4. Biopharma Shakti – Science & Technology

The Union Budget 2026 has introduced a transformative initiative, Biopharma SHAKTI, marking a strategic pivot in India's pharmaceutical landscape. This program specifically targets the development of biologics and biosimilars while accelerating the transition from traditional animal testing to advanced Non-Animal Methodologies (NAMs).

1. Background and Definitions

What are Biologics?

Biologics are large, complex medicines derived from living organisms (such as bacteria, yeast, or mammalian cells) using biotechnology, including recombinant DNA technology.

Nature- Unlike traditional drugs which are chemically synthesized "small molecules," biologics are protein-based therapies.

Complexity- Their structure is sensitive to the manufacturing environment, making them difficult to characterize and replicate exactly.

What are Biosimilars?

A biosimilar is a biologic product that is "highly similar" to an already approved "reference" biologic.

Similarity, not Identity- Because they come from living cells, biosimilars are not exact copies (unlike generic versions of chemical drugs) but must show no clinically meaningful differences in safety or efficacy.

Purpose- They increase the affordability of expensive biological treatments, particularly in oncology and immunology.

What are Non-Animal Methodologies (NAMs)?

NAMs are scientific approaches—including in vitro (cell-based), in silico (computational), and human-based models—designed to replace, reduce, or refine animal testing.

Technologies- These include Organ-on-a-Chip (microchips lined with human cells), Organoids (3D tiny organ-like structures), and 3D Bioprinting.

2. Biopharma SHAKTI- The Strategic Initiative

Biopharma SHAKTI stands for Strategy for Healthcare Advancement through Knowledge, Technology and Innovation.

1. Financial Outlay- ₹10,000 crore allocated over five years (announced in Union Budget 2026).
2. Nodal Ministry- Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers.
3. Focus Area- Domestic production and R&D for advanced Biologics and Biosimilars.
4. Core Objective- To enhance India's healthcare security, foster industrial competitiveness, and build a self-reliant ecosystem for high-end biopharmaceuticals.

3. Comparison- Traditional Drugs vs. Biologics

Feature	Traditional Chemical Drugs	Biologics
Size	Small, simple molecules.	Large, complex molecules.
Structure	Well-defined and stable.	Complex and sensitive to heat/shear.
Production	Chemical synthesis (predictable).	Living cell cultures (variable).
Immunogenicity	Generally low risk.	High potential for immune response.
Example	Aspirin, Paracetamol.	Insulin, Monoclonal Antibodies.

4. Types of Biopharmaceuticals Covered

The initiative supports a wide array of biological therapies-

Monoclonal Antibodies (mAbs)- Laboratory-made proteins that mimic the immune system's ability to fight off harmful pathogens like cancer cells (e.g., *Adalimumab*).

Vaccines- Preparations that stimulate the body's immune response to prevent specific diseases (e.g., COVID-19 vaccines).

Recombinant Proteins- Artificially produced human proteins used to treat deficiencies, such as insulin for diabetes.

Gene & Cell Therapies- Cutting-edge treatments that involve modifying or replacing defective genes or using living stem cells to treat chronic conditions.

5. The Shift to Non-Animal Methodologies (NAMs)

The push for NAMs under the New Drugs and Clinical Trials (Amendment) Rules, 2023 and Biopharma SHAKTI is driven by three critical factors-

A. Ethical and Moral Imperatives

There is a global and domestic movement to reduce animal suffering. Ethical concerns regarding the welfare of laboratory animals have led to stricter international regulations.

B. Scientific Limitations of Animal Models

Animals often fail to replicate human physiology accurately, leading to "false positives" in safety tests-

The 2006 Northwick Park Trial- The drug Tregalizumab caused multiple organ failure in 6 human volunteers despite being proven "safe" in animal trials.

The 2022 Semorinemab Failure- An Alzheimer's drug succeeded in mouse models but failed to show efficacy in a trial of 457 human patients.

C. Technological Advancements

Modern technology allows for more accurate human-relevant systems-

1. In Silico Models- Advanced AI and computational simulations that predict drug interactions.
2. Organ-on-a-Chip- These devices simulate the physiological environment of human organs, providing data that is far more relevant to human biology than animal data.

6. Way Forward- Strengthening the Ecosystem

To maximize the impact of the ₹10,000 crore outlay, India must focus on the following-

Regulatory Integration- Formally integrate NAMs into the drug approval pathway, following the UK's model for phasing out animal testing.

Shared Infrastructure- Use Biopharma SHAKTI funds to create "Common Testing Facilities" so MSMEs and startups can access expensive NAM technologies like 3D bioprinters.

Economic Incentives- Highlight the cost-efficiency of NAMs. Research shows that Organ-on-chip tech can reduce drug development costs by 10–26% and speed up lead optimization by 19%.

Entrepreneurial Support- Scale up support through agencies like DBT (Department of Biotechnology) and ICMR to encourage biopharma startups to adopt "animal-free" research from the inception phase.

7. Conclusion

The Biopharma SHAKTI initiative represents a double-win for India- it positions the nation as a global leader in complex biologics while modernizing scientific research through the adoption of more humane and accurate NAMs. This alignment of technology, ethics, and economy is a vital step toward a Viksit Bharat 2047.

Source- https-//epaper.thehindu.com/ccidist-ws/th/th_international/issues/177234/OPS/GVVFNPI1P.1+GJ9FOSD6U.1.html