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Pharma cos likely to climb US generics value chain

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The Indian pharmaceutical industry is likely to benefit from a major wave of patent expiries in the US, as small-molecule drugs worth $63.7 billion are expected to go off-patent between 2025–29, a 65 per cent rise over the previous five years, according to a report by Antique stock broking limited.

The boost for the Indian drugmakers is also likely to be combined with a broader Loss of Exclusivity (LoE) opportunity across the US and EU projected to reach $180 billion by 2035, the report said.

The shift is expected to drive a sharp increase in generic drug launches, positioning Indian drugmakers for strong growth, particularly those with emerging US operations and expertise in complex generics.

Indian players with smaller US bases, such as Alembic pharmaceutical and Shilpa Medicare, and strong positions in complex generics, such as Cipla and Lupin- which have invested early in differentiated products such as injectables and respiratory therapies- are well positioned to gain market share.

Indian players are also stepping up to fill the volume gap, as global majors like Teva, Viatris and Sandoz have cut back operations and manufacturing footprints — each having shuttered dozens of sites since 2018.

However, this wave of opportunity is unfolding against a backdrop of strategic discipline. US Abbreviated New Drug Application (ANDA) filings have declined 25 per cent year-on-year (Y-o-Y), with FY25 filings likely to close around 550, down from 740 in FY24 and 857 in FY22. This suggests a strategic shift towards prioritising portfolio quality, regulatory compliance, and margin protection over volume.

Commenting on this shift, Nilaya Varma, group CEO and cofounder of Primus Partners, said, "India's pharma exports have grown from $15 billion in 2013–14 to nearly $28 billion in a decade. With 750+ USFDA-approved plants and rising strength in complex generics and biosimilars, India is primed to lead the next wave of affordable, high-quality medicines. Tapping the $180 billion LoE opportunity will require continued focus on compliance and quality systems."

Growth pill

- **$63.7 bn:** Worth of US small molecule drugs going off-patent between 2025 and 2029
- **$180 bn by 2035:** Loss of exclusivity likely in the US and EU
- **$15 bn in FY14 to $28 bn in FY24:** Increase in India's pharma exports
- **750+:** USFDA-approved plants in India

Regulatory headwinds that once plagued the Indian sector are also easing as the share of US FDA inspections resulting in Official Action Indicated (OAI) for Indian firms have dropped from 19 per cent in 2013 to 9 per cent in 2023.

Companies like Cipla are further de-risking US supply chains by adopting multi-site manufacturing and digital quality systems.

Cipla, with a robust US portfolio of 284 ANDA and NDA filings— 175 of which are approved and 73 under review— is sharpening its focus on commercialisation-ready products, including PEPFAR-approved generics. The company is betting on complex respiratory and injectable therapies to drive growth.

Pharma giant Lupin, which continues to benefit globally from its blockbuster autoimmune biologic, Etanercept, plans to finalise its US commercialisation strategy closer to the drug's 2029 patent expiry.

Similarly, Sun Pharma, despite a conservative FY26 outlook amid global uncertainties, is aggressively expanding its oncology portfolio. Its newly acquired UNLOXCYT (cosibelimab) is expected to contribute significantly to US revenues, with the company clarifying that Keytruda's upcoming patent expiry was already factored into the acquisition.

UNLOXCYT targets only one of Keytruda's multiple indications, and Sun remains confident in its potential to become a meaningful contributor to the company's US specialty business. In parallel, Sun is also strengthening its immunotherapy pipeline through a global licensing agreement with Philogen.