

**GOVERNMENT OF INDIA  
MINISTRY OF CHEMICALS AND FERTILIZERS  
DEPARTMENT OF PHARMACEUTICALS**

RAJYA SABHA  
UNSTARRED QUESTION NO. 2737  
TO BE ANSWERED ON THE 17<sup>th</sup> MARCH, 2026

**Biopharma SHAKTI Scheme**

**2737 Shri Kesridevsinh Jhala:  
Dr. Parmar Jashvantsinh Salamsinh:  
Smt. Kiran Choudhry:  
Shri Harsh Mahajan:  
Shri Sadanand Mhalu Shet Tanavade:  
Shri Narhari Amin:  
Shri Narayana Koragappa:  
Shri Mithlesh Kumar:  
Smt. Seema Dwivedi:  
Shri Mayankkumar Nayak:  
Shri Brij Lal:  
Shri Shambhu Sharan Patel:**

Will the Minister of **Chemicals and Fertilizers** be pleased to state:

- (a) the details of the financial outlay and the year-wise allocation proposed under the Scheme;
- (b) the steps proposed for creation of accredited clinical trial sites across the country and the expected outcomes thereof;
- (c) the initiatives taken to strengthen the regulatory framework, including capacity enhancement of Central Drugs Standard Control Organisation (CDSCO) for faster approval of biologics and biosimilars; and
- (d) the manner in which the Scheme is expected to reduce import dependence and enhance India's share in the global biopharmaceutical market?

**ANSWER**

**THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS**

**(SMT. ANUPRIYA PATEL)**

(a) to (d) : With a view to strengthen the domestic biopharmaceutical sector and enhance global competitiveness in biologics and biosimilars, the Government has announced the Biopharma SHAKTI scheme with an outlay of ₹10,000 crore over five years with an objective to build a globally competitive domestic ecosystem for biologics and biosimilars to support affordable healthcare in India and enable India to emerge as a global biopharma manufacturing and innovation hub. The contours of the scheme are under deliberation.

The Biopharma SHAKTI aims to focus on following components:

- i. Biopharma Discovery Grant Fund & Discovery & Development Equity Fund

- ii. Biopharma-focused NIPER Network + National Biopharma R&D Network
- iii. India Clinical Trial Sites Network (1,000 accredited sites)
- iv. Fermentation-based Bulk Drugs & Building Blocks Manufacturing Incentive
- v. Biopharma Delivery Devices & Packaging Manufacturing Ecosystem
- vi. Biosimilars & Emerging Biologics Manufacturing Initiative
- vii. Regulatory Strengthening for Global-best Drug Review Standards and Approval Timeframes

Under the scheme, it is envisaged to enable faster, globally credible approvals by strengthening the CDSCO through creation of a dedicated Scientific Review Cadre of reviewers and specialist positions for advanced fields like gene therapy. It is also envisaged to expand India's clinical research footprint by creating a nationally accredited network of 1,000 clinical trial sites under ICMR.

The Biopharma SHAKTI initiative envisages to build the ecosystem for domestic production of biologics and bio-similars. Further by supporting research and development, strengthening clinical trial infrastructure and promoting collaboration between academia, research institutions and industry, the Scheme seeks to encourage domestic innovation and manufacturing capabilities in the biopharmaceutical sector. Such initiatives are expected to contribute towards reducing import dependence over time and enhance India's participation in the global biopharmaceutical market.

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