*REGULATIONS PERTAINING TO MEDICAL DEVICES [4-6]

*REGULATORY AGENCIES WORLDWIDE	
COUNTRY	**REGULATORY BODY**
INDIA	• **CDSCO(**central drugs standard control organisation**)**
CHINA	• **SFDA(**state food and drug administration**)**
AUSTRALIA	• **TGA(**therapeutic goods administration**)**
JAPAN	• **MHLW(**ministry of health, labour & welfare**)**
EUROPEAN UNION	• **EMEA(**European Medicines Evaluation Agency**)**
UK	• **MHRA(**Medicines and Healthcare Products Regulatory Agency**)**
KOREA	• **KFDA(**Korea Food & Drug Administration**)**

REGULATION IN INDIA

The first definition of Medical Devices was introduced in Drugs & Cosmetics Act, 1940 under Section 3(b)(iv) in the year 1982.

- Medical Devices Rules, 2017 were notified by the Government vide notification no. GSR 78 (E) dated 31.01.2017 which were came into force w.e.f. 01.01.2018
- MDR 2017 contains :
  - ✓ *12 chapters* : Sections detailing various provisions related to medical devices
  - ✓ *08 Schedules:* Lists of classes and requirements for medical devices
  - ✓ *97 Rules :* Legal obligations and guidelines for medical devices
  - ✓ *43 forms :* Documents for compliance and reporting of various parameters including safety of medical devices


MEDICAL DEVICES RULES, 2017

MINISTRY OF HEALTH AND FAMILY WELFARE
(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 31st January, 2017

G.S.R. 78(E).—WHEREAS the draft of the Medical Devices Rules, 2016 was published, as required under sub-section (1) of Section 12 and Sub-section (1) of Section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), vide notification number G.S.R. 983(E), dated the 17th October, 2016, by the Central Government, after consultation with the Drugs Technical Advisory Board, inviting objections and suggestions from all persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which copies of the said Gazette containing the said notification were made available to the public;

AND WHEREAS, copies of the Gazette containing the said notification were made available to the public on the 17th October, 2016;

AND WHEREAS, all objections and suggestions received in response to the said draft notification have been duly considered by the Central Government;

