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नई दिल्ली-110077
Pocket- 14, Sector- 8,
Dwarka,
Phase – 1, New Delhi-110077

राष्ट्रीय आयुर्विज्ञान आयोग
नैतिकता और चिकित्सा पंजीकरण बोर्ड
National Medical Commission
Ethics & Medical Registration Board

R-13014/28/2022-Ethics

Date: 05.09.2026

ADVISORY

Subject: Order dated 30.01.2026 of the Hon'ble Supreme Court in *Yash Charitable Trust & Ors. vs. Union of India & Ors.*, W.P. (C) No. 369 of 2022 [2026 INSC 96]- Regulation of Stem Cell Therapy for treatment of ASD as Clinical Practice.

Attention of all Registered Medical Practitioners (RMPs), medical institutions, State Medical Councils (SMC) and other concerned stakeholders is invited to the aforesaid subject. The Hon'ble Supreme Court has observed that Stem Cell Therapy for treatment of ASD cannot be offered as routine commercial medical treatment outside the regulatory framework of clinical trials.

2. In view of the aforesaid order and the applicable regulatory framework governing Stem Cell research and therapy, it is hereby reiterated that Stem Cell Therapy for use as standard care in routine clinical practice shall be permitted only for such disease conditions/indications which are included in the list approved by the Ministry of Health and Family Welfare (MoHFW). A copy of the Advisory no. CDN-2011/105/2026-COORDINATION-NMC dated 25.03.2026, issued earlier by NMC, in this regard, is enclosed for ready reference.

3. In this connection the related sections of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 are as under-

- i. *"1.9 Evasion of Legal Restrictions: The physician shall observe the laws of the country in regulating the practice of medicine and shall also not assist others to evade such laws. He should be cooperative in observance and enforcement of sanitary laws and regulations in the interest of public health. A physician should observe the provisions of the State Acts like Drugs and Cosmetics Act, 1940; Pharmacy Act, 1948; Narcotic Drugs and Psychotropic substances Act, 1985; Medical Termination of Pregnancy Act, 1971; Transplantation of Human Organ Act, 1994; Mental Health Act, 1987; Environmental Protection Act, 1986; Pre-natal Sex Determination Test Act, 1994; Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954; Persons with Disabilities (Equal Opportunities and Full Participation) Act, 1995 and Bio-Medical Waste (Management and Handling) Rules, 1998 and such other Acts, Rules, Regulations made by the Central/State Governments or local Administrative Bodies or any other relevant Act relating to the*

protection and promotion of public health.”

- ii. *“7.22 Research- Clinical drug trials or other research involving patients volunteers as per the guidelines of ICMR can be undertaken, provided ethics considerations are borne in mind. Violation of existing ICMR guidelines in this regard shall constitute misconduct. Consent taken from the patient for trial of drug or therapy which is not as per the guidelines shall also be construed as misconduct.”*
- iii. *“8.2 It is made clear that any complaint with regard to professional misconduct can be brought before the appropriate medical council for disciplinary action. Upon receipt of any complaint of professional misconduct, the appropriate medical council would hold an enquiry and give opportunity to the registered medical practitioner to be heard in person or by pleader. If the medical practitioner is found to be guilty of committing professional misconduct, the appropriate medical council may award such punishment as deemed necessary or may direct the removal altogether or for a specified period, from the register of the name of the delinquent registered practitioner. Deletion from the Register shall be widely publicized in local press as well as in the publications of different Medical Associations/Societies/Bodies.”*

All RMPs, medical institutions, SMC(s) and other stakeholders are, therefore, again advised that Stem Cell Therapy may be offered as standard clinical care, ONLY for approved indications as listed in ICMR/DHR/MoHFW guidelines. Any unauthorized administration, prescription, promotion or advertisement thereof, beyond such approved indications, shall constitute professional misconduct.

All State Medical Councils shall examine individual cases of such alleged violation brought to their notice and, where misconduct by a RMP is established after due process, appropriate disciplinary action in accordance with applicable statutory and regulatory provisions, shall be taken.

Digitally signed by

Dr.Raghav Langer

Date: 05-09-2026

14:23:14

(Dr. Raghav Langer)

Secretary, National Medical Commission

Encl. : As above.

All Stakeholders/Registered Medical Practitioners (RMPs)

Copy to :

- (i) ACS/Pr. Secretary/Secretary (Health & Medical Education Department) of all States/UTs
- (ii) DG/Director, DME of all States/UTs
- (iii) Registrars of all State Medical Councils (SMCs)
- (iv) Dean/Principal of all Medical Colleges/ Institutions
- (v) Director EMRB, NMC

Copy for kind information to :

- (i) PPS to the Secretary, Department of Health & Family Welfare, MoHFW, GoI,

Kartavya Bhawan-I, New Delhi.

(ii) PPS to the Secretary, Department of Health Research, MoHFW, GoI, IRCS Building, Red Cross Road, New Delhi.

(iii) PPS to the Chairman, National Medical Commission, Dwarka, New Delhi.



CDN-20011/105/2026-COORDINATION-NMC
Government of India
National Medical Commission
(Policy & Coordination Division)



Pocket - 14, Sector - 8,
Dwarka Phase - 1, New Delhi - 110 077.
Dated: 25th March, 2026.

ADVISORY

Subject : Compliance with Hon'ble Supreme Court Judgement dated 30.01.2026.

A D. O. letter no. M - 11019 / 5 / 2026 - CG dated the 10th March, 2026 with respect to Judgement (D. No. 14452 / 2022 / SEC-X dated 3rd February, 2026) of the Hon'ble Supreme Court of India in the matter of *Yash Charitable Trust & Ors. versus Union of India & Ors.* (W.P. (C) No. 369 of 2022) concerning issues related to the use of stem cell therapy for the treatment of Autism Spectrum Disorder (ASD) is attached herewith.

