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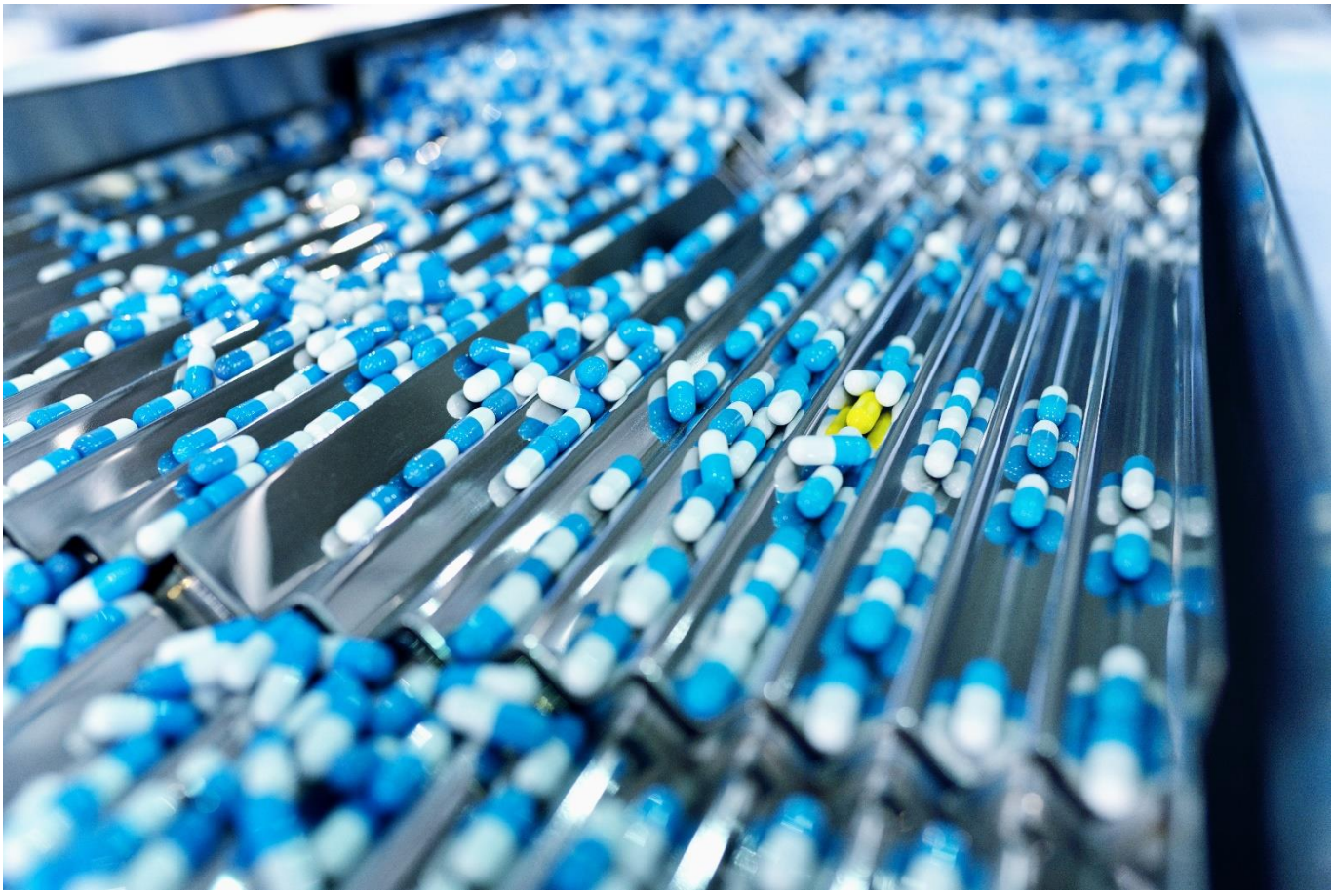
Pharma recovery nigh

