

3. Biotherapeutics – Governance

How is the global precision medicine market shaping up? Precision biotherapeutics offer personalized treatments based on genetic and molecular profiles to combat complex diseases, yet India faces significant hurdles in regulation and infrastructure despite classifying it as a priority sector under the new BioE3 policy.

Concept & Definition

Core Definition – Precision biotherapeutics refers to advanced medical interventions that are specifically designed and optimised based on a patient’s unique profile, covering their –

1. Genetic makeup.
2. Molecular structure.
3. Cellular characteristics.

The Convergence – It represents a multidisciplinary field that brings together three critical domains to identify and rectify the root cause of illness –

1. Genetic Science.
2. Molecular Biology.
3. Data Analytics.

2. Key Technologies Involved

The field relies on a combination of cutting-edge technologies to deliver targeted treatments –

Genomic and Proteomic Analysis – Involves decoding a person’s genetic sequences and protein signatures.

Purpose – To identify specific mutations or dysfunctions that are the root cause of the disease.

Gene Editing Therapies – Focuses on directly modifying genes to correct underlying genetic defects.

Example – CRISPR-based treatments used for curing blood disorders.

mRNA and Nucleic Acid Therapeutics – Utilizes RNA molecules as instructions.

Mechanism – These molecules instruct cells to either produce specific beneficial proteins or suppress the production of harmful ones.

Monoclonal Antibodies and Biologics – These are laboratory-engineered molecules.

Function – They are designed to bind to precise disease targets, such as specific cancer cells or viral proteins, sparing healthy cells.

AI-Driven Drug Discovery – Leverages Big Data and Machine Learning (ML).

Application – Used to predict how potential drug molecules will interact within the human body, speeding up the development process.

3. The Necessity for Precision Biotherapeutics in India

There is a growing urgency to adopt these therapies due to the following factors –

Rising Burden of Complex Diseases – Non-communicable diseases (NCDs) like diabetes, cardiovascular illnesses, and cancers are surging.

Statistic – NCDs now account for nearly 65% of deaths in India.

Need for Clinical Precision (Reduction of Collateral Damage) – Conventional therapies often harm healthy tissues along with diseased ones.

Benefit – Targeted biologics or gene/cell therapies offer higher precision, significantly reducing side effects compared to traditional methods.

India’s Unique Genetic Diversity – India possesses a highly genetically diverse population.

Issue – "One-size-fits-all" global drugs may not work equally effectively across different Indian sub-populations.

Inefficacy of Foreign Solutions – Pharmaceuticals developed and tested in foreign countries (on different genetic pools) might not work effectively in the specific Indian biological context.

Comparison – Conventional vs. Precision Therapy

Feature	Conventional Therapy (e.g., Chemotherapy)	Precision Biotherapeutics
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Ap- proach	"One-size-fits-all"; generalized treatment.	tailored to the patient's genetic/molecular profile.
Impact	Often causes significant collateral damage to healthy cells.	Highly precise; targets only disease markers.
Efficacy	Variable efficacy across diverse populations.	Higher efficacy as it addresses the root cause.

4. Challenges in Implementation

Despite the potential, several structural barriers exist –

Lack of Regulatory Framework – There is no clear, unified regulatory framework for the diverse technologies underlying gene and cell therapies.

Limitation – Current guidelines restrict the use of emerging technologies for therapeutic purposes without clearly defining the scope of therapy.

Cost & Affordability Issues – These therapies are extremely expensive to develop and manufacture.

Consequence – There is a high risk of these treatments remaining inaccessible to large segments of India's lower and middle-income population.

Infrastructure & Capacity Gaps – India currently suffers from limited local manufacturing capacity specifically for high-end biologics and advanced therapies.

5. India's Strategic Efforts

Both the government and private sectors are taking steps to build this ecosystem –

Policy Priority (Department of Biotechnology) – Precision biotherapeutics has been identified as one of the six focus areas. It falls under the Biotechnology for Economy, Environment, and Employment (BioE3) policy.

Genetic Mapping & Research – Leading Indian institutions are working to map genetic diversity and understand disease susceptibility across Indian populations.

Key Institutions Involved – Institute of Genomics and Integrative Biology (IGIB) & National Institute of Biomedical Genomics (NIBG) & Translational Health Science and Technology Institute (THSTI).

Private Sector Participation – Several biopharma companies in India have begun exploring and investing in precision therapy development.

6. Way Ahead & Future Outlook

Global Market Potential – The global market for precision medicine is projected to exceed \$22 billion by 2027, offering a massive economic opportunity.

India's Competitive Advantage – India is positioned to become a potential hub for affordable precision therapies due to three strengths –

1. Skilled workforce.
2. Strength in data analytics.
3. Cost advantage in manufacturing.

Manufacturing Hub – India can leverage its existing expertise in biologics manufacturing to support cutting-edge therapies for both domestic use and international exports.

Ethical & Data Safeguards

Urgent Requirement – There is a critical need for strict data protection and consent frameworks.

Risk – Without these, sensitive genomic information could be misused.

Source – [https://epaper.thehindu.com/ccidist-
ws/th/th_international/issues/156846/OPS/GSVF531PI.1+GSLF66DED.1.html](https://epaper.thehindu.com/ccidist-
ws/th/th_international/issues/156846/OPS/GSVF531PI.1+GSLF66DED.1.html)