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Pricing pressures, regulatory scrutiny persist in US generics pharma industry: ICRA

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Off-late, Indian pharma companies have reported sizeable provisioning and settlement pay-outs against some of the ongoing litigations, which have impacted their earnings and balance sheets to an extent

The US has always been a key market for Indian pharma companies, accounting for ~29 per cent of FY2022 revenues of ICRA's sample set of eight leading pharma companies. However, over the past few years, the revenues from the US market have grown at a relatively modest pace, reflecting a confluence of challenges being faced by companies in the form of consistent pricing pressure, lack of major generic product launches and increased regulatory scrutiny.

In FY2022, the revenues from the US pharma market for our sample of leading pharma companies declined marginally by 0.2 per cent owing to high single-digit to low teens price erosion. Accordingly, the share of revenues from the US for ICRA's sample set has declined from ~40 per cent earlier over the last few years on account of muted revenue growth in the overall US generics market in FY2021 and FY2022, coupled with an increased focus on other regulated and semi-regulated markets. Nonetheless, the US remains one of the most important markets for Indian pharmaceutical companies, both from a growth and 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.

Companies with a limited basket of products and deriving a majority of their revenues from the oral solids segment are relatively more vulnerable to heightened competitive intensity in the segment. With a relatively lower number of approvals for new products, the players who had earlier reduced their focus on some molecules re-entered these products, impacting the realisations, and in turn leading to higher pricing pressures in the oral solids segment. Moreover, citing continued pricing pressures and intense competition in the US generics business, in recent quarters, some major Indian pharmaceutical companies reported sizeable impairment losses and also announced the discontinuation of some products or segments due to lower earnings potential.

The pace of ANDA approvals as well as the issuance of warning letters to Indian pharma companies have been lower over the past two years, given USFDA's inability to conduct physical inspections in the light of the pandemic-induced restrictions. However, the same is likely to pick up over the medium term as inspections gain traction.