CRISIL opinion

March 2018



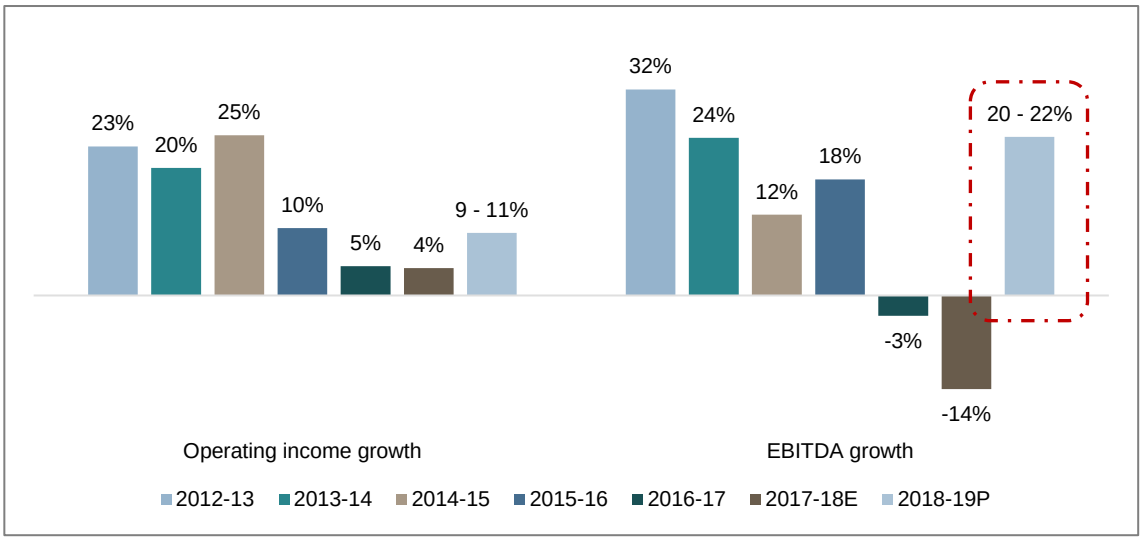
Operating profit to jump 20-22% in fiscal 2019

After a bruising two years, the Indian pharmaceuticals industry appears set for a sharp turnaround in fiscal 2019.

CRISIL Research projects earnings before interest, taxes, depreciation and amortisation (EBITDA) to increase 20-22% on-year – the fastest pace of growth since fiscal 2014. Revenue is expected to improve 9-11% on-year.

The projected good run is premised on a decline in regulatory alerts for larger companies as well as a bigger pipeline of high-value drugs compared with the past two years.

