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USFDA gives nod to more than 300 Indian pharma industries

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Domestic pharmaco received USFDA approval in 2017 to launch generic drugs in the US

Domestic pharma companies received more than 300 approvals in 2017 to launch generic drugs in the US, which is an all-time high.

The clearances came despite regulatory pressure from the US Food and Drug Administration (FDA), and unprecedented warning letters issued to the pharma companies' facilities.

The final approvals for Indian players are up by nearly 43% from 211 in 2016, and corner about 40% of all global filings in the highly lucrative around $70-billion US market.

The US generics market, a key driver of Indian pharma's growth, has always been a dynamic market. But the pace of change has accelerated in the last few years.

The increase in competition and consolidation of distribution channels have led to the US generics business getting commoditised.

Price erosion has been at an all-time high and this has impacted operating margins significantly. Major domestic companies earn at least 40% of their overall sales from the US.

To maximise margins, companies are now launching complex generics and speciality products.