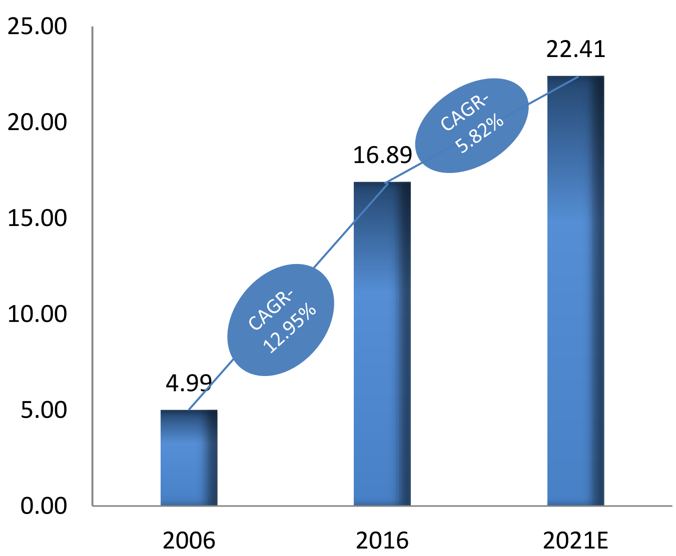
Overview of Indian pharma industry exports market and the impact of ensuing the rise of FDI on it

Overview of Indian Pharmaceutical Industry:

The Indian Pharmaceutical Industry (IPI) is ranked third globally in terms of volume and thirteenth in terms of value. The lower market share in terms of value can be attributed to the predominance of IPI in generic medicines which command lower prices. As per estimates, the industry size is expected to grow at a compound annual growth rate (CAGR) of 12.89% from USD 30 billion in 2015 to USD 55 billion by 2020 given the huge export potential coupled with steady growth in the domestic formulation market. Growth in the domestic pharma market is expected to be driven by increase in the penetration of health insurance, improving access to healthcare facilities, rising prevalence of chronic diseases and rising per capita income. The export growth is expected to be led by increasing generic penetration in the regulated markets on the back of enhanced focus on the niche and complex product segments, patent expiries and growing demand from semi-regulated pharma markets. In the long term, growth in the export market will be sustained by emerging markets such as Russia, Brazil, and South Africa, etc.

