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New Rules Bring Gene and Cell Therapies Under Central Licensing

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WHY IN NEWS

Reported through July 2 to 3, 2026, the Central Government notified the Drugs (Eighth Amendment) Rules, 2026 (in force from June 29, 2026), bringing gene therapies, cell and stem-cell products and xenografts under a single national licensing framework.

WHAT THE AMENDMENT DOES

The Central Government amended the Drugs Rules, 1945 through the Drugs (Eighth Amendment) Rules, 2026. The amendment brings a new class of frontier medical products under the Central License Approving Authority (CLAA) framework, so that they are regulated uniformly across the country by a central authority rather than differently by each state.

These frontier products are collectively termed Advanced Therapeutic Products (ATPs).

PRODUCT CATEGORY	PLAIN-LANGUAGE MEANING	EXAMPLE USE
Cell and stem-cell-derived products	Therapies built from living human cells	Regenerative medicine
Gene therapeutic products	Treatments that add, edit or silence genes, including CAR-T and gene-editing therapies	Certain cancers, inherited disorders
Xenografts	Products made from animal tissue implanted in humans	Heart valves, orthopaedic grafts

A gene therapy works by changing a patient's genetic material to treat disease. CAR-T (Chimeric Antigen Receptor T-cell) therapy re-engineers a patient's own immune cells to attack cancer. A xenograft uses tissue from another species, for example a pig or cow heart valve, in a human patient.

The Regulatory Chain

The change follows a clear statutory (https://ujiyari.com/vocab/statutory/) hierarchy, which is important for both Prelims and Mains:

ELEMENT	DETAIL
Parent statute	Drugs and Cosmetics Act, 1940
Rules amended	Drugs Rules, 1945 (via the Eighth Amendment Rules, 2026)
Advisory body consulted	Drugs Technical Advisory Board (DTAB)
Regulator	Central Drugs Standard Control Organisation (CDSCO)
Licensing authority	Central License Approving Authority (CLAA)
In force from	June 29, 2026

The DTAB is the highest statutory body on technical drug matters under the Drugs and Cosmetics Act, 1940, and the amendment was made after its consultation. The CDSCO, headed by the Drugs Controller General of India (DCGI), is India's national drug regulator; the CLAA function within it now approves licences for these advanced therapies.

WHY THIS WAS NEEDED

Until now, cell, gene and tissue-based therapies fell into regulatory grey zones, sometimes handled inconsistently by different states. Advanced therapies involve complex manufacturing, specialised scientific evaluation and long-term safety monitoring, so they need enhanced and uniform scrutiny compared with conventional pills. Bringing them under central CLAA licensing ensures a single national standard, clearer accountability and better patient safety, while also giving legitimate innovators a defined legal pathway.

ANALYSIS AND WAY FORWARD

The reform sits at the intersection of patient safety and innovation. Too little regulation risks unsafe or unproven cell and gene products being sold to desperate patients, a real problem India has faced with unapproved stem-cell clinics. Too much or too slow regulation can push innovators abroad and delay life-saving therapies. A central, science-led framework aims to strike this balance.

The move also supports India's BioE3 policy (Biotechnology for Economy, Environment and Employment, approved in 2024), which explicitly promotes precision biotherapeutics such as cell and gene therapy and mRNA medicines. A clear regulatory regime is a precondition (https://ujiyari.com/vocab/precondition/) for building a domestic advanced-therapy industry.

An important ethics dimension (a GS4 angle) arises here. Gene-editing therapies raise questions about consent, equity of access given very high costs, and the line between treating disease and human enhancement, especially where edits could be heritable. Xenotransplantation raises animal-welfare concerns and cross-species infection risk. The way forward includes transparent pricing and access mechanisms, strong pharmacovigilance and long-term patient registries, ethical-review safeguards for germline editing, and skilling of regulators and clinicians to evaluate these complex products.

UPSC RELEVANCE

GS Paper 3: Developments in biotechnology and their applications; issues relating to intellectual property, indigenisation (https://ujiyari.com/vocab/indigenisation/) and regulation of frontier science.

GS Paper 2: Government policies and interventions for development in the health sector; issues relating to health, regulation and patient safety.

Prelims pointers:

- Drugs (Eighth Amendment) Rules, 2026 amend the Drugs Rules, 1945; parent Act is the Drugs and Cosmetics Act, 1940; in force from June 29, 2026.
- Brings cell/stem-cell products, gene therapies (including CAR-T and gene-editing) and xenografts under the Central License Approving Authority (CLAA); collectively called Advanced Therapeutic Products (ATPs).
- Regulator is CDSCO; advisory body is the DTAB (Drugs Technical Advisory Board).
- CAR-T = Chimeric Antigen Receptor T-cell therapy; xenograft = animal-tissue product used in humans (e.g., heart valves).

Mains question: "Frontier therapies such as gene editing and xenotransplantation demand a regulatory framework that protects patients without stifling innovation." In this light, examine the significance of bringing Advanced Therapeutic Products under central licensing in India. (15 marks, 250 words)

FACTS CORNER

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The rule: Drugs (Eighth Amendment) Rules, 2026, amending the Drugs Rules, 1945; in force from June 29, 2026, reported July 2 to 3, 2026.

What it covers: cell and stem-cell-derived products, gene therapeutic products (including CAR-T and gene-editing therapies) and xenografts (animal-tissue products such as heart valves), collectively termed Advanced Therapeutic Products (ATPs).

Framework: brings these products under the Central License Approving Authority (CLAA) for uniform national regulation, after consultation with the Drugs Technical Advisory Board (DTAB).

Statute and regulator: parent law is the Drugs and Cosmetics Act, 1940; the regulator is the Central Drugs Standard Control Organisation (CDSCO), headed by the Drugs Controller General of India (DCGI).

Definitions: CAR-T (Chimeric Antigen Receptor T-cell) therapy re-engineers a patient's immune cells to fight cancer; a xenograft uses animal tissue in a human patient.

Policy link: supports India's BioE3 policy (Biotechnology for Economy, Environment and Employment, 2024), which promotes precision biotherapeutics including cell and gene therapy.

Ethics angle (GS4): raises questions on access and cost equity, consent, heritable (germline) gene edits, animal welfare and cross-species infection risk in xenotransplantation.

Sources: The Hindu (https://www.thehindu.com), PIB (https://www.pib.gov.in), CDSCO (https://cdsco.gov.in)

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