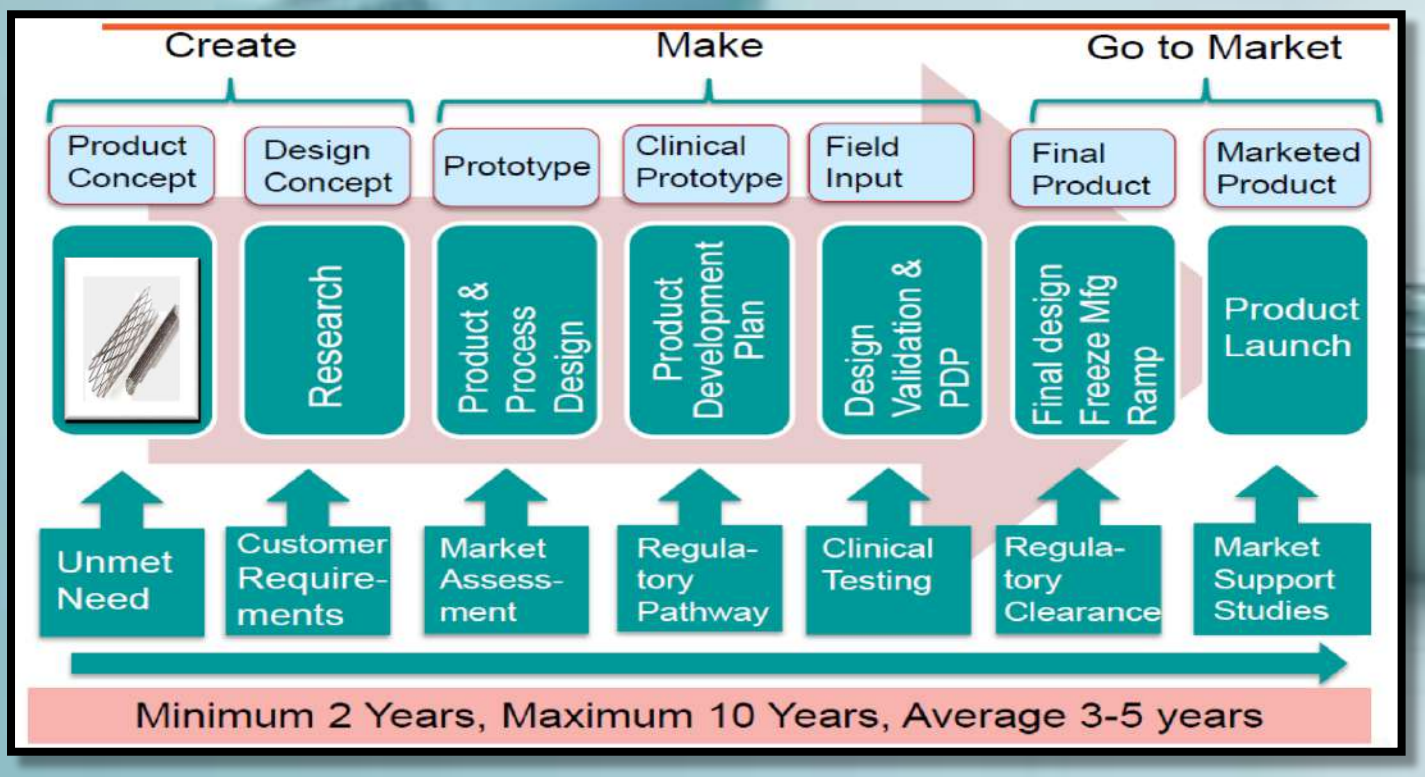
NOW, THEREFORE, in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules, namely,-

LICENCE PROCESS IN INDIA [7]

- For Class A & B medical devices, licenses are to be issued by State licensing authorites and for Class C & D medical devices, licenses are to issued by central licensing authorites.

- Manufacturer should apply for license application on Sugam Portal, designed by CDSCO office.
  - *CLASS A: No pre inspection is required, SLA will issue the license on Form MD-5.*
  - *CLASS B: Notified body will inspect the manufracturing premises and SLA will issue the license on Form MD-5*
  - *CLASS C & D: Officers from CDSCO, Delhi will inspect the manufacturing premises and CLA will grant license on MD-9*

*MEDICAL DEVICE DEVELOPMENT LIFE CYCLE[8-11]



*DRUGS VS MEDICAL DEVICES

SIMILARITIES BETWEEN DRUGS & MEDICAL DEVICES

- Preclinical Testing, Clinical Trials required for both.
- Regulatory Oversight and submission processes are almost similar.
- Post Marketing surveillance essential for both.

Differences between Drugs & Medical devices

COMPARATOR	DRUGS	MEDICAL DEVICES
Nature of product	Chemical/ Biological	Bioengineered ± Chemical/ Biological
Development complexity	Crucial steps: 1. Identify MOA 2.Pharmacokinetis/Pharmacodynamics studies 3.Potential interactions 4.Toxicity studies	Engineering, design, validation, optimization, usability studies
Research requirements	Well-defined phases as per regulatory framework	Ill defined – Different for disposable needles vs coronary stent, CT scanner
Regulatory pathways	New Drug Application (NDA)/ Abbreviated NDA/ Biologics (BLA) pathway – Mostly same for all drugs	Depends on the level of risk and similarity to existing devices
Developmental timeline	Usually takes longer (average 7-10 years)	Generally shorter but can vary based on complexity (average 3-5year)

*INDIAN MARKET OF MEDICAL DEVICES

Indian Market Size of Medical Device Sector– $11 billion (2022)

- *Expected to increase at a CAGR (compounded annual growth rate) of 37% by 2025*
- *More than 4000 startups*