Exports scenario of IPI



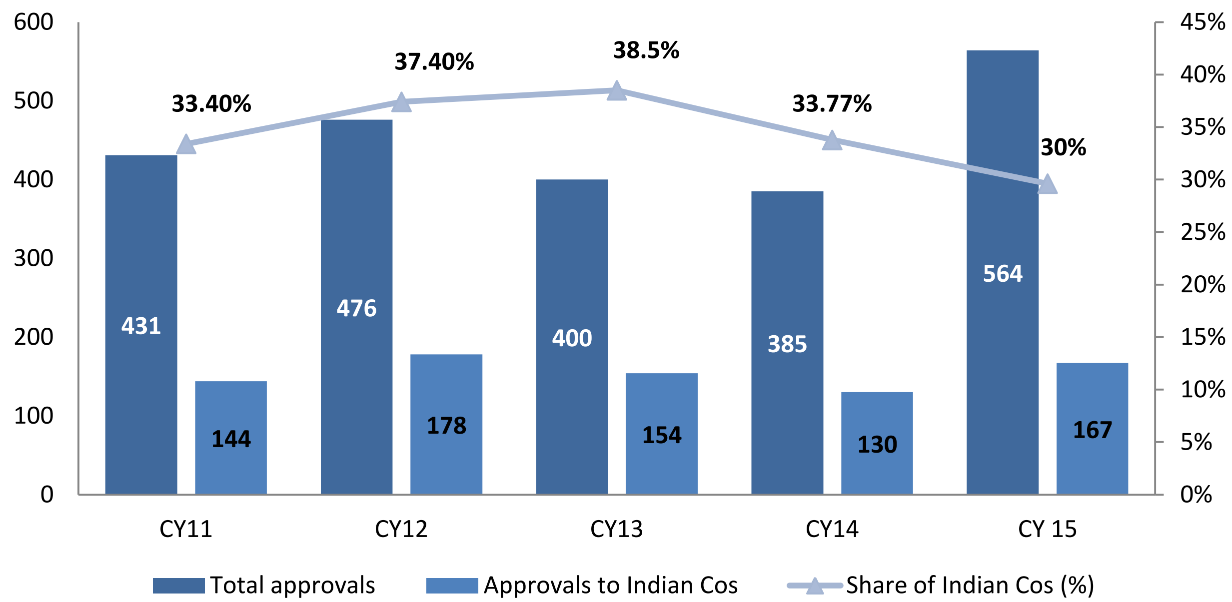
Source: Compiled by CARE

The top 30 companies of IPI which share about 60% of the market derive about 40-50% of their revenue from exports. Furthermore, India is the largest provider of generic medicines globally accounting for about 20% of the total generic medicine exports of the world. Lower cost of manufacturing has given competitive edge for India over many developed nations. The cost of manufacturing in India is almost half of that in Europe and about 60% lower than that in the US as per IBEF. It is expected that by 2020, the Indian Pharmaceutical market would be sixth largest market globally in size.

Export Markets and its Prospects

India's drug and pharmaceutical industry witnessed healthy growth in exports during 2015-16 on account of increase in the number of approvals and access to new markets. The exports grew by 9.4% during 2015-16 as against 3.2% and 1.9% during previous two years. After consecutive decline in the number of Abbreviated New Drug Applications (ANDA) approvals during the last couple of years, the number of US FDA approvals for ANDAs have increased by about 46% from 385 approvals during 2014 to 564 approvals during 2015. During the same period, the Indian pharmaceutical majors