1. Global Biopharma Hub- Science & Technology

Union Budget 2026–27 proposed the Biopharma SHAKTI with an outlay of Rs. 10,000 crores over five years, aimed at strengthening India's ecosystem for production of biologics and biosimilars

Biopharma- Concept and Scope

Biopharma (Biopharmaceuticals) refers to the segment of the pharmaceutical industry that develops therapeutic products using living biological systems rather than purely chemical synthesis. These products are derived from human cells, animal cells, microbes (bacteria, yeast), fungi, or genetically engineered organisms. Biopharma products are typically high-value, high-complexity medicines requiring advanced R&D, stringent quality control, and sophisticated regulatory oversight.

Major categories include-

1. Vaccines (traditional and mRNA-based)
2. Monoclonal antibodies and antibody-drug conjugates
3. Gene therapies and cell-based therapies
4. Recombinant proteins (e.g., insulin, growth hormones)
5. Biosimilars (biological equivalents of patented biologics)

Compared to small-molecule drugs-

1. Biopharma products have higher development costs
2. Longer regulatory pathways
3. Greater dependence on skilled human capital and advanced infrastructure

Strategic Importance of Biopharma for India

Biopharma is a knowledge-intensive and innovation-driven sector, aligning with India's demographic advantage and STEM talent base.

Global biopharma markets are expanding rapidly due to-

1. Ageing populations
2. Rise in non-communicable diseases
3. Demand for personalised and precision medicine

India already has strengths in-

1. Vaccine manufacturing
2. Biosimilars
3. Cost-efficient clinical trials

Government Aim-

1. Transform India into a leading global biopharma hub
2. Capture 5% of the global biopharmaceutical market
3. Move up the value chain from generics to innovation-led biologics

Key Budget Announcements for Biopharma (Union Budget 2026–27)

Biopharma SHAKTI Initiative- Biopharma SHAKTI is designed as a targeted industrial and innovation push for biologics.

Core objectives include-

1. Supporting domestic development and manufacturing of high-value biologics
2. Reducing import dependence on critical biologics
3. Integrating Indian firms into global biologics supply chains

The scheme strengthens India's role in-

1. Vaccines
2. Advanced therapeutics
3. Biosimilars for global markets

Expansion of Pharmaceutical Education and Human Capital

Establishment of three new National Institutes of Pharmaceutical Education and Research (NIPERs). Upgradation of seven existing NIPERs with advanced research and training facilities.

This addresses-

1. Shortage of highly specialised biopharma professionals
2. Need for expertise in biologics R&D, GMP manufacturing, clinical trials, and regulation

It supports the creation of a biopharma-ready workforce across-

1. Research scientists
2. Regulatory experts
3. Bioprocess engineers

Strengthening the Clinical Research Ecosystem

Proposal to develop over 1,000 accredited clinical trial sites across India.

This will-

1. Enhance India's capacity to conduct Phase I–IV trials for biologics and biosimilars
2. Improve credibility of Indian clinical data globally
3. Reduce time and cost of drug development

A strong clinical trial ecosystem is critical because- Biologics require extensive safety and efficacy evaluation. Global acceptance depends on robust trial standards

Regulatory Capacity Building

Strengthening of the Central Drugs Standard Control Organisation (CDSCO) through-

1. Induction of specialised scientific and technical personnel
2. Upgradation of regulatory infrastructure

Focus areas include-

1. Faster approvals without compromising safety
2. Alignment of approval timelines with global regulators such as the US FDA and EMA

This improves-

1. Ease of doing business
2. Investor confidence
3. Global market access for Indian biologics

India's Pharmaceutical and Biopharma Ecosystem- Context

India is-

1. The largest supplier of generic medicines globally
2. A major vaccine producer

However, traditional strengths lie in small-molecule generics, not complex biologics.

The policy thrust is therefore to-

1. Shift from volume-driven generics to value-driven biopharma
2. Build end-to-end capabilities from discovery to commercialization

Major Government Initiatives Supporting Biopharma

National Biopharma Mission (NBM)

The National Biopharma Mission – Innovate in India (i3) was launched in 2017.

Objective- Transform India into a $100 billion global biotech industry. Implemented by Biotechnology Industry Research Assistance Council (BIRAC). Co-funded by the World Bank.

Focus areas-

1. New vaccines
2. Biotherapeutics
3. Diagnostics
4. Medical devices

Emphasis on-

1. Affordability
2. Accessibility
3. Indigenous innovation

BIRAC-Led Innovation Support

BIRAC was established in 2012 under the Department of Biotechnology (DBT). It acts as a bridge between academia, startups, and industry.

Support mechanisms include-

1. Grant funding
2. Incubation infrastructure
3. Mentorship and industry partnerships

BIRAC has played a crucial role in-

1. Nurturing biotech startups
2. Translating lab research into marketable products

Manufacturing and Industrial Strengthening Measures

Production Linked Incentive (PLI) Scheme for Pharmaceuticals- Encourages domestic manufacturing of high-value drugs

Strengthening of Pharmaceutical Industry (SPI) Scheme- Upgrades infrastructure and quality standards

Bulk Drug Parks Scheme- Reduces dependence on imported active pharmaceutical ingredients (APIs)

These schemes collectively-

1. Lower manufacturing costs
2. Improve supply chain resilience
3. Enhance global competitiveness

PRIP Scheme (Pharma-MedTech)

Promotion of Research and Innovation in Pharma-MedTech (PRIP) launched in 2023.

Objective- Transition India towards an innovation-driven Pharma-MedTech ecosystem

Supports-

1. Industry-academia collaboration
2. Advanced research platforms
3. Commercialisation of indigenous technologies

BioE3 Policy

BioE3 (Biotechnology for Economy, Environment and Employment) Policy, approved in 2024.

Focus areas-

1. Biomanufacturing
2. Bio-AI hubs
3. Bio foundries

The policy aligns biotechnology with-

4. Economic growth
5. Environmental sustainability
6. Employment generation

Contributes to the vision of Viksit Bharat.

Bio-RIDE Scheme

Launched in 2024 by merging earlier DBT umbrella schemes. Full form- Biotechnology Research Innovation and Entrepreneurship Development (Bio-RIDE). Introduced a new component- Biomanufacturing and Bio foundry.

Three broad components-

1. Biotechnology Research and Development (R&D)
2. Industrial and Entrepreneurship Development (I&ED)
3. Biomanufacturing and Bio foundry

Aims to create an integrated biotech innovation pipeline.

Conclusion

India's biopharma strategy reflects a coordinated, multi-dimensional policy approach.

The focus spans-

1. Research and innovation
2. Skilled human capital
3. Advanced manufacturing
4. Robust regulation
5. Startup and entrepreneurship support

The Biopharma SHAKTI scheme, announced in the Union Budget 2026–27, emerges as a critical policy lever to-

1. Accelerate India's transition from generics to biologics
2. Strengthen global positioning
3. Build a resilient, innovation-driven biopharma ecosystem
4. Collectively, these measures place biopharma at the core of India's future industrial and health security strategy.

Source- https-//www.pib.gov.in/PressNoteDetails.aspx?NoteId=157147&ModuleId=3&reg=3&lang=2