Indian Pharma Industry to surpass USD 60 billion in two years

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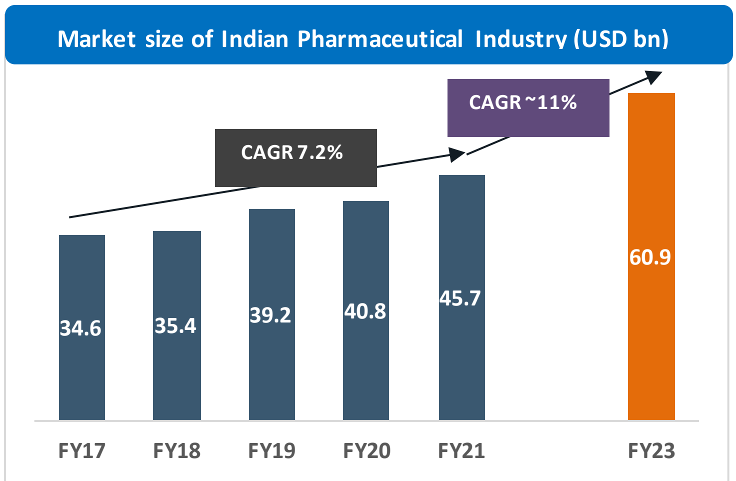
With market size of around USD 45 billion in FY21, Indian pharmaceutical industry globally ranks third in terms of volume and thirteenth in terms of value. The reason for higher rank in terms of volume while lower rank in terms of value is primarily attributed to the predominance of Indian pharma market in the generic segment. The industry has exhibited compound annual growth rate (CAGR) of about 7.2% during FY17-FY21 and registered a growth of about 12% during FY21. However, with the change in dynamics, CARE Ratings expects the industry to grow at about 11% in next two years and reach a size of over USD 60 bn. The main factors that are expected to drive the growth of industry are (a) ability to leverage the opportunity available for Indian pharma companies due to expiry of the patent drugs across the globe, (b) ebbing of regulatory risks, (c) adoption of various strategies to de-risk from dependency on China for key raw materials, (d) increasing trend in PE investments, and (e) solid fundamentals of the industry. Exploiting these opportunities, CARE Ratings expects the credit risk profiles of its rated entities to remain stable to positive during FY22 and FY23.

Past performance and estimated growth rate of Indian Pharmaceutical Industry

The Indian domestic pharma market which was at about USD 18 bn during FY17 has exhibited a CAGR of about 4.5% to reach USD 21 bn during FY21. Further, the pharma exports which contributed about USD 17 bn during FY17 have reported a CAGR of about 10% to reach USD 24 bn during FY21. Especially during FY21, on account of increase in the demand for Covid-19-related drugs, the exports have grown by 18%. Thus, on account of better export growth rate, the contribution of domestic to exports has changed from 52:48 during FY17 to 47:53 during FY21. CARE Ratings expects that with better prospects in regulated and semi-regulated markets, the contribution of domestic to exports would widen to 45:55 by FY23.

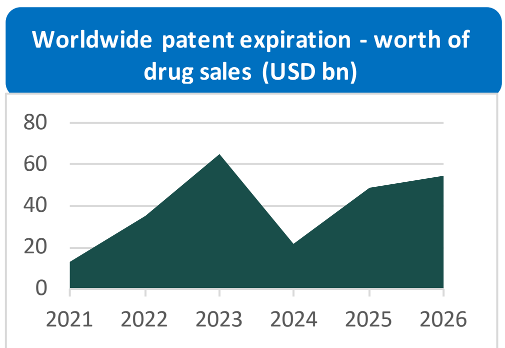


Source: CARE Ratings

Following are the main factors that would drive the growth of Indian Pharma Industry:

A. Opportunity available for Indian Pharma companies due to patent cliff:

Patent expiry allows the generic drugs to penetrate in the market and diversify product offerings. Over the next 5-6 years till 2026, the patented products worth of about USD 240 bn are expected to go off-patent. This provides a large opportunity to Indian generic formulation companies. Many of the Indian pharma companies are already working to develop the generic version of patented products to exploit the upcoming opportunity. It is expected that Indian pharma companies might get an opportunity worth around USD 5-6 bn due to patent expiry in next 4-5 years.