secured 167 ANDA approvals as against 130 ANDA approvals during the previous year registering a growth of 28.5% on account of higher investments in R&D expenditure and focus on new product launches.

ANDA approvals granted by USFDA (CY2011-15)



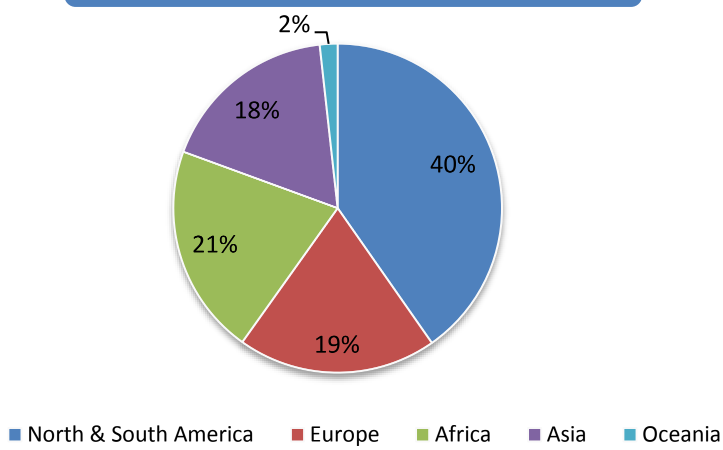
Source: IMS Health &Compiled by CARE

However, as per CMIE data, the drug exports growth is expected to slow down to 4.9% during 2016-17 on account of decline in the number of block buster drugs going off patent during CY17-CY20 and stricter regulatory mechanism. Also, consolidation of buyers in the US, one of the major importers of Indian drugs, accounting for around 32% of the total exports from India, has resulted in downward pressure on the prices of exports of Indian companies.

Export Share of Key Markets

The share of Indian exports towards key regulated markets (include USA, Germany, UK and Canada) has increased from 34% during FY14 (refers to the period April 1 to March 31) to 39% during FY16 and that of key emerging markets (include Brazil, Kenya, Nigeria, South Africa, Russia and Vietnam) has remained stable at ~15% during the same period. This, to certain extent, indicates the strengthening aspect of drug manufacturing and compliance aspects syncing with international standards.

