

Stem Cell Therapy Regulation in India

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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**.*

Core Regulatory Position

	Standard clinical care	▶ Stem cell therapy permitted only for disease conditions/indications approved by MoHFW.
	Unapproved indications	▶ Cannot be offered as routine/standard clinical care.
	Autism Spectrum Disorder (ASD)	▶ Stem cell therapy restricted to duly approved clinical trials.
	Clinical trials	▶ Must have necessary regulatory approvals.
	Commercial promotion	▶ Unproven therapies should not be promoted or offered as routine services.
	Regulatory framework	▶ Clinical Establishments Act + National Guidelines for Stem Cell Research, 2017 + other applicable rules.

- **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](#)

