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Budget 2026 aims at positioning India as a global hub for biologics, biosimilars and advanced therapies: Sheetal Sapale

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Regulatory modernisation is a major theme of Budget 2026

“Budget 2026 marks a defining inflection point for India pharma’s next growth cycle, as the government’s Biopharma Shakti initiative signals a decisive shift from a volume-led generics model to a value-driven, innovation-centric biopharma ecosystem,” said Sheetal Sapale, Vice President – Commercial at Pharmarack Technologies. The Budget lays out a long-term structural framework aimed at positioning India as a global hub for biologics, biosimilars and advanced therapies rather than merely a low-cost manufacturing base.

In a presentation on the topic ‘Budget 2026: The Inflection Point for India Pharma’s Next Growth Cycle’ Sheetal Sapale said “A key pillar of the Budget is the creation of a manufacturing flywheel through stronger capex and production-linked incentives for complex drugs and biologics, coupled with encouragement for export-oriented growth. These measures reduce India’s dependence on imports for advanced therapies while creating long-term scaling opportunities for domestic players to build globally competitive, export-ready biopharma manufacturing capabilities.”

The Budget also makes a significant push toward strengthening India’s clinical trials and R&D ecosystem, an area that has historically constrained innovation. She noted that the planned network of over 1,000 accredited clinical trial sites across the country could dramatically reduce fragmentation, improve trial efficiencies and shorten time-to-market for new drugs. “Alongside this, the creation of three new NIPERs and the expansion of seven existing institutes will deepen India’s pool of specialised biopharma talent, supporting not just manufacturing but early-stage research and translational development,” she added.

Regulatory modernisation is another major theme of Budget 2026. The strengthening of the Central Drugs Standard Control Organization (CDSCO) with dedicated scientific review cadres and specialist expertise is expected to align Indian approvals more closely with global regulatory standards. “Faster approvals and lower compliance friction are critical for complex therapies, and these reforms can significantly improve development timelines and cost efficiency for pharma companies,” Sheetal Sapale said.

Beyond structural reforms, the Budget also delivers direct market enablers, including customs duty exemptions on 17 select high-impact medicines, largely comprising oncology, immunotherapy and advanced therapies. She highlighted that these exemptions are likely to reduce the landed cost of critical treatments, improve patient access and simultaneously enhance portfolio economics for companies focused on specialty drugs.

“Taken together, Budget 2026 represents the government actively underwriting the entire biopharma value chain—manufacturing, clinical development, regulation and talent,” Sheetal Sapale said. “Biosimilars and complex therapies now move from being adjacent opportunities to core growth engines. For Indian pharma players, the roadmap is clear: accelerate biologics pipelines, strengthen clinical capabilities, rebalance portfolios toward specialty and chronic therapies, and invest early in export-ready manufacturing. Those who act decisively stand to gain first-mover advantage in the next decade of Indian pharma growth,” she concluded.