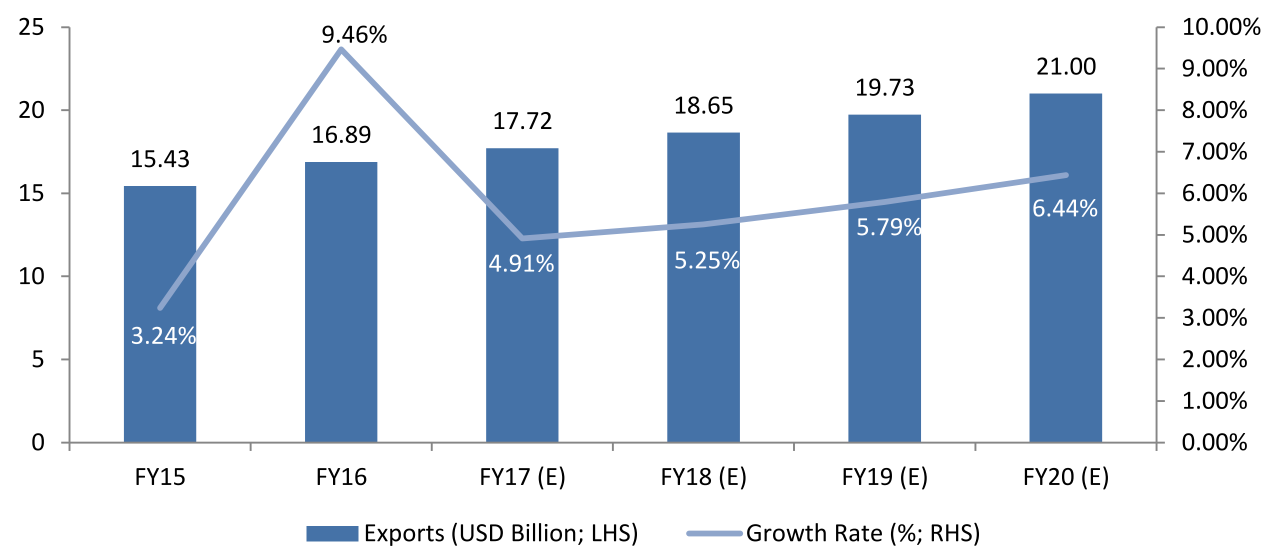
Indian Pharma Exports during FY16



Source: CMIE

Of the top 25 destinations of India's Pharmaceutical Exports, though North & South America has contributed about 40%, USA remains the top export destination with a share of 32.59% and a growth of 27.72%. Among the top 10 destination countries, exports to South Africa, Kenya and Australia, have grown exceptionally in comparison with the average growth.

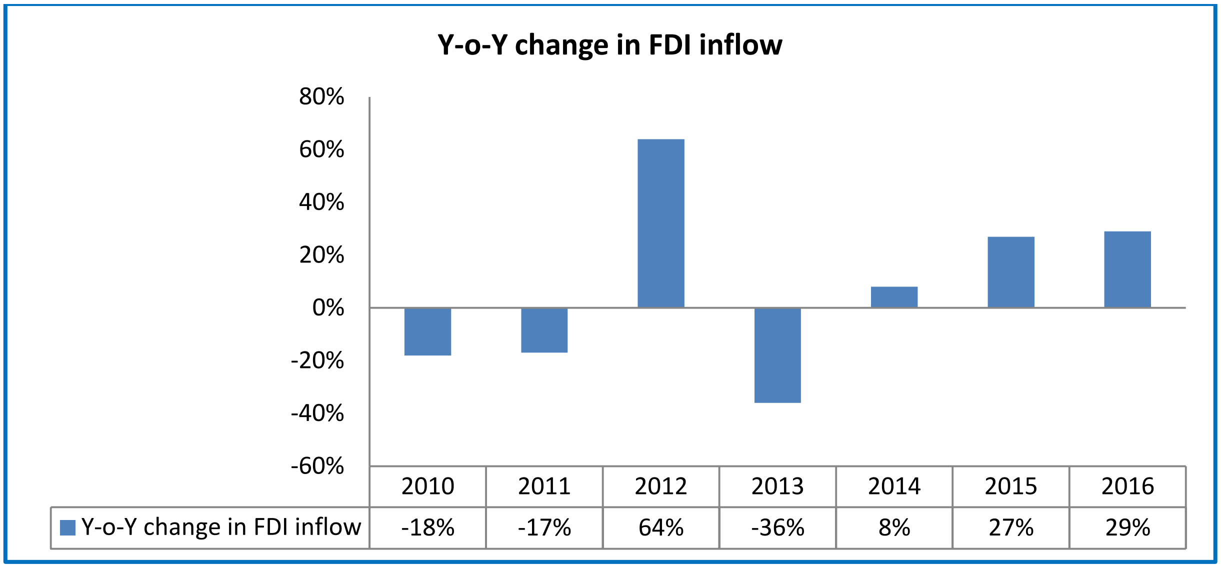
IPI's exports aggregated US$ 16.89 bn during FY16 as against US$ 15.43 bn during FY15. US being the country's biggest market for pharma exports accounted for about 33%, followed by South Africa and United Kingdom (source: CMIE).