Operating income and profit to see a course reversal



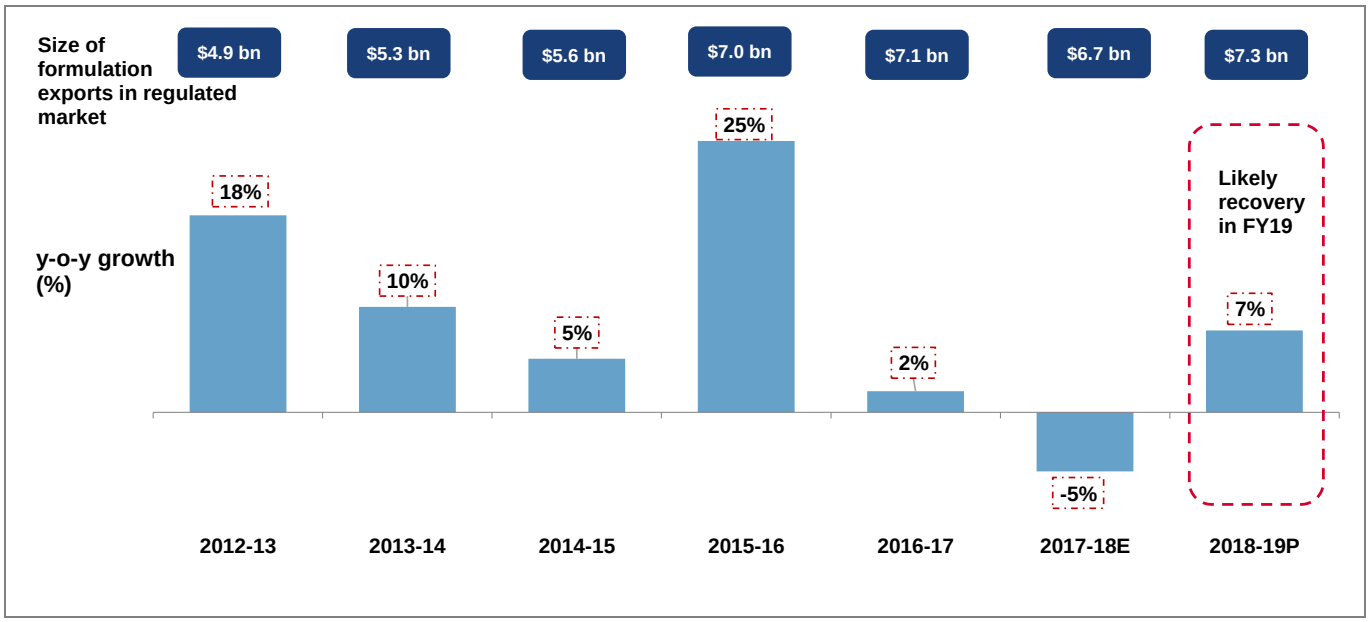
E: Estimated; P: Projected

Source: Company reports, CRISIL Research

The reversal in fortune will be primarily on the back of strong growth in the overseas market, particularly to regulated markets of the US and the EU, amid continued healthy growth in the domestic market. Although exports account for 50% of the revenue of the Indian pharmaceuticals industry, its contribution at the EBITDA level is higher owing to relatively superior profitability of products sold in regulated markets.

In fact, the haemorrhage over the past two years can be pinned squarely on dwindling exports to regulated markets, particularly the US and the EU. These two regions together account for over 90% of regulated market exports and close to 50% of formulation exports from India. Lower generic opportunity, rising competition, supplier consolidation, and increase in regulatory alerts on Indian plants were the major headwinds.

Share of formulation exports in regulated markets seen improving



E: Estimated; P: Projected

Source: CRISIL Research

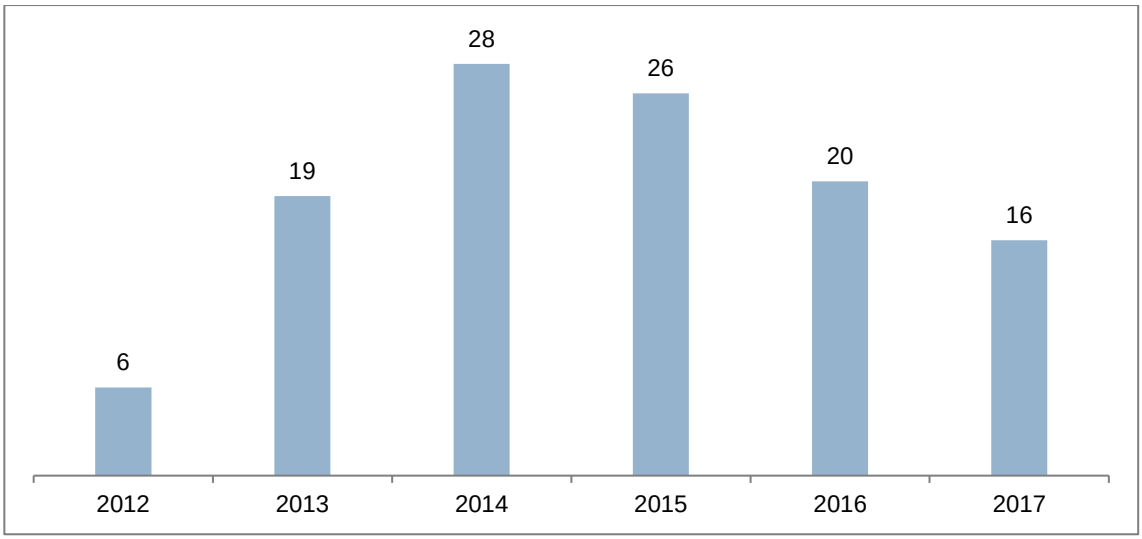
Relief from regulatory alerts to increase ANDA flow

Despite high competition and supplier consolidation (translating into pricing pressure) continuing to impact exports to regulated markets in fiscal 2019, sales to these markets are expected to rise 7% on-year vis-à-vis a decline of 3% CAGR seen between fiscals 2016 and 2018.

One of the factors working in favour of larger Indian pharmaceutical companies is a marked reduction in the number of regulatory alerts in 2017, a welcome change from 2015 and 2016. Official Action Indicated (OAI) reduced significantly to 16 in 2017 from 28 in 2014. This was possible because of efforts taken by large formulation companies over the past 2-3 years towards remediation.

Issuance of an OAI indicates objectionable conditions were found and will result in regulatory and/or administrative sanctions by the US Food and Drug Administration (FDA). Typically, non-closure of an OAI results in a warning letter or import alert.