Growth drivers in India

- *New Manufacturing Capacity development*
- *Increasing funds for private/ public sector*
- Supportive medical device policy

*MEDICAL DEVICES ECOSYSTEM

BIO-MEDICAL TECHNOLOGY FOR DEVICES: -

- Design, development
- Validation, optimization
- Production

⟺

PHARMACOLOGY OF DEVICES: -

- Preclinical devices testing
- Clinical trials, surveillance, regulatory processes
- Use guidelines, policies, HTA, training

*ROLE OF A PHARMACOLOGIST IN MEDICAL DEVICES & RELATED ISSUES[12]

Collaborator between

- Bioengineers
- Clinicians
- Regulatory experts
- Quality assurance personnel

Research & Development

- MD that incorporate pharmaceutical agents
  -Drug-eluting stents, implantable drug delivery systems, infusion pumps, controlled delivery systems, nanosensors
- Support designing of these devices to deliver drugs in controlled doses and monitor the effects

Preclinical testing

- Compatibility of medical devices with pharmaceutical agents in laboratory and animal studies
- Pharmacokinetics, pharmacodynamics of the drugs released by the devices
- Adverse device reactions, Drug –device/tissue interactions

Clinical Trials

- Designing, conducting, analysing clinical trials for medical devices
- Help determine appropriate drug dosing
- Monitor patient response

Regulatory compliances

- Regulatory submissions and compliance with relevant authorities
- Provide data and expertise to support the safety and efficacy of the device's drug component

Risk assessment

- Potential risks associated with drug-device interactions, allergies, adverse events, and other safety concerns
- Recommendations to mitigate these risks and ensure patient safety

Product Labelling and Documentation

- Development of product label
- Instructions for use and other documents that help healthcare professionals and patients understand how to use the medical device safely and effectively

Education and Training

- For healthcare professionals
- About the proper use and potential interactions of medical devices with pharmaceutical agents

Post-Marketing Surveillance

- Monitoring the real-world performance of medical devices
  --To fulfil the regulatory requirements
- Analyse adverse event reports, patient outcomes, and other data to identify any potential issues and contribute to device improvements

Materiovigilance

- Deals with medical devices associated with adverse events and their monitoring.

Policy decisions

- Policy decisions Essentiality of medical devices
- Price regulation, Health technology assessment

Thank You

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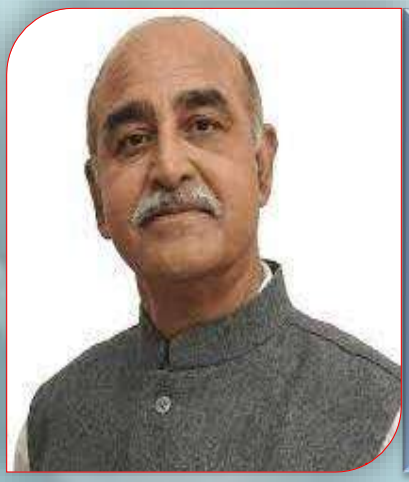
Quiz

1. In what phase of medical device development do pharmacologists typically play a significant role?
a) Preclinical testing
b) Post-market surveillance
c) Clinical trials
d) Manufacturing

2. What regulatory bodies are required to liaise with during the approval process for medical devices in India?
a) Food and Drug Administration (FDA)
b) European Medicines Agency (EMA)
c) World Health Organization (WHO)
d) The Central Drugs Standard Control Organization (CDSCO)

3. How do pharmacologists contribute to the safety of medical devices?
a) By ensuring the device is comfortable to use
b) By conducting preclinical studies to identify potential risks
c) By marketing the device to healthcare professionals
d) By developing user manuals for the device

***Answers**: c), d), b)*



Message from Executive Director

"I heartily congratulate the department of pharmacology for bringing this informative newsletter on "Pharmacology of Medical Devices" – an emerging branch in healthcare industry. My best wishes to the entire team……

Dr. (Col)C.D.S. Katoch, Executive Director, AIIMS, Rajkot.

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