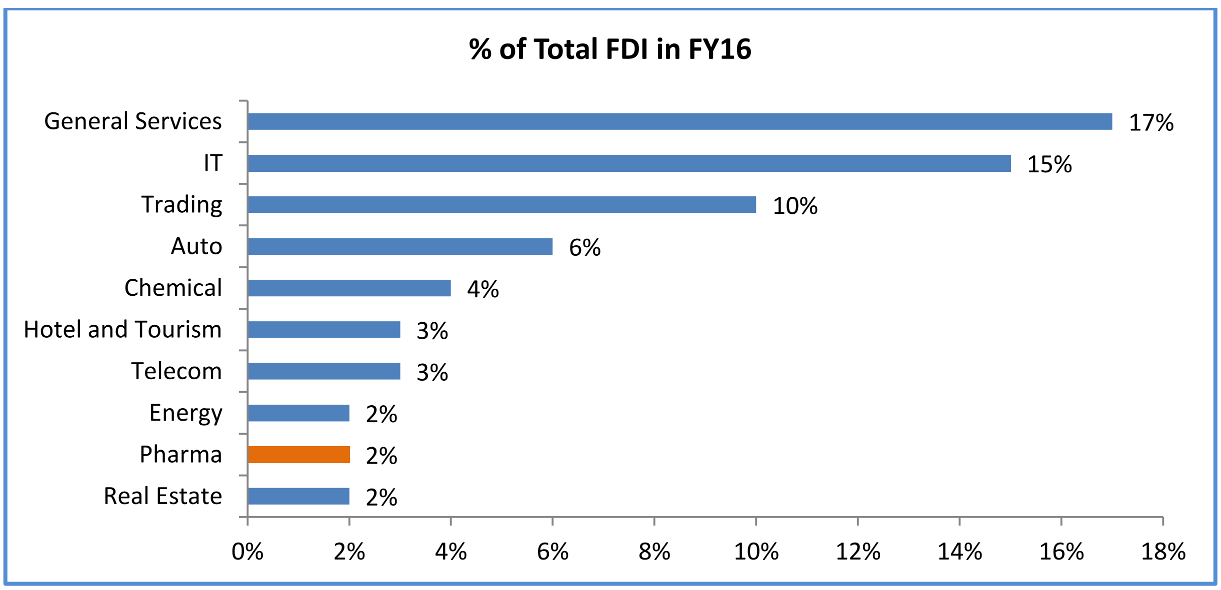
Scenario of Indian FDI market

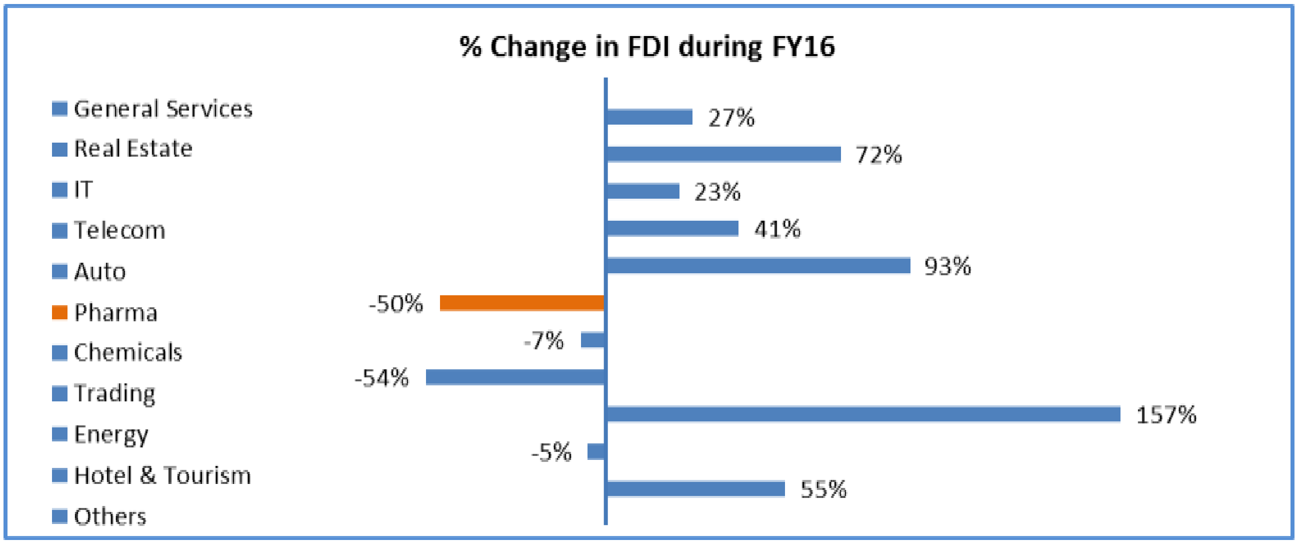
FDI forms one of the strong avenues of strategic investments in India and the country has attracted consistent growth in such investment during last three years. The FDI investment in India has shown considerable improvement from $ 30.9 bn during FY15 to $ 40 bn during FY16 registering growth rate of about 29%.

Following tables depicts FDI Scenario in India



The IPI although has made mark in the global pharma market, has attracted meager FDI. The FDI in the sector has rather depleted by about 50% to $ 754 bn during FY16 contributing to just about 2%, majorly on account of warning letters, alerts and bans issued by USFDA and ban by European EMA.



