



Union Health Ministry Issues Advisory on Regulation of Stem Cell Therapy

Stem Cell Therapy as Standard Care to be Permitted Only for Disease Conditions/Indications Included in Ministry-Approved List

Therapeutic Use of Stem Cells for Autism Spectrum Disorder (ASD) Restricted to Clinical Trials with Necessary Regulatory Approvals

Unproven Stem Cell Interventions, Including Stem Cell Therapy for ASD, Not to be Offered as Routine, Standard or Commercial Clinical Services

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The Ministry of Health & Family Welfare has issued an advisory dated 16 September 2026 to all States and Union Territories that have adopted the **Clinical Establishments (Registration and Regulation) Act, 2010**, regarding regulation of stem cell therapy. The advisory has been issued in view of the judgment dated 30 January 2026 of the Hon'ble Supreme Court in *Yash Charitable Trust & Ors. v. Union of India & Ors.*, W.P. (C) No. 369 of 2022 [2026 INSC 96].

The advisory reiterates the existing framework governing stem cell research and therapy and seeks to ensure that **stem cell therapy is permitted as standard care in routine clinical practice only for disease conditions/indications included in the list approved by the Ministry of Health & Family Welfare.**

With regard to **Autism Spectrum Disorder (ASD)**, the advisory stipulates that the therapeutic use of any type of stem cell in autism is to remain restricted to duly approved clinical trials, in accordance with the **National Guidelines for Stem Cell Research, 2017**, issued jointly by Indian Council of Medical Research (ICMR) and the Department of Biotechnology (DBT) and other applicable Government instructions issued by the Government of India from time to time.

The Ministry has requested the States and Union Territories to widely disseminate the directions of the Hon'ble Supreme Court to all concerned State and District Regulatory Authorities and Government and private clinical establishments involved in stem cell research, treatment, promotion or administration, for strict compliance with the applicable framework.

The advisory also draws attention to the consequences of non-compliance with the framework governing stem cell therapy. The Hon'ble Supreme Court, in Para 151(xiii) of its judgment dated 30 January 2026, held that non-compliance with the statutory mandate must attract consequences, including professional misconduct under Regulation 7.22 of the IMC Regulations, 2002, as well as action under Sections 32 and 40 of the **Clinical Establishments (Registration and Regulation) Act, 2010**, which provide for cancellation of registration and penalty.

The Ministry has accordingly requested the concerned State and District Regulatory Authorities and clinical establishments to ensure strict compliance with the applicable framework governing stem cell research and therapy.

Reinforcing the regulatory position, the National Medical Commission (NMC), in its advisory dated 5 September 2026, reiterated that stem cell therapy may be offered as standard clinical care only for the approved indications. The advisory further states that unauthorised administration, prescription, promotion or advertisement of stem cell therapy beyond the approved indications would constitute to professional misconduct.

The NMC has further advised State Medical Councils to examine cases of alleged violations brought to their notice and, where professional misconduct by a Registered Medical Practitioner is established after due process, take appropriate disciplinary action in accordance with the applicable statutory and regulatory provisions.

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