Fewer OAIs issued to Indian pharmaceutical plants last year



Source: US Food and Drug Administration

Increased efforts towards remediation have also resulted in closeout of some regulatory alerts for big pharmaceutical companies in the past one year. We expect this to continue in 2018 for some of the larger players, allowing companies to receive Abbreviated New Drug Application approvals of products stalled owing to the alerts, thereby improving exports.

Regulatory alerts for big domestic pharmaceutical companies closed in last few years

Company name – plant	Year of issuance of warning letter/import alert	Close out date
Cadila – Moraiya unit	2015	2017
Dr Reddy's – Srikakulam unit 1 (formulations)	2015	2017
Divi's Laboratories -Vishakhapatnam	2017	2017

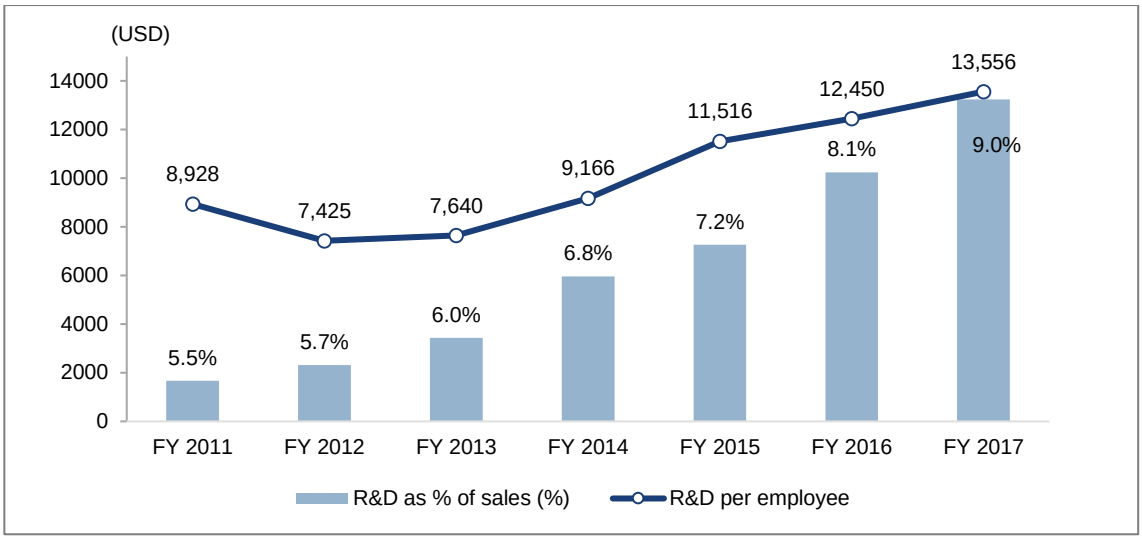
Source: Company filings

Increased focus on R&D to improve product mix

Companies are also likely to benefit from increased investments on research and development (R&D) over the past few years. Alongside developing capabilities via the inorganic route, domestic companies have been focusing on strengthening their in-house product pipeline via R&D owing to increasing pricing pressure on conventional generics and lower patent expiry opportunity.

Companies are also shifting focus from conventional generics to complex generics and biosimilars as competition within the conventional generics space is intensifying. The move also ensures healthy growth prospects. This, though, requires considerably higher R&D investment. For example, the cost of developing a biosimilar is ~$150 million compared with $1-5 million for developing a generic drug. While the cost of developing niche complex drugs and biosimilars is substantially high, the potential market opportunity and profitability are commensurate.

R&D investment of Indian pharmaceutical companies



Source: Company reports, CRISIL Research

The higher investment in niche and complex drugs over the past few years is expected to start bearing fruit in fiscal 2019. The number of high value drugs likely to be launched during the year is three times that of fiscal 2018. Even the market potential of drugs to be launched is significantly higher than in the previous year.

Opportunity from high-value drug launches huge

Year	No. of high value drugs launched	Market opportunity of launched drugs in regulated markets ($ mn)
FY18	**6**	**1,500-2,000**
FY19 P	**18**	**11,500-12,000**

P: Projected

Source: Company reports, CRISIL Research

Signs of recovery are already visible, with some high value drugs already approved in the past 2-3 months. For instance, Biocon received approval in December 2017 from the US FDA to launch its biosimilar version of Herceptin – developed in joint venture with Mylan. Sun Pharmaceuticals received approval in March 2017 to launch its specialty drug Tildrakizumb.

Bottomline: Sustaining high profitability will require continuous investments in niche and complex segments even as the battle in conventional generics intensifies.

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