Stem Cell Therapy Regulation in India

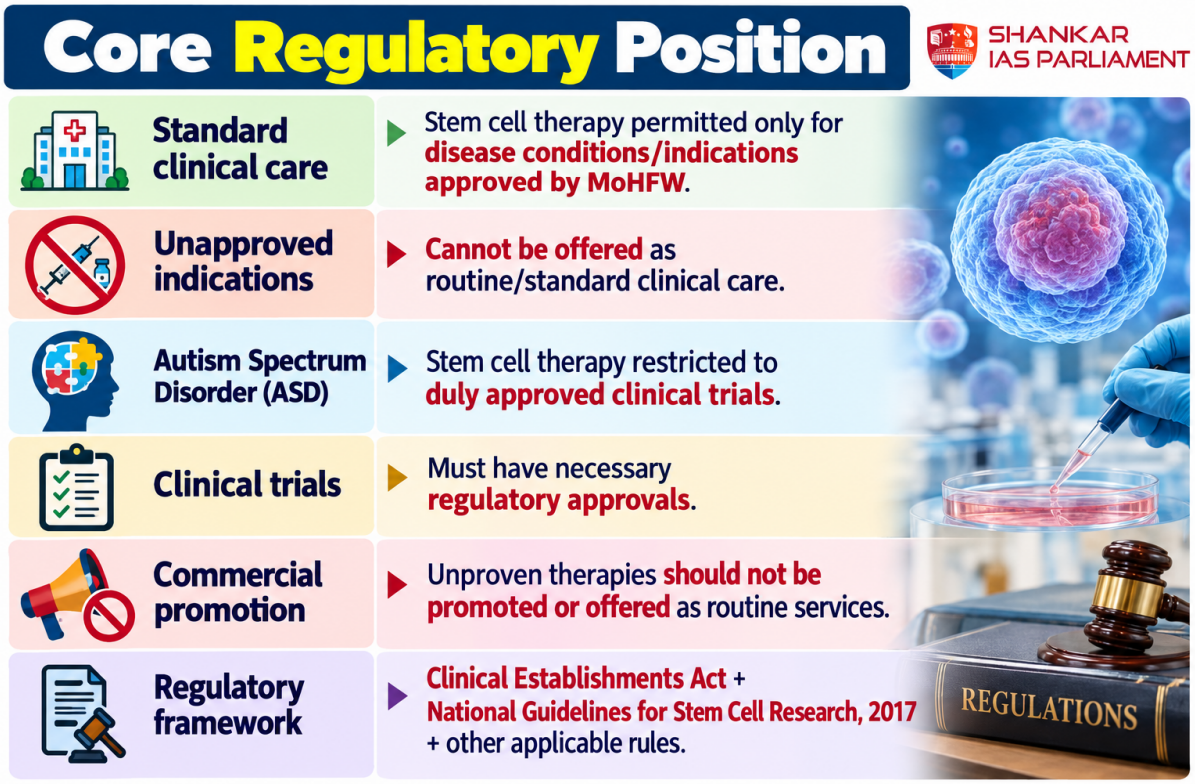
Prelims: *Current events of national and international importance | Science & Technology | Health*

Why in News?

Recently, the Union Ministry of Health & Family Welfare issued an advisory to regulate the use of stem cell therapy, particularly stressing that unproven stem cell interventions.

- **Autism Spectrum Disorder (ASD) –** This advisory specifically addresses the application of stem cells in the treatment of **autism**.
- **Current position**
  - Stem cell therapy is not **approved as a routine standard of care.**
  - Use of stem cell therapy is permitted only within **duly approved clinical trials.**
  - All applications must comply with the **National Guidelines for Stem Cell Research, 2017.**

*It is important to note that this restriction applies to the **therapeutic use of all types of stem cells in the context of autism.***



- **National Guidelines for Stem Cell Research, 2017 –** The guidelines were jointly issued by the following organizations:
    - **Indian Council of Medical Research (ICMR)**
    - **Department of Biotechnology (DBT)**
- These guidelines establish the framework for **stem cell research and its translation into clinical applications**.
- **Supreme Court's Role –** The Ministry's 2026 advisory is issued pursuant to the Supreme Court judgment in **Yash Charitable Trust & Ors. v. Union of India & Ors.**
    - The Court underscored the necessity of adhering to the statutory framework regulating stem cell therapy.
- **Consequences of Non-Compliance –** The Supreme Court has held that violations of statutory requirements may result in the following consequences:
- **Professional misconduct –** This is addressed under **Regulation 7.22 of the Indian Medical Council (IMC) Regulations, 2002**.
- **Clinical Establishments Act, 2010 –** Sections 32 and 40 of the Act specify the following consequences:
    - Cancellation of registration
    - Imposition of penalties
- **Advisory from the National Medical Commission (NMC) –** It reaffirmed the following points:
- Stem cell therapy is permitted as standard clinical care exclusively for indications that have received official approval.
- The following actions, when conducted without proper authorization, are prohibited:
    - **Administration**
    - **Prescription**
    - **Promotion**
    - **Advertisement** of stem cell therapy for unapproved indications may constitute

professional misconduct.

- **Role of State Medical Councils –** State Medical Councils have been instructed to **investigate alleged violations, adhere to due process, determine the presence of professional misconduct, and implement appropriate disciplinary measures.**

Reference

PIB | Advisory on Regulation of Stem Cell Therapy