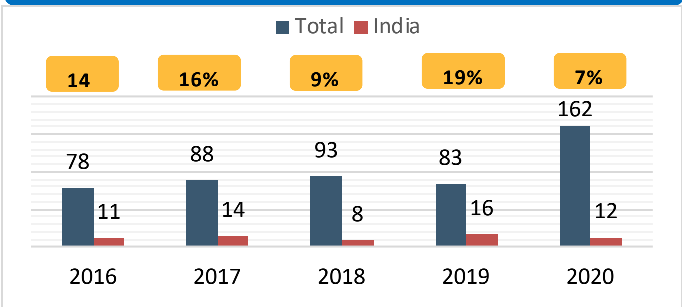
Source: CARE Ratings

India has a significant cost advantage in production, R&D and clinical trial costs over developed market. The cost of production, R&D cost and clinical trial cost in India is almost 50%, 87% and 90% respectively cheaper than developed market costs. These factors give India an advantage over developed countries. With these factors in favour of India, generic formulation companies in India have been investing in their capabilities to develop complex and specialty drugs. Given the opportunity, majority of the existing product pipelines are targeted towards the US market. It is also to be noted that of the total Abbreviated New Drug Application (ANDA) approvals granted by U.S. Food and Drug Administration (USFDA), India commands major share in product approvals. India's share in total ANDA approvals has increased to around 40% during CY20 and to around 44% in CY21 till June 2021 from 36% during CY17. India has the distinction of having the largest number of USFDA-compliant pharma plants outside of the US. With the available USFDA compliant infrastructure, it is expected that India will lead the patent cliff opportunity in US.

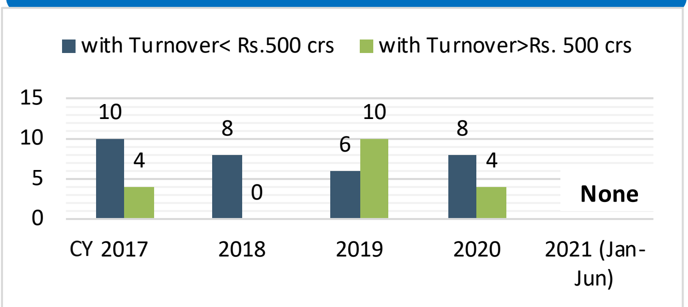
B. Ebbing of regulatory risks:

With increasing presence in developed market like the US, the regulatory risk remains a critical monitorable. In the past, India had faced regulatory challenges by USFDA. However, with experience, Indian companies have strengthened the compliances. Despite rise in the number of USFDA audits, the instances of adverse observation by USFDA came down since 2018. USFDA classified the audit observation in the form of official action initiated, or warning letter (WL) or import alert. The number of such adverse observation decreased over a period of the last 5 years. Furthermore, out of the total number of WL, those received by relatively large companies, having annual revenue more than Rs.500 crore, have reduced to 4 in 2020 compared with 10 in 2019. Moreover, large pharma companies are also hedging themselves through sight transfer and filing of ANDA from two sites. Though greater scrutiny by USFDA for compliances of GMP norms remains key risk for the Indian pharma given its dependency on US market, it is observed that during CY2020 and H1CY2021, the number of USFDA inspections have reduced considerably on account of prevailing Covid-19 situation. Although the adverse observations have reduced during past few years, nevertheless, CARE Ratings views any developments from regulatory authorities to be a key monitorable.

