GOVERNMENT OF INDIA
MINISTRY OF SCIENCE & TECHNOLOGY
DEPARTMENT OF BIOTECHNOLOGY

RAJYA SABHA
UNSTARRED QUESTION NO. 3169
ANSWERED ON 19.03.2026

Self reliance in CRISPR and gene editing

3169. SHRI K. R. SURESH REDDY:

Will the Minister of **SCIENCE AND TECHNOLOGY** be pleased to state:

(a) the steps being taken to ensure the regulatory approval, safety and ethical deployment of CRISPR-based therapies in India;

(b) the details of steps taken to support large-scale manufacturing and commercialization of indigenous gene-editing products, ensuring affordability and widespread access; and

(c) the mechanisms for regulation of gene editing in the country?

ANSWER

MINISTER OF STATE (INDEPENDENT CHARGE) FOR THE MINISTRY OF SCIENCE AND TECHNOLOGY & EARTH SCIENCES
(DR. JITENDRA SINGH)

(a) To ensure regulatory approval, safety, and ethical deployment of CRISPR-based therapies in India, regulatory bodies CDSCO, ICMR, and DBT have issued the "National Guidelines for Gene Therapy Product Development and Clinical Trials, 2019", guiding stakeholders to comprehend and comply with regulatory requirements for research and development of gene therapeutic products (GTPs) in India.

(b) The Department, through various medical related programs has been steadily advancing the precision medicine ecosystem with a strong emphasis on next-generation cell and gene therapies that includes approaches to modify cells or genetic material through gene augmentation, gene editing, gene silencing, and other cell-based approaches.

The first-in-human Phase-I clinical trial for gene therapy of Hemophilia A was supported by the Department and has shown clinically significant outcomes, whereby, stable production of Factor VIII, has been observed, offering potential treatment for long-term reduction of bleeding episodes. The results of this pioneering study have been published in

the prestigious New England Journal of Medicine. Efforts for further studies in human subjects are underway.

The BioE3 (Biotechnology for Economy, Environment, and Employment) Policy, approved by the Union Cabinet on August 24, 2024, aims to transform India into a global biomanufacturing hub, promoting sustainable growth and reducing import reliance. Implemented by the Department of Biotechnology (DBT), it focuses on high-performance biomanufacturing for chemicals, enzymes, agriculture, and therapeutics.

This policy being implemented by DBT and BIRAC jointly is providing R&D and pilot-scale manufacturing support to biotech Startups, MSMEs through cutting edge infrastructure, public- private partnerships and institutional support by facilitating synergy between industry and research institutes.

Under precision biotherapeutic vertical of the BioE3 policy, academia projects recommended for support includes development of gene therapies for hematological diseases such as Hemophilia A; Gene editing therapy for Thalassaemia; Proof-of-Concept of mRNA based protein replacement therapy for Hemophilia B. In the domain of CAR-T Cell therapies, academia projects are focused on development of Bi-specific CAR in Multiple Myeloma and proof-of-concept demonstration for in situ CAR-T cell reprogramming *via* viral vector delivery in a humanized mouse model.

DBT is also supporting a research grant at Tata Institute for Genetics and Society, Bangalore for indigenous development of mRNA-based *in vivo* gene-editing platform for propionic academia (a rare, inherited metabolic disorder).

Under the BioE3 Policy, the मूलांकुर BioEnablers scheme has facilitated the creation of biomanufacturing hubs; offering state-of-the-art infrastructure for large-scale, compliant, and cost-effective production of clinical-grade cell and gene therapies (CGTs), and supporting the translation of laboratory innovations into clinically and commercially viable therapies.

A public sector undertaking of DBT, Biotechnology Industry Research Assistance Council supports startups across biotechnology domains through structured funding, incubation support, and mentoring to facilitate technology development, scale-up, and commercialization, thereby enabling affordable and accessible biotechnology solutions, including gene-editing technologies. Some of the key programs initiated by BIARC include:

- Biotechnology Ignition Grant (BIG),
- Sustainable Entrepreneurship and Enterprise Development (SEED) Fund,
- Launching Entrepreneurial Driven Affordable Products (LEAP) Fund, and
- Public-Private Partnership (PPP)

Through BIRAC support was provided for indigenous development and clinical trial of two anti-CD19 directed autologous Chimeric Antigen Receptor T (CAR-T) cell therapy products (Qartemi& NexCAR19). These are currently commercially available and in use for treating specific blood cancers.

ICMR is supporting several research projects from academia, start-ups, and industry for the indigenous development of affordable gene therapy tools, ensuring widespread access through various grant initiatives. These include the Investigator Initiated First-in-the-world-challenge grant, Small Grant, Intermediate grant, Centre for Advanced Research, and ICMR-initiated National Health Research Priority projects.

Additionally, ICMR's initiatives such as "Biomedical Innovations Patent Mitra" facilitate patent filing and technology transfer to industry, "MedTechMitra" enables regulation-compliant development, and the "Indian Clinical Trial and Education Network (INTENT)" with 85 trial sites supports regulation-compliant clinical trials. These efforts are supporting the large-scale manufacturing and commercialization of indigenous gene-editing products, ensuring affordability and widespread access.

CSIR-Institute of Genomics and Integrative Biology (CSIR-IGIB) is working with Serum Institute, Pune, towards commercialisation of the gene therapy, having executed a technology transfer agreement in November 2025 for clinical translation and upscaling of the novel gene therapy developed at CSIR-IGIB.

These programs strengthen translational research, infrastructure development, and industry-academia collaboration to create a sustainable pipeline of indigenous CGTs and to ensure that advanced gene-editing therapies are affordable and have widespread access.

(c) The regulatory frameworks governing genetic engineering, including CRISPR-based therapies, a type of gene-editing, are administered through a coordinated effort by multiple authorities in India. The frameworks in place include several guidelines and regulations that ensure the safe and ethical development of these therapies.

The Biosafety Framework established under the Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro-organisms/Genetically Engineered Organisms or Cells, 1989 (the "Rules, 1989"), which notified under the Environment (Protection) Act, 1986 (EPA). The EPA is administered by the Ministry of Environment, Forests and Climate Change (MoEF&CC). Development of CRISPR-based therapies is conducted under strict contained-laboratory conditions. During this phase, regulatory oversight is exercised by Institutional Biosafety Committees (IBSCs), and by the Review Committee on Genetic Manipulation (RCGM).

Under the Biosafety framework, the regulatory oversight of such therapies is guided by the "Regulations and Guidelines for Recombinant DNA Research and Biocontainment, 2017" and "Handbook for Institutional Biosafety Committees (IBSC), 2020".

The gene-editing led healthcare technologies (including CRISPR-based therapies) are subject to stringent oversight by the Central Drugs Standard Control Organisation (CDSCO)under the New Drugs and Clinical Trials (NDCT) Rules, 2019 of the Drugs and Cosmetics Act, 1940. Additionally, they are governed by a framework of ethical guidelines and regulatory standards, primarily ensuring the protection of human research participants through Institutional Ethics Committees (IECs). These committees operate under the ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants (2017) and the New Drugs and Clinical Trials Rules (2019).

Similarly, the National Guidelines for Gene Therapy Product Development and Clinical Trials (2019), released by ICMR, CDSCO & DBT, provide a framework for safe, ethical development and testing of gene therapy products.

After successful clinical trials, a comprehensive dossier on quality, safety, and efficacy is submitted to CDSCO for final marketing approval.

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