INTERNATIONAL SOCIETY FOR STEM CELL RESEARCH

Dr. Kiran Kumar Karlapu
Director (Drugs Regulation)
Ministry of Health and Family Welfare
Government of India
Room No. 407, A Wing
Nirman Bhavan
New Delhi, India 110011

14 November 2025

Dear Director Karlapu,

On behalf of the International Society for Stem Cell Research (ISSCR), I write to share our comments regarding the draft amendments to the Drugs Rules, 1945, to strengthen the Government of India's regulatory framework for cell- and stem cell-derived products. The ISSCR is the leading professional organization of stem cell scientists, representing nearly 5,000 members around the world, including in India. Our members are scientists, clinicians, ethicists, and educators dedicated to the responsible advancement of stem cell research and its translation to the clinic. The ISSCR commends the Government of India for taking steps to strengthen its regulatory framework for advanced therapeutic products, including cell- and stem cell-derived products.

As stem cell research and its translation to the clinic advances, ensuring a regulatory framework that encourages responsible innovation while safeguarding patient well-being is essential. The Government of India should maintain and enforce rigorous review pathways to ensure that stem cell-based products conform to the highest standards of evidence-based medicine. Further, these products should be subjected to appropriate manufacturing regulations to ensure their quality and safety.

Without such guardrails, patients face significant health and financial risks from unproven cell- and stem cell-derived products. Severe adverse events, including lifelong disability and death, arising from the administration of these products have been documented across the world, including in India. The Indian Council of Medical Research has identified the need for evidence-based use of cell- and stem cell-derived products, noting in a recent report that "Several instances of public exploitation and grievances from members of the public have been received by the ICMR and other government agencies" regarding unproven cell and stem cell-derived products, with demands for action to curb such practices.

To that end, the proposed Drugs Rules Amendments, 2025, advances regulatory clarity for cell- and stem cell-derived products in India and would help to promote the rigorous regulatory reviews necessary to protect patients. Again, we commend the Government of India for taking these steps and would welcome the opportunity for further dialogue.

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Respectfully,

Hideyuki Okano, MD, PhD
President
ISSCR