GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH RESEARCH

RAJYA SABHA
UNSTARRED QUESTION NO. 2666
TO BE ANSWERED ON 11TH AUGUST, 2026

REGULATORY FRAMEWORK FOR REGENERATIVE MEDICINE

2666. DR. AJEET MADHAVRAO GOPCHADE:

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether Government has assessed the therapeutic potential and public-health relevance of regenerative medicine, including stem cell therapy, gene therapy, tissue engineering and biomaterials, for diseases with limited treatment options;

(b) whether international best practices, including regulatory frameworks adopted by countries such as South Korea, have been examined;

(c) whether Government proposes to establish a dedicated, ethical and time-bound regulatory framework to promote research, clinical trials and indigenous manufacturing in this sector; and

(d) whether measures are under consideration to reduce high development costs and ensure affordable patient access to regenerative therapies?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI PRATAPRAO JADHAV)

(a) and (b): The following guidelines have been issued and are available in public domain to address the relevant issues-

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.

(c): 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 Organisation (CDSCO).

(d): 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.

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