

### **US Generics Market**

Pricing pressures and regulatory scrutiny - A bitter pill for Indian pharma companies?

SEPTEMBER 2022



#### Agenda









Regulatory environment and recent developments

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## Highlights



ICRA expects mid to high single-digit price erosion to continue to exert pressure over the near term, resulting in muted revenue growth for the Indian pharmaceutical companies from the US generics market in FY2023.

Further, impact of elevated raw material prices and packaging costs, in addition to relatively higher freight rates, and the impact of supply chain disruptions, if any, on their margins will remain the key monitorables



The US continues to be the largest pharmaceutical market in the world, accounting for around 45% of the global pharmaceutical industry by value. The US has always been a key market for most leading Indian pharma companies as well, accounting for a sizeable proportion of its revenues.



However, these companies have faced challenges such as consistent pricing pressure, lack of major blockbuster product launches and increased regulatory scrutiny in recent years. Consequently, the share of revenues from the US market declined to ~30% of aggregate revenues of ICRA's sample set^ in FY2022/Q1 FY2023 from 38% in FY2017.

Revenue growth in the US market for major Indian pharma companies remained suppressed over the last several quarters owing to continued price erosion in the US generics market.



Mid-to-high single digit pricing pressure is expected to continue over the near term with some normalisation expected only after a few quarters.

In the recent past, some large Indian pharmaceutical companies have reported sizeable provisioning and settlement pay-outs against some of the ongoing litigations in the US market; this has impacted their earnings and balance sheets to an extent. Further, some major Indian pharmaceutical companies reported sizeable impairment losses and announced discontinuation of some products or segments due to lower earnings potential.

Nonetheless, the US remains one of the most important markets for Indian pharmaceutical companies, both from the growth and the earnings perspective. Companies will continue to focus on new product launches and complex generics, including first-to-file opportunities to improve margins for the US business.



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