

PARLIAMENT QUESTION: INDIGENOUS MANUFACTURING IN BIOPHARMACEUTICAL SECTOR

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The Government of India has taken steps to encourage and support entrepreneurship and indigenous manufacturing in the biopharmaceutical sector.

Department of Biotechnology (DBT) has set up Biotechnology Industry Research Assistance Council (BIRAC), a not-for-profit Section 8 Public Sector Enterprise, in 2012, as an interface agency to nurture and strengthen the startup ecosystem and encourage entrepreneurship with a focus on healthcare sector that covers Pharma and Biopharma. BIRAC through funding grants has supported startups, SMEs, and innovators. Some of the key achievements of BIRAC include:

- *Funding and supporting early-stage innovation*

Launched flagship funding schemes such as BIG (Biotechnology Ignition Grant), SPARSH (Social Innovation Programme for Products: Affordable & Relevant to Societal Health), Equity Schemes like SEED Fund (Sustainable Entrepreneurship and Enterprise Development) and LEAP Fund (Launching Entrepreneurial Driven Affordable Products), to strengthen the startup ecosystem and incentivize private sector R&D by addressing funding gaps post-ideation and pre-commercialization. Nearly 1000 Startups and entrepreneurs have benefitted from BIG scheme and SPARSH has awarded 150+ fellowships, creating 100+ startups and 65+ IPs.

- *Strengthening India's biotech innovation ecosystem*

BIRAC has established a strong network of incubators, including 94 Incubation and pre-incubation centres, supporting 3000+ incubates and fellows, across 25 states and UTs of the country. Opportunities have been provided through BioNEST (Bioincubators Nurturing Entrepreneurship for Scaling Technologies) and E-YUVA (Empowering Youth for Undertaking Value-Added Innovation Translational Research) schemes.

The Department of Biotechnology (DBT) is supporting the National Biopharma Mission (NBM), a Cabinet approved Program entitled Industry-Academia Collaborative Mission for Accelerating Discovery Research to Early Development for Biopharmaceuticals – “Innovate in India (i3) Empowering biotech entrepreneurs & accelerating inclusive innovation”; being implemented through Biotechnology Industry Research Assistance Council (BIRAC). This Program is enhancing India's innovation research and product development capabilities, especially by focusing on development of vaccines, biologics and medical devices for combating public health concerns.

Some key achievements of NBM include:

- Under NBM, support has been provided to over 100 biopharma-oriented projects, involving many MSMEs/startups, and facilitating creation of shared facilities (testing, validation, manufacturing) — driving domestic capacity for biologics, vaccines, diagnostics.
- *Product Development*- The Mission has successfully delivered 02 COVID-19 vaccines, ZyCoV D and Corbevax, biosimilar Liraglutide for diabetes, pegylated interferon alpha-2b for COVID-19, first indigenous MRI scanner, single-use bioreactors, 09 Covid-19 diagnostic kits, ventilators and reagents, Laboratory Information Management System, CHO Cell culture media, which have been developed and commercialized.
- *Ecosystem strengthening*- NBM has supported setting-up research and GMP manufacturing facilities where over 500 services have been rendered via 18 functional facilities. For the first time in India a network of 7 Technology Transfers Offices (TTOs) has been set up to facilitate patent filings and technology transfers. A network of 46 GCP-compliant clinical trial sites has been set up to facilitate trials for vaccines and therapeutics.

DBT with the approval of the Cabinet, in 2024, is implementing the BioE3 policy towards fostering High-performance Biomanufacturing in the country impacting the economy, environment and employment.

Under this initiative, Biofoundries and Biomanufacturing hubs are being established across the country in all the identified thematic verticals of the Biomanufacturing program including "Precision biotherapeutics" for promoting domestic manufacturing of monoclonal antibodies, mRNA therapies, cell and gene therapies and other such advanced precision medicines. The programs are under support.

Department of Pharmaceuticals is implementing Production Linked Incentive (PLI) scheme for Pharmaceuticals, which has a total budgetary outlay of Rs. 15,000 crores, aims to enhance India's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification to high-value goods in the pharmaceutical sector. Under the scheme, biopharmaceuticals are covered as one of the eligible product categories, where incentive at the rate of 10% on incremental sales is available.

Achievements:

- As of September, 2025, 46 biopharmaceutical products including vaccines are being manufactured under the scheme.
- The cumulative sales (from FY 2022-23 till September 2025) of the eligible biopharmaceuticals under the scheme is worth Rs. 26,832 crore which includes exports of Rs. 16,290.

Indian Council of Agricultural Research (ICAR) Animal Science Institutes are advancing entrepreneurship and indigenous biopharmaceutical manufacturing. ICAR–NIHSAD (National Institute of High Security Animal Diseases) develops priority vaccines and diagnostics. The ICAR–IVRI (Indian Veterinary Research Institute) Pashu Vigyan Incubator under RKVY-RAFTAAR supports livestock biopharma startups through ₹5 lakh (Navodaya) and ₹25 lakh (Samriddhi) grants, along with providing R&D infrastructure, mentorship, and regulatory/commercialization assistance.

Some key achievements:

- Indigenous poultry vaccines and diagnostics now commercially produced, reducing import dependence.
- Four companies are manufacturing NIHSAD's H9N2 vaccine, enhancing avian influenza preparedness.
- One industry partner has commercialized the Indirect ELISA kit, enabling affordable nationwide surveillance.
- GeNext Genomics Pvt. Ltd., funded under RKVY-RAFTAAR, developing diagnostics for Classical Swine Fever and Brucella and advancing therapeutic antibodies, cell lines, and biosimilars.

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