Steps taken for Promotion and Regulation of Regenerative Medicines

Union Health Ministry has Issued Comprehensive Guidelines to Promote Safe and Evidence-Based Use of Regenerative Medicines

Department of Biotechnology supports fundamental and translational research towards development of indigenous regenerative medicine technologies involving stem cell/in-vitro systems for various diseases including hematological and genetic disorders

Biotechnology Research and Innovation Council - Institute for Stem Cell Science and Regenerative Medicine, an autonomous institute under DBT has contributed to the advancement of translational regenerative medicine in India through innovations

Department of Health Research has established mechanism to facilitate and promote biomedical research and conduct of clinical trials in the country through ethics committees registered with DHR

ICMR promotes indigenous research and innovation in regenerative medicine through support for basic, preclinical and clinical research, development of indigenous technologies, and generation of scientific evidence through various funding programmes

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The following guidelines on regenerative medicines have been issued and are available in public domain-

i. Centre for Evidence Based Guidelines, Ministry of Health and Family Welfare has issued *'Evidence based guidelines for the use of stem cell therapy'* in 2025-2026 regarding the efficacy and safety of stem cell therapy in various disease indications. These recommendations were formulated after careful

consideration of the available evidence based on the methodology as described by international agencies like the World Health Organization (WHO) and National institute for Health and Care Excellence (NICE) in UK. These Guidelines can be accessed online at:- https://www.dhr.gov.in/offerings/schemes-and-services/details/centre-for-evidence-based-guidelines-EzN1MTMtQWa

ii. Indian Council of Medical Research (ICMR) has informed that it issued a document in 2023 on '*Guidelines for Umbilical Cord Blood Banking Collection, Processing, Testing, Storage, Banking and Release for Clinical Application'*. It can be accessed online at: https://www.icmr.gov.in/icmrobject/custom_data/pdf/resource-guidelines/GUCBB_F.pdf

iii. ICMR has issued "*National Guidelines for Hematopoietic Cell Transplantation (NGHCT)"* in 2021. This document can be accessed online at:- https://www.icmr.gov.in/icmrobject/custom_data/pdf/resource-guidelines/Nat_Guide_HCT.pdf

iv. ICMR in collaboration with Department of Biotechnology (DBT) has issued *"National Guidelines for Gene Therapy Product Development and Clinical Trials"* in 2019 to guide and enable the stakeholders to comprehend and comply with the regulatory requirements for research and development of Gene Therapy Products in India. These can be accessed online at:- https://www.icmr.gov.in/icmrobject/custom_data/pdf/resource-guidelines/guidelines_GTP.pdf

v. ICMR along with DBT has also issued *'National Guidelines for Stem Cell Research (NGSCR-2017)'*. This document provides guidance to all stakeholders including scientists, clinicians and industry and can be accessed online (https://www.icmr.gov.in/icmrobject/custom_data/pdf/resource-guidelines/Guidelines_for_stem_cell_research_2017.pdf).

Further, DBT has informed that it supports fundamental and translational research towards development of indigenous regenerative medicine technologies involving stem cell/in-vitro systems for various diseases including hematological and genetic disorders. Department's autonomous institute, Biotechnology Research and Innovation Council – Institute for Stem Cell Science and Regenerative Medicine (BRIC-inStem) has also contributed to the advancement of translational regenerative medicine in India through innovations. For example, country's first-in-human gene therapy clinical trial was conducted by the Centre for Stem Cell Research (CSCR), Vellore, a unit of BRIC-inStem, in collaboration with Christian Medical College (CMC), Vellore.

The Department of Health Research (DHR) has established mechanism to facilitate and promote biomedical research and conduct of clinical trials in the country through ethics committees registered with DHR. The National Stem Cell Research Regulation Committee (NSRC) provides oversight of clinical stem cell research involving minimally manipulated stem cells. All proposals approved by an Institutional Ethics Committee for such research must be forwarded to NSRC before the research commences. Clinical trials and manufacture of regenerative medicine products that fall within the ambit of the Drugs and Cosmetics Act, 1940 and the New Drugs and Clinical Trials Rules, 2019 continue to be regulated by Central Drugs Standard Control Organization (CDSCO).

ICMR promotes indigenous research and innovation in regenerative medicine through support for basic, preclinical and clinical research, development of indigenous technologies, and generation of scientific evidence through various funding programmes. DBT has informed that it also nurtures and caters support to develop solutions using cell and gene-based therapies to reduce the high developmental cost burden through its multidisciplinary research and advanced research programmes.

The Union Minister of State for Health and Family Welfare, Shri Prataprao Jadhav stated this in a written reply in the Rajya Sabha today.

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HFW/PQ-Steps taken for Promotion and Regulation of Regenerative Medicines/11 August 2026/4

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