

# 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 <u>Central Drugs Standard Control Organisation</u> (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 Vision

- 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** 

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