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Indian Lifesciences Industry Going Ahead in its Innovation Journey While Navigating Challenges

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While India is a hub for biosimilar manufacturing and continues to build its capabilities to manufacture these complex therapeutics, Indian biopharma companies are building R&D capabilities and establishing public-private collaborations and Centre of Excellences (CoEs) to develop innovative biologics and advanced therapeutic modalities like cell and gene therapy (CGT) and mRNA vaccines and therapies, biopharma sector remained robust in 2023, accounting for $53.8 billion (35 per cent of the BioEconomy). The growth was primarily driven by advances in biotechnology, personalised medicine innovations, and an expanding market for biosimilars in 2024.

India is a major supplier of vaccines, with more than 50 per cent of the world's vaccines coming from India. According to the WHO Global Vaccine Market Report, the vaccine major Serum Institute of India (SII) accounted for 24 per cent of the global vaccine market. SII joined the CEPI, (the Coalition for Epidemic Preparedness Innovations), network of vaccine producers, which will support rapid, agile responses to possible future infectious disease outbreaks. In addition to conventional vaccines, India has also emerged strong with two mRNA vaccines approved for the omicron variant. Innovations have also increased, with Indian Immunologicals Ltd (IIL), launching India's 'first' indigenously developed Hepatitis A vaccine, Havisure in February 2024.

Many Indian startups and academic organisations have been relentlessly working to advance affordable cell and gene therapies for oncology, rare diseases, and other indications. The push to develop more efficacious and accessible CAR-T therapies to millions of patients finally saw fruition, with the first indigenous CAR-T cell therapy receiving approval in 2023, making it the most affordable CAR-T therapy. The commercial launch of NexCAR19 in 2024 has helped India firmly establish its position in the advanced cell and gene therapy space. This launch has also sparked interest in investors and companies

investing in cell and gene therapy developers. Other players like Cellogen Therapeutics are developing advanced CAR-T therapies by developing bi-specific CARs and adding immunostimulatory molecules. They received a $2 million investment from Natco Pharma in 2024 to support the R&D programmes. Immuneel Therapeutics also received $12 million in funding in 2024, which will help propel its CAR-T therapy manufacturing and development platform. Other notable developments included approving the country's first gene therapy clinical trial for Hemophilia A in February 2024.

Growing Focus on Precision Health

Globally, there is a notable push for value-based precision medicine approaches, and India has also embarked on the precision medicine journey with several federal and corporate initiatives and projects. Council of Scientific and Industrial Research (CSIR) launched the Phenome India project in December 2023, which aims to develop country specific prediction models for cardio-metabolic diseases targeted at the Indian population. Phenome India project exemplifies CSIR's commitment to advancing precision medicine through Predictive, Personalised, Participatory, and Preventive healthcare.

Pharma and biopharma companies have focused on utilising digitalisation and AI to accelerate precision medicine efforts with flagship projects and collaborative initiatives. Notable collaborations, such as the one between Siemens Healthineers and the Indian Institute of Science (IISc) with the launch of the Siemens Healthineers-Computational Data Sciences (CDS) Collaborative Laboratory for AI in Precision Medicine in January 2024 will develop open-source AI-based tools to automate digital pathology results in neuroimaging, will help in accurate diagnosis and population health analytics. As healthcare becomes more patient-centric, Indian hospitals strive to provide personalised offerings. Apollo Hospitals launched India's first AI-Precision Oncology Centre at Apollo Cancer Centres in Bengaluru in 2024. This, along with many other examples of how pharma companies, hospitals, diagnostics developers, and other stakeholders across the healthcare and life sciences value chain are adopting AI and digitalisation, is also indicative of the progress India is making to keep itself abreast in terms of tech-enabled innovations.

Partnerships Play a Pivotal Role in Sustaining Momentum

Building a strong and sustainable infrastructure for biomanufacturing will keep India ahead in its global position, and the recent BioE3 (Biotechnology for Economy, Environment, and Employment) Policy approved in August 2024 will help position India as a global leader.

While the 2024 Indian budget did not particularly have special provisions or policy announcements to foster pharma and biopharma R&D, specific announcements, such as the government setting up a mechanism for private sector-driven research and innovation, the pool of Rs 1 lakh crore and more than Rs 2000 crore of The Production Linked Incentive (PLI) allocation for the pharmaceutical industry for this fiscal year.

Expediting access to advanced therapies is also critical for improved accessibility, and the Central Drugs Standard Control Organisation (CDSCO) recently waived off the requirement for local trials for drugs that already have approval in certain foreign markets. Advanced therapies such as cell and gene therapies, drugs for orphan diseases, and other advanced therapeutic modalities that have been approved by the US, Japan, Europe, and other major countries would be eligible for waiver of the local clinical trials.

The life sciences sector has witnessed strategic partnerships to expand capabilities and market access. In May 2024, Merck inked a partnership with Aurobindo Pharma-owned TheraNym Biologics to expand its biologics manufacturing facilities and advance contract manufacturing. In July 2024, Miltenyi Biotec, a global biomedical solutions company, partnered with the Translational Health Science and Technology Institute (THSTI), an autonomous institute under the Department of Biotechnology, collaboratively developed innovative cell and gene therapies for oncology and haematological indications.

Facing Flaks over Quality and Compliance

Despite the advances and the strong position of the Indian Contract Development and Manufacturing Organisation (CDMO) industry, many of the Indian companies have been under scanner due to significant quality control and regulatory lapses in the last two years. The CDSCO inspected 400 drug manufacturing units over the past year and a half, ordering the closure of more than 36 per cent due to non-compliance leading to quality concerns.

The CDSCO has intensified its monitoring and enforcement if such lapses are found and flagged several drugs in 2023 and 2024 due to quality or efficacy issues from many renowned pharma companies.

With pharma exports accounting for a substantial share of the global market, India is taking solid measures to regain its reputation and re-emerge as a reliable supplier of generic, high-quality, affordable medicines. Since August 2024, more than 200 fixed-dose drug combinations have been banned, citing potential risks to human health.

Many companies, such as Astra Zeneca and Novartis, are re-evaluating their India business strategy, trimming down portfolios and refraining from making new investments. Facing regulatory hurdles, IPR challenges, and pressure to generate revenue and net profit, most multinational corporations are reevaluating their strategies for the Indian market.

What is on the horizon?

The innovation ecosystem is expected to strengthen further in 2025 and the years ahead, with more advanced therapies like cell and gene therapies, mRNA therapies, and advanced antibodies entering clinical development. With stringent monitoring and streamlining regulatory measures, pharma companies are expected to collaborate with regulatory bodies to make quality control and production processes more airtight and transparent.

Stakeholders eagerly await specific policies and initiatives to drive biopharma R&D in the next annual budget, not a mere reduction in taxes and regimes. Incentivisation of high-value, high-risk projects for innovative therapeutics must be in place for India to make a mark in the biotech race.

Geopolitical changes resulting in a significant legislative shift with the U.S. Biosecure Act coming into force in September 2024 are likely to have positive implications for the Indian pharma CDMOs. This Bill aims to reduce US dependence on Chinese pharmaceutical supply chains by restricting collaborations with certain Chinese biotech firms, which would directly increase demand from US pharma companies for Indian Contract Research Organisations (CROs) and CDMOs in the next year. However, Indian CDMOs can seize the opportunity by levelling up in terms of infrastructural investments and regulatory protocols, and reducing dependence on China to make its supply chain more resilient.

Ruplekha Choudhurie, Research Manager, Advanced SciTech, Everest Group