



Drug Firms Expect Pricing Pressure to Stabilise in US

Pricing pressure in the US, the world's largest single country drug market, is showing signs of easing. Analysts expect the pricing pressure to normalise in a year or so reverting to earlier levels of low to mid-single digit. This is primarily because the companies have off late focussed on nationalising product portfolios as well manufacturing facilities and have exited products with thin margins.

The US market has seen price erosion levels of 5-6 per cent. However, with faster drug approvals and higher rate of launches coupled with consolidation in the wholesale and distribution network, the price erosion got worse in the last few years, rising to high single digit to low teens.

Several Indian Pharma majors have already indicated in their earnings calls that they expect pricing pressure to stabilise over the coming months. The largest generic drug manufacturer in the US, Teva Pharmaceuticals, plans to exit 80 percent of their generic portfolio in response to pricing pressure and has closed more than 10 manufacturing facilities so far.

In a note, ICRA said over the last 12-15 months, companies had been exiting several products where pricing was untenable. For example Dr

Reddy's Laboratories has sold two of its manufacturing facilities – one in India and another in the US – to streamline its manufacturing operations and optimise the cost structure. It tried to get out of the commodities antibiotic portfolio. These initiatives are likely to reduce competitive pressures enabling normalisation of prices, felt Gaurav Jain, vice president and co-head corporate ratings, ICRA.



Companies, however, are being cautiously optimistic. A Cipla spokesperson said: "It's difficult to say at this point whether the pricing environment in the US has completely stabilised, and how this will play out in the second half of the quarter, but there is certainly more optimism now."

He said with no products getting added Cipla business to business (B2B) was experiencing natural decline by design. A relatively late entrant in the US market, Cipla is focussing on complex generics in that market. "Our effort to improve our production mix with more emphasis on limited competition assets has already started to deliver significant margin improvement and revenue growth," he said.

Lupin CEO had indicated in the Q2 earnings call: "The US market is gone through a lot of pressure over the last couple of years, but we are starting to see some level of stabilisation and moderation in price erosion setting in."

Meanwhile, drug makers are consolidating manufacturing facilities and rationalising their product portfolio in the US as they battle price erosion and weak profits.

Sun Pharma is closing down its manufacturing site at Cranbury in New Jersey, and consolidating operations at the Ohm facility in the same state. It has more than 40 plants globally including five in US. (Source: Business Standard)

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Texas Judge Strikes Down Obama's Affordable Care Act as Unconstitutional

WASHINGTON — A federal judge in Texas struck down the entire Affordable Care Act on the grounds that its mandate requiring people to buy health insurance is unconstitutional and the rest of the law cannot stand without it.

The ruling was over a lawsuit filed this year by a group of Republican governors and state attorneys general. In his ruling, Judge said that the individual mandate requiring people to have health insurance "can no longer be sustained as an exercise of Congress's tax power."

Accordingly, the Judge, said that "the individual mandate is unconstitutional" and the remaining provisions of the Affordable Care Act are invalid.

At issue was whether the health law's insurance mandate still compelled people to buy coverage after Congress reduced the penalty to zero dollars as part of the tax overhaul that President Trump signed last December.

When the Supreme Court upheld the mandate as constitutional in 2012, it was based on Congress's taxing power. Congress, the court said, could legally impose a tax penalty on people who do not have health insurance.

"The ruling is an assault on 133 million Americans with pre-existing conditions, on the 20 million Americans who rely on the A.C.A.'s consumer protections for health care, on America's faithful progress toward affordable health care for all Americans," Mr. Becerra said in a statement. "The A.C.A. has already survived more than 70 unsuccessful repeal attempts and withstood scrutiny in the Supreme Court."

If Judge decision ultimately stands, about 17 million Americans will lose their health insurance, according to the Urban Institute, a left-leaning think tank. That includes millions who gained coverage through the law's expansion of Medicaid, and millions more who receive subsidized private insurance through the law's online marketplaces.

Insurers will also no longer have to cover young adults up to age 26 under their parents' plans; annual and lifetime limits on coverage will again be permitted; and there will be no cap on out-of-pocket costs.

