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M&As peak in pharma industry

Globally, 2015 saw record mergers led by $160 billion deal between Pfizer and Allergan

NEW DELHI: Facing an increasingly watchful eye of the health regulator in the U.S., Indian pharmaceutical firms are gearing up to tap new markets in 2016 as they look to consolidate their positions after a spate of mergers and acquisitions consummated this year.

Globally, it remained a year marked with record mergers led by the 160-billion-dollar deal between Viagra-maker, Pfizer Inc and Botox manufacturer, Allergan.

YEAR IN REVIEW

These deals came at a time when the domestic pharma firms continued to remain under intense regulatory spotlight, specially of the U.S. Food and Drug Authority (FDA) while they stared at yet another challenge domestically over possibility of prices of more drugs coming under government control.

The biggest of the deals came from Pfizer which stitched a 160-billion-dollar deal to take over Allergan creating a global pharmaceutical behemoth.

It wasn't Pfizer's only deal. The U.S. giant also bought Hospira Inc., a leading provider of injectable drugs, infusion technologies and biosimilars, in a 17-billion-dollar deal.

Indian firms, including Sun Pharma, Cipla and Lupin, too, took the acquisition path in their quest for international footprint expansion.

The biggest acquisition by an Indian firm in 2015 was by Lupin which agreed to pay $880 million (over Rs.5,610 crore) to take control of the U.S.-based Gavis. Drug major Sun Pharma also inked deal of over $48 million to acquire the U.S.-based eye-care firm InSite.

Another homegrown pharma major, Cipla, also paid 26-million-dollar (around Rs.166 crore) upfront to acquire majority stake in Uganda's Quality Chemicals.

Reflecting on implications of the events of 2015, Novartis India Vice Chairman and Managing Director Ranjit Shahani, who was earlier the President of industry body, OPPI, told PTI: "As pharma companies globally look at consolidating in some way or the other, Indian pharma firms would do well to negotiate the new pharma landscape. It will also provide them the opportunity to actually benefit from spin-offs."

Almost a year after announcing the four-billion-dollar deal, Sun Pharma completed the merger of Ranbaxy with itself.

The deal fortified Sun's position as the world's fifth largest specialty generic pharmaceutical firm and the top ranking Indian pharma company with significant lead in market share.

In contrast, Japanese drug maker Daiichi Sankyo sold its entire stake of around nine per cent in Sun Pharma for over Rs.20,420 crore, which it had received after merger of Ranbaxy with the Indian firm, ending its seven years of tumultuous experience in the country.

On the regulatory front, the year witnessed many Indian firms coming under the scanner of the regulator in the U.S., which remains a key market for Indian generic drugmakers.

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>
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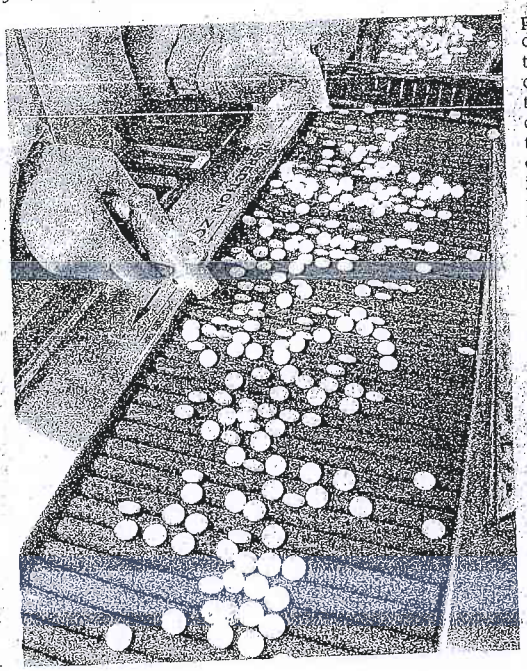
> Secretary General, Indian Pharmaceutical Alliance



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Sun Pharma was forced to take remedial action at its Halol facility for lapses in manufacturing norms and was given a warning letter. Earlier, its another plant at Karkhadi, also in Gujarat, had received a warning letter from the USFDA after investigators found similar violations.

Hyderabad-based Dr. Reddy's Laboratories also received a warning letter from the U.S. drug regulator over quality issues at its two API manufacturing plants and a formulation unit in Andhra Pradesh and Telangana.

"Pharmaceutical companies will have to gear up to meet the increasingly watchful eye of the USFDA and this is bound to have an impact in the near term for companies who export heavily to the U.S.," Mr. Shahani said.

Wockhardt had to recall 13 drugs in the U.S., manufactured at its two units at Chikalthana and Waluj in Maharashtra, which were under import restrictions from the USFDA.

In the U.S., Cipla also recalled 1.41 lakh vials of Levalbuterol Inhalation solution used for relieving shortness of breath and coughing caused by asthma and chronic obstructive pulmonary disease for failed impurities and degradation specifications.

Likewise, Mylan got a warning letter from the USFDA for violation of current good manufacturing practice (CGMP) norms at its three plants in Karnataka.

Drug maker Sharon Biomedicine was issued a warning letter by the USFDA for failing to pay generic drug user fee by its owner for three years starting 2013, saying its Dehradun-based facility would be barred from shipping products to the U.S. if the dues are not cleared. "Unless the major companies are successful in expeditious resolution of regulatory issues, the developed markets will continue to hurt the growth. The opening up of Japanese generic market and focus on the Latin America and Africa may bring some relief," Indian Pharmaceutical Alliance Secretary General D G Shah told PTI.

The year also saw the government making an attempt to expand drugs under price control by revising the National List of Essential Medicines which, the industry felt, would hamper growth of the sector.

"The volume and value are consistent with the character of the generic industry...but new products growth is grossly below its potential. This is mainly due to slowdown in marketing approvals during the preceding two-year period and delay/denial of price approvals by the NPPA for new products during 2015," Mr Shah said.

On expectations for the next year, Mr Shah said 2016 is expected to maintain the current year's growth rate in the domestic market, against its potential of about 18 per cent growth.

"This below potential growth is due to the change over to the NLEM 2015, which will enlarge the span of control adversely impacting value growth. It may in fact have negative impact. Besides, intense competition will lead to price erosion," he added.

The government, on its part, took steps such as measures to improve bulk drug manufacturing in India to reduce dependence on China and planning a separate ministry for pharmaceuticals sector to boost the domestic industry.

It also brought in the Uniform Code of Pharmaceuticals Marketing Practices (UCPMP) effective till January 2016, for ethical marketing. —PTI

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