2. All Medical Colleges / Institutions are requested to ensure compliance with the directions of the Hon'ble Supreme of India.

(Dr. Raghav Langer)
Secretary, National Medical Commission

Enclosure : D. O. letter no. M - 11019 / 5 / 2026 - CG dated the 10th March 2026 alongwith Annexure.

To,
Dean / Principal all the Medical Colleges / Institutions

Digitally signed by
Dr.Raghav Langer
Date: 25-03-2026
12:27:42



सत्यमेव जयते

डॉ. राजीव बहल, एमडी, पीएचडी.
DR. RAJIV BAHL MD, PhD



icmr
INDIAN COUNCIL OF
MEDICAL RESEARCH

सचिव, भारत सरकार

स्वास्थ्य अनुसंधान विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय एवं
सहाय्यिदेशक

भारतीय आयुर्विज्ञान अनुसंधान परिषद

Secretary, Government of India
Department of Health Research
Ministry of Health & Family Welfare
Director-General
Indian Council of Medical Research

D.O No. M-11019/5/2026-CG

Date: 10th March, 2026

Subject: Compliance with Hon'ble Supreme Court Judgment dated 30th January 2026

Dear Dr. Sheth,

This has reference to the judgment (D. No. 14452/2022/SEC-X dated 3rd February 2026) of Hon'ble Supreme Court of India in the matter of *Yash Charitable Trust & Ors. versus Union of India & Ors.* (W.P. (C) No. 369 of 2022), concerning issues related to the use of stem cell therapy for the treatment of Autism Spectrum Disorder (ASD). This judgement has important implications for giving stem cell therapy in India. The following is being conveyed to ensure compliance with the directions of the Hon'ble Court.

2. Stem cell therapies in routine practice shall be permitted only for disease conditions specified in the list of MoHFW approved indications as Standard Care (enclosed herewith).
3. Other than the approved indications, Stem cell therapy is permissible only in the context of research. If stem cells have undergone more than minimal manipulation, the research will be regulated by CDSCO. If stem cells have undergone less than minimal manipulation, research will be regulated by DHR, and in this case, in addition to the recommendations of the Institutional Ethics Committee (IEC) registered with DHR, the trials will have to be approved by the National Stem Cell Research Regulation Committee. The levels of manipulation for stem cell therapy have been defined by CDSCO.
4. Stem cell research shall be permissible only as part of an approved clinical trial. This research will be required to comply with all ICMR ethical guidelines including written informed consent, no cost to the patient and provision of compensation in case of injury or death.
5. Any stem cell treatment not included in the list of standard care indications, or not approved by CDSCO or DHR shall be deemed illegal and liable to action in accordance with

law. It is reiterated that biomedical research can only be approved by IEC registered with DHR.

6. You are requested to issue an advisory stating that **firstly, Routine practice should be restricted ONLY to the approved indications listed in ICMR/DHR/MoHFW guidelines. Secondly, beyond the approved list of disease conditions, Stem cell research needs to be conducted in compliance with ICMR Ethical Guidelines and with prior approval of either CDSCO or DHR depending on the level of manipulation of stem cells.**

7. This advisory may be circulated to all registered medical practitioners, medical colleges, and affiliated institutions under the jurisdiction of the Commission to ensure strict compliance. Any deviation from the above shall be liable to regulatory and legal action in accordance with law.

With warm regards,

With warm regards,

Yours Sincerely,

Rajiv Bahl
(Rajiv Bahl)

Dr Abhijat Chandrakant Sheth
Chairman, National Medical Commission
Pocket- 14, Sector - 8
Dwarka Phase -1, New Delhi - 110077

LIST OF MOHFW APPROVED DISEASE CONDITIONS FOR STEM CELL THERAPY
AS STANDARD CARE

Only safe and appropriately performed hematopoietic stem cell transplantation is recommended as Standard of Care for the following indications**. Mesenchymal stem cell transplantation is not recommended for any disease condition.

Adults:

1. Acute Myeloid Leukemia
2. Acute lymphoblastic leukemia
3. Chronic Myeloid Leukemia
4. Myelofibrosis
5. Myelodysplastic syndromes
6. Chronic lymphocytic leukemia
7. Diffuse Large b cell lymphoma
8. Follicular lymphoma
9. Mantle cell lymphoma
10. Peripheral T cell lymphoma
11. Hodgkin's Lymphoma
12. Multiple Myeloma
13. Acquired Severe Aplastic Anemia
14. Constitutional Severe Aplastic Anemia
15. Aplastic Anemia/Paroxysmal hemoglobinuria
16. Germ Cell tumors
17. Multiple Sclerosis
18. Systemic Sclerosis

Pediatrics:

1. Acute Myeloid Leukemia
2. Acute lymphoblastic leukemia
3. Chronic Myeloid Leukemia
4. Myelodysplastic syndromes/ Juvenile myelomonocytic leukemia
5. Non-Hodgkin Lymphoma
6. Hodgkin lymphoma
7. Primary immunodeficiency diseases
8. Mucopolysaccharidoses
9. Thalassemia/ SCD
10. Osteopetrosis
11. Acquired Severe Aplastic Anemia
12. Inherited Bone Marrow failure syndromes
13. Ewings Sarcoma
14. Neuroblastoma

**For details, refer to Hematopoietic Cell Transplantation Guidelines 2021 (Annexure I- Standard of Care only)