Also gone will be the law's popular protections for people with pre-existing conditions, which became a major talking point in the November midterm elections, as Democratic candidates constantly reminded voters that congressional Republicans had tried to repeal the law last year.

Many Democrats successfully centered their midterm campaigns on protecting the Affordable Care Act's insurance mandates for pre-existing conditions. (Source: New York Times)

Coeptis Pharma Enters into Agreement to Acquire Elto Pharma

NEW YORK and WEXFORD, Pa., Coeptis Pharmaceuticals, Inc., a diversified commercial biopharmaceutical company, announced that it has entered into a binding agreement to acquire all outstanding shares of Elto Pharma, Inc. Elto Pharma is developing eltoprazine, a serotonergic agonist in Phase 2b development for the treatment of Parkinson's disease levodopa-induced dyskinesias (Parkinson's LID). Elto Pharma is a joint venture between Amaranthus Bioscience Holdings, Inc. and Psychogenics, Inc.

"Eltoprazine will be a key long-term growth driver for Coeptis given its outstanding profile as a potential therapy across several brain-related conditions," said David Mehalick, President & CEO of Coeptis. "As we focus on the near-term commercialization of our 505(b)2 and generic pipeline, with the launch of our first FDA-approved 505(b)2 product expected in 2019, Coeptis will be strongly positioned to successfully launch its products across multiple disease areas in the years ahead. Eltoprazine has blockbuster potential as a new chemical entity treatment for multiple neurological conditions, beginning with Parkinson's LID."

"After a thorough review of strategic options for Elto Pharma, we believe this transaction with Coeptis represents the best outcome for Amaranthus and its various stakeholders," said Gerald E. Commissiong, President & CEO of Amaranthus, and interim-CEO of Elto Pharma. "Coeptis has a strong operational team and a robust pipeline of products preparing to be commercialized that we believe will drive shareholder value in the years ahead. We are very excited to become part of the Coeptis organization." (Source: Globe Newswire)

India's Sun Pharma to Acquire Japan's Pola Pharma for USD One Million

Pola Pharma's portfolio mainly comprises dermatology products. It has two manufacturing facilities in Saitama with capabilities to manufacture topical products and injectables.

Sun Pharma will acquire Japan-based Pola Pharma for around USD 1 million to strengthen its presence in dermatology segment across the globe.

The company has entered into a definitive agreement to acquire Pola Pharma, which is engaged in research and development, manufacture, sale and distribution of branded and generic products in Japan, Sun Pharmaceutical Industries said in a statement.

Pola Pharma's portfolio mainly comprises dermatology products. It has two manufacturing facilities in Saitama with capabilities to manufacture topical products and injectables.

It also has R&D capabilities to develop new technologies and formulations.

"This acquisition is in line with our strategy to strengthen our global dermatology presence. Pola Pharma is a leading dermatology company and it will help us launch our speciality and generic dermatology products in the Japanese market in future," Sun Pharma Executive Vice-President Kirti Ganorkar said.

Sun Pharma Japan Country Head Junichi Nakamichisaid said that by combining its global strengths with Pola Pharma's local expertise, the company will have a great opportunity to further strengthen its presence in Japan, especially in dermatology.

Pola Pharma had an annual revenue of around USD 108 million and net loss of USD 7 million for the 12 months ended December 2017 on consolidated basis.

"The equity consideration, on debt-free and cash-free basis, for the 100 per cent stake in Pola Pharma is around USD 1 million," Sun Pharma said.

The transaction is expected to close on or before January 31, 2019, subject to completion of closing conditions, it added.

Sun Pharma forayed into the Japanese prescription market in 2016, with the acquisition of 14 established prescription brands from Novartis. The size of the Japanese pharmaceutical market is estimated at USD 84.8 billion, accounting for around 7.5 per cent of the USD 1.13-trillion global pharmaceutical market. (Source: PTI)

Western Markets Hold Back Global Growth For Neurology Drugs

LONDON, As a new report, Pharmaceutical Drugs Global Market Opportunities And Strategies To 2021, from The Business Research Company, shows, North America and Western Europe, the world's two largest markets for neurology drugs to treat diseases of the brain, spinal cord and nerves, are holding back global growth to around 5% annually, despite vigorous growth in other regions. Asia Pacific's market, which is nearly as large as that of Western Europe, will grow at almost 9% year on year to 2021, and so will the smaller market of the Middle East. Africa and South America will also see above-average growth. Increased incidence of age-related disease in the developed world and greater affordability of treatments with growing GDP per capita in the emerging markets help account for growth in the markets for these drugs.

