First Indigenously Developed Animal-Derived Biomedical Device

Why in News?

Recently, Indian Drugs Controller approved the first indigenously developed animal-derived **Class D Biomedical Device, Cholederm**, that can rapidly heal skin wounds at low-cost with minimum scarring.

- As per the **Medical Devices Rules, 2017**, medical devices are classified into four classes based on the risk level: Class A (low risk), Class B (low moderate risk), Class C (moderate high risk); Class D (high risk).

What are the Key Details of the Development?

- **About:**
  - The **Sree Chitra Tirunal Institute for Medical Sciences and Technology** (SCTIMST), an **autonomous institution under the Department of Science and Technology (DST), developed** the tissue engineering scaffold.
  - It is the first institution in India to develop Class D medical devices that meet the requirements of the Central Drugs Standard Control Organisation **(CDSCO)**.
  - It is an **innovative technology for preparing tissue** engineering scaffolds from mammalian organs.
  - The **concept of using animal-derived materials** as advanced wound care products **is not new.**
    - However, indigenous technology was so far not available for fabricating quality products that satisfy the requirements of the Drugs Controller General
- **Healing Capabilities:**
  - The tissue **engineering scaffold, called Cholederm**, demonstrated **the ability to heal various types of skin wounds**, including **burn and diabetic wounds,** in rat, rabbit, or dog models faster than existing products in the market, while minimizing scarring.
  - It **showed that graft-assisted healing** was regulated by **anti-inflammatory M2 type of macrophages**, which helped modulate or mitigate scarring reactions in different tissues.
- **Cost Reduction and Market Potential:**
  - The introduction of Cholederm to the Indian market **is expected to reduce treatment costs from Rs 10,000/- to Rs 2,000/-,** making it more affordable.
  - Additionally, the technology **provides a competitive advantage in the international market and creates an income-generating opportunity.**
- **Future Developments:**
  - The research team is **currently developing injectable gel formulations** of the scaffold **for easier application in treating cardiac injuries,** aiming to revolutionize the management of patients suffering from myocardial infarction.

Note:

- Medical devices are **regulated as drugs under the Drugs and Cosmetics Act, 1940.**
- **CDSCO** is the national regulating authority **for medical devices and pharmaceuticals** while

NPPA is empowered by the Drugs (Price Control) Order, 2013, to control the prices of drugs and medical devices.

What is CDSCO?

- The CDSCO is the Central Drug Authority for discharging functions assigned to the Central Government **under the Drugs and Cosmetics Act, 1940.**
- The CDSCO under Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India is the **National Regulatory Authority (NRA)** of India.
- Its headquarter is in New Delhi
- Major Functions:
    - Regulatory control over the import of drugs, approval of new drugs and clinical trials.
    - Approval of certain licences as Central Licence Approving Authority.

What is the National Pharmaceuticals Pricing Authority (NPPA)?

- NPPA is an organization **under Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers which was set up in 1997** to revise the prices of controlled bulk drugs and formulations and to enforce prices and availability of medicines in the country, under the Drugs (Prices Control) Order (DPCO), 1995.
- The prices are now fixed/revised under Drugs (Prices Control) Order (DPCO), 2013.
- It also monitors the prices of decontrolled drugs in order to keep them at reasonable levels.

Source: PIB