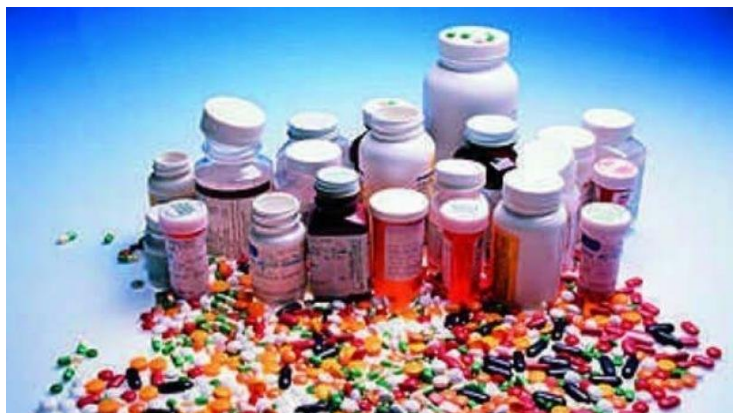


Pharma players to step up regulatory compliance

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Indian manufactures are likely to spend a higher proportion on capex for upgrading infrastructure for regulatory compliance over FY20-FY30



India Ratings and Research (Fitch Group) believes that US-focused Indian pharmaceutical players would be required to step up regulatory compliance in FY20-FY30 as they invest in a complex generics/specialised/innovative play. The agency expects Indian formulators' product portfolio mix to undergo a structural shift in the coming decade on account of movement up the value chain leading to near doubling of research and development investments. As operating environment in the US markets has undergone a shift in the wake of rising competition and increasing customer buying power, product quality and uninterrupted supply has become focus points for commercial success. This translates to a robust approach to regulatory compliance for manufacturing facilities.

From 2H2017, the industry witnessed resolution of key manufacturing facilities of large manufacturers under warning letters and import alerts with an average period of 24 to 36 months after regulatory restriction. While this is encouraging, a reduction in resolution times and limited repeat observations would indicate regulatory discipline retuning to the industry. Input quality risk stemming from high dependence on Chinese players has been an emerging concern in 2018-2019, leading to product recalls initiated by major players. The agency believes that securing supply chain is likely to emerge as top priority as several complex generics and innovative pipeline will hit the markets in the next decade.

The credit profiles and return ratios of Indian players with regulatory deviations have been adversely impacted attributed to remediation cost and restricted market presence. Indian manufactures are likely to spend a higher proportion on capex for upgrading infrastructure for regulatory compliance over FY20-FY30.

Ankit Bhembre, Senior Analyst - Corporate Ratings says "Indian pharmaceutical companies need to step up their regulatory compliance to secure impeccable reputation as reliable suppliers and provide the targeted return on the ongoing and planned research and development and capital investments over the next decade".