Share of Warning letters (WL) issued by USFDA to India

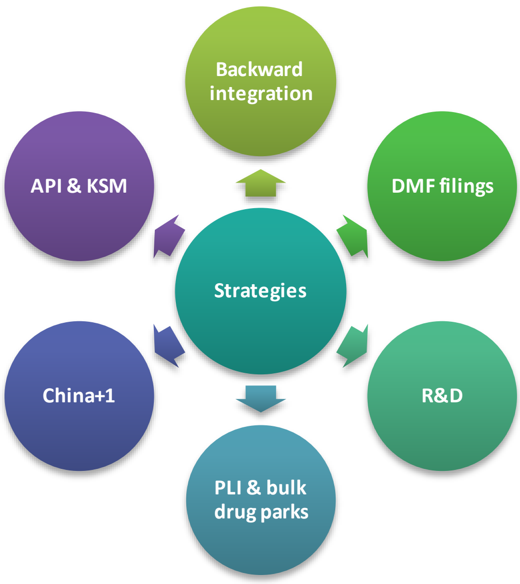


Number of WL received by Indian Pharma companies by Turnover



Source: USFDA and CARE Ratings

C. Strategies adopted to de-risk from dependency on China for sourcing key raw materials:



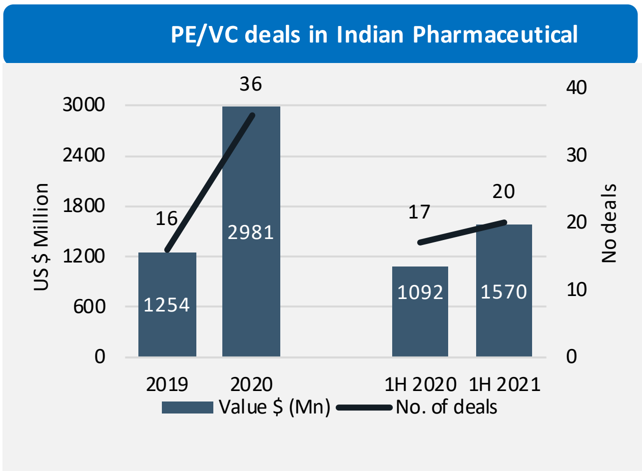
In order to mitigate the risk arising from dependency on China, one of important initiatives that majority of the Indian Pharma Cos have taken is to incur capex for their backward integration at least for some of the critical Key Starting Materials (KSMs). Most of the companies have increased their spend on R&D in order to produce cost and process-efficient raw materials. CARE Ratings expects the R&D expenditure by Indian Pharma Cos to remain at about 8% of the total sales for FY22-FY23. Furthermore, several global and domestic companies have sought for China +1 supplier base to have diversified supplier base. This, to some extent, has also proved advantageous for Indian pharma API companies as certain pie of global orders that was earlier more focussed towards China are shifting to India. The Drug Master Files by Indian Pharma companies have consistently remained over 300 during CY2017 to CY2020 and the trend is expected to continue.

As a part of the industry efforts, even Government of India (GoI) has recognised the need to support the industry to reduce its import dependency and has thus introduced several schemes and policies such as Production Linked Incentive (PLI) and setting up of large API parks.

GoI has provided budgetary allocation of around Rs.15,000 crore for PLI. Under PLI scheme for KSM and APIs, the government has already approved 46 applications till June 2021 which targets to incur capex of Rs.5,000 crore.

D. Increasing trend in PE investments towards the sector:

The value of total PE deals that took place during CY2020 was about USD 50 bn out of which 6%, i.e., about USD 3 bn worth deals were in Indian Pharma sector. Number of deals and aggregate value of those deals have more than doubled during CY2020 with continued buoyance during H1CY2021 as pharma sector gets more attractive. During H1FY2021, the industry has attracted PE deals worth USD 1.6 bn, which is 50% higher than the previous year. It is observed that some of the global top PE players have evinced interest in Indian Pharma players. Some of the notable PE deals during CY2020 and H1CY2021 include – KKR acquiring 65% stake in J.B. Chemicals and Pharmaceuticals Limited, Carlyle acquiring 20% and 74% stake in Piramal Pharma and SeQuent Scientific Limited, respectively, and Advent International acquiring almost 100% and 80% in RA Chem Pharma and ZCL Chemicals Limited, respectively.



Source: Indian PE & VC Association

Other large global PE players that were active during the said period were Goldman Sachs, ChysCapital, True North, etc. Many of these top PE players have their stakes in other pharma players across the globe. Thus, it is expected that with global experience of these players combined with their global network and operational expertise would eventually act as the catalyst for the overall growth of industry.

E. Solid fundamentals of the industry

During FY13-FY18, Indian Pharmaceutical Industry has faced headwinds in the form of significant price erosion, issues from regulatory authorities, spiralling of imported raw material prices from China due to change in pollution norms in that country, stiff competition amongst the domestic players, etc. However, the industry has absorbed those headwinds. It has to be noted that although the phenomena of price erosion of drugs continue to exist in US generic formulation market, the same has eased to a great extent since 2019. The industry has been benefitted with favourable movement of exchange rate thus providing healthy opportunities to grow its margins. The relatively inelastic demand of pharmaceutical products insulates Indian players from turbulences caused due to economic downturn or due to the prevailing pandemic. Furthermore, relatively strong credit metrics of Indian pharma companies also provide room to focus on organic and inorganic growth. Nevertheless, CARE Ratings perceives regulatory risk as the major barrier for the Indian ambition to grow its share in the global pharma market. Any adverse outcome of regulatory audit delays the launch of new product and increases the compliance cost.

Conclusion:

With the wide opportunity that exists ahead for Indian pharma due to patents expirations, increase in penetration of health insurance, growing chronic diseases, pharma companies endeavoring to move up in value chain towards New Chemical Entity (NCE), biosimilars and specialty drugs combined with support from government, backward integration and China+1 for supplier diversification, increase in interest expressed by PE players in the industry definitely provide healthy growth prospects to the sector. Furthermore, the huge opportunity provided by Covid-19 vaccine is expected to further boost the growth of industry for the next 2-3 years. The opportunity available for Indian pharma companies on account of Covid-19 vaccine is about USD 10-11 bn for the next 2-3 years. CARE Ratings expect that with all the opportunities mentioned above (excluding the opportunity provided by Covid-19 vaccine), the Indian Pharmaceutical Industry would exhibit growth of about 11% and reach a size of over USD 60 bn over the next two years. Furthermore, CARE Ratings expects the credit risk profiles of its rated entities to remain robust and capital structure to remain strong on the back of expected healthy cash accruals and minimal reliance on debt for capex.

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