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Pharma exports growth heading for a sharp decline: CRISIL Research

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CRISIL Research foresees exports growth in formulations (in US dollar terms) decling sharply to 10-125 annually over the next 5 years, compared with a growth of 19% seen in the last decade.

Exports of generics have been the growth engine of the industry for a long hile now, but the script is changing because the value of drugs going off patent is declining even as pricing pressures are increasing. for example, annual sales growth of generic drus in US is seen slowing to 8-9% over the next five years, and decelerate even more after that. Therefore, for growth to sustain beyond 2020, domestic companies will have to step up investments in new molecules and draw up a roadmap to deal with lower generics growth.

In the past decade and more, what came in handy was process chemistry skills--which helped companies clone drugs going off-patent by tweaking their molecules--and low-cost manufacturing. But competition has been intensfying, particularly for the large players, because of the huge number of abbreviated new drug applications (ANDAs) being filed with the USFDA, including by mid-sized domestic ones looking to step up presence in the biggest market.

Furthermore, consolidation of distribution channels in the US could reduce the pricing power of domestic drug makers.

Says Ajay Srinivasan, Director CRISIL Research,"Sharper focus on innovation and R&D has become an imperative. Our analysis of new drug applications approved by USFDA reveals that Indian companies got approvals for just 26 products between Jan 2006 and June 2015- a fraction of the 840 garnered by global pharma companies. Their global generic competitors such as Teva and Mylan has 48 and 33 NDAs to their credit as of Feb 2016."

To be sure, Indian companies have indeen increased their R&D spend; for the top 30, it has shot up to 6.5% of revenue fiscal 2015 from 3.8% a decade back. Howver, this pales in comparison with global majors, who spend close to 16%. Typically, a chunk of the expenditure of domestic pharma companies for launching generic therapies, changing product mix in generics and process development.

Some top one have launched R&D programmes aimed at new drug discovery. CRISIL Research's analysis indicates that a good 14 companies together have 39 products in various stages of clinical development. These companies have adopted various approaches-such as inhouse development, joint development and out licensing-to manage the risk return trade off. However, none has launched a new molecule in a regulated market such as the US.