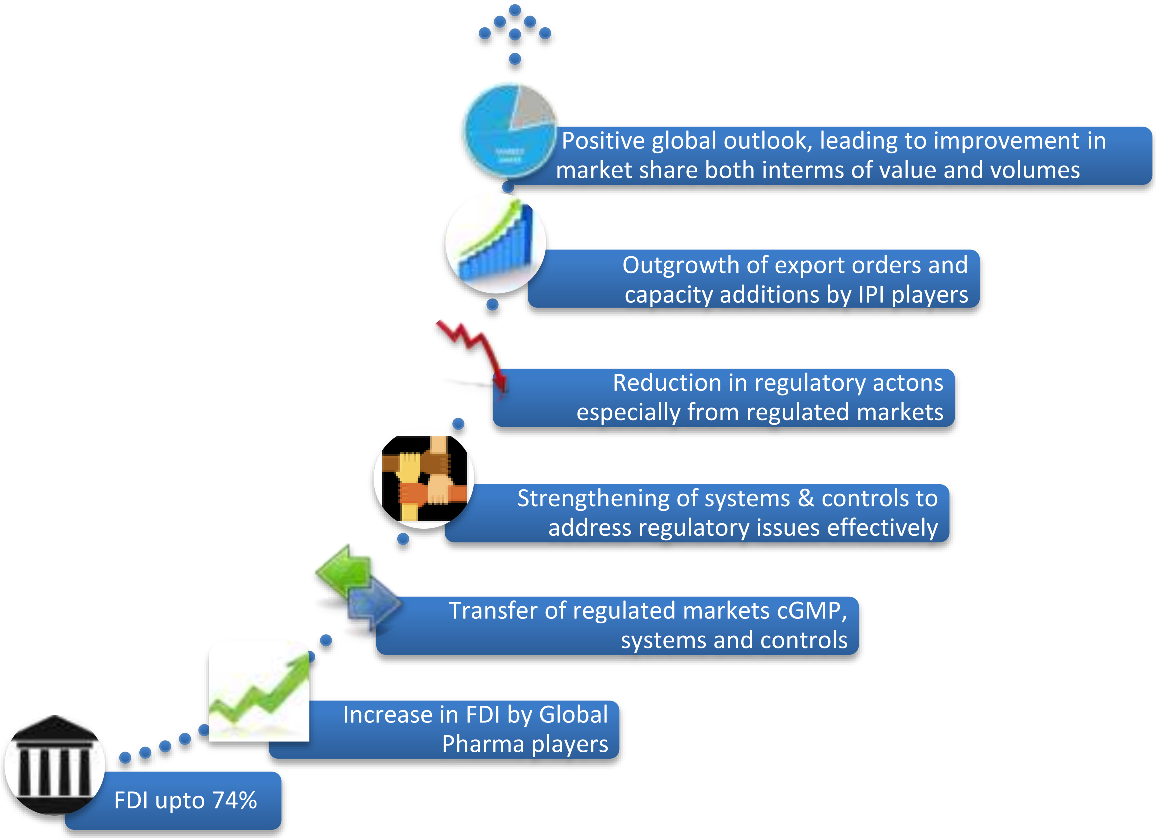


Of the sprawling sectors, there are very few industries which could sail through crests and troughs of economic cycles and other geo-political demographic vicissitudes. IPI is one such industry which has faced all such headwinds and thrived thus marking its presence having ranked third globally in terms of volume and thirteenth in terms of value. Despite all the aforesaid accolades IPI has failed to attract global pharma companies to invest in India, which can be inferred both in terms of contribution of total FDI in IPI (about 2%) and percentage growth in FDI during FY16 in IPI (a de-growth of about 50%).

Following is the graphical representation of impact of ensuing rise of FDI in Pharma Industry

The government, in order to benefit the pharma industry, has raised the FDI for brownfield projects to 74% under automatic route. This initiative by the government is expected to enthuse the global pharma players to invest in domestic companies leading to JVs, mergers or acquisitions, which in turn would benefit the entire stratum of the pharma industry. Beyond the said threshold, approval has to be obtained from Foreign Investment Promotion Board (FIPB). Under the existing policy, 100% FDI was allowed in Greenfield projects under automatic route whereas FDI in brownfield projects was allowed only with government approval.

The recent move by the government to allow FDI up to 74% under automatic route is expected to bring technological know-how in the Indian market which has been lagging behind in terms of innovation, research and development of new products. Apart from above most importantly CARE expects that the industry would derive benefits through transfer of cGMP (Current Good Manufacturing Practices), systems and controls. This development would soothe the industry by addressing the regulatory issues effectively which in turn would lead to reduction in regulatory actions especially from regulated markets. The aforementioned move would automatically increase the confidence in IPI thus attracting more number of export orders from across the globe. With all the above-mentioned ensuing developments, the market share of IPI is expected to improve both in terms of value and volumes going forward.



Conclusion:

The IPI has witnessed turbulence during last financial year, on account of compliance-related issue, which has reflected in significant decline in FDI in the sector. With cost leadership position and strong R&D capabilities, IPI is expected to bounce back and perform in line with the past. However, restoration of pharma industry reputation among foreign investors and to witness FDI inflow is bound to take some time. The new regulation for FDI in brown field investment upto 74% through automatic route will interest the existing investors to seek for better management control in India companies in the short term. Furthermore, this regulation is expected to result in sizable mergers and acquisitions in the medium term, which will help innovator companies having direct control in Indian companies and boost their profit margins at parent level.

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