Neurology drugs are used to treat conditions such as epilepsy, Alzheimer's disease and other dementias, cerebrovascular diseases including stroke, migraine and other headache disorders, multiple sclerosis, Parkinson's disease, neuro infections, traumatic disorders of the nervous system due to head trauma, and neurological disorders as a result of malnutrition. Anaesthetics is the largest subsegment in the neurology (central nervous system) drugs market and its growth rate is accelerating. The high market size for this segment can be attributed to the rising prevalence of preventive surgery for cardiovascular diseases and chronic respiratory diseases. Analgesics are the fastest-growing segment, but is maintaining a stable growth rate rather than an accelerating one; anti-epileptics growth rate is also stable but at a much slower pace than analgesics, while both anti-Parkinson drugs and other central nervous system drugs are showing a slight decline in their growth rates.

The top-selling neurological medications in 2016 include Copaxone, Lyrica, and Tecfidera. The market for neurology drugs is more concentrated than that for most drugs, as the leading ten competitors account for two-thirds of the total instead of, as in the case of cardiovascular drugs, around one-third. America's Biogen is the market leader, closely followed by the Swiss Hoffman-La Roche, both with close to 12% of global sales; Johnson and Johnson are in third place with about an about 9% share.

Pharmaceutical Drugs Global Market Opportunities And Strategies To 2021 is one of a series of new industry reports from The Business Research Company that identify opportunities and explain strategies in over 300 markets, covering over 2400 market segments and 56 geographies. It provides a pharmaceutical industry overview, pharmaceutical industry analysis, past drug industry statistics and forecasts. Like the other reports in the series it also provides market growth rates, market trends, market drivers, market restraints, market revenues, market shares and company profiles of the leading competitors. These industry reports draw on 150,000 datasets. Extensive secondary research is augmented with exclusive insights and quotations from industry leaders obtained through interviews. Market analysis and forecasts are provided by a highly experienced and expert team of analysts and modelers. Key actionable strategies are explained and opportunities identified by country and segment. (Source: EIN Press Wire)

Lupin to Cipla, Pharma Firms on Course to Shed 'Underperformer' Tag in FY19

After underperforming the broader indices for each of the last three fiscal years, the Nifty Pharma — with returns of over 20 per cent — has been one of the best performing indices this fiscal. And the trend is likely to continue.

One of the reasons for the rally has been the 15 per cent depreciation of the Indian Rupee compared to the greenback. While Divi's is the biggest beneficiary (90 per cent of revenue exposure to the dollar), Dr Reddy's, Aurobindo and Cadila Healthcare, too, will benefit as over half their revenues are denominated in dollars.

Further, what has helped is the street's preference for defensives with Indian pharma companies experiencing a gradual turnaround in the US. Most experts believe the sector is poised to improve its financials and returns trajectory.

Analysts led by Deepak Malik of Edelweiss Securities expect a revival in revenue and earnings growth, to be led by normalising regulatory and concentration risks, entry into complex and especially drugs, and currency tailwinds.

A key indicator of the turnaround has been the improvement in pricing environment in the US. Price erosion — which had been hovering low to mid teens last year — has come down to single digits with the trend likely to continue over the next two quarters.

While the September Quarter (Q2) results point to a mixed bag, Kunal Dhamesha of SBICAP securities expects pricing pressures in the US — which accounts for 20-50 per cent of revenues for larger pharma firms top abate on two counts. First companies continue to rationalise portfolios. With returns on some of the molecules turning negative, companies are pulling out even approved molecules, with withdrawals increasing to 548 over the last one year, this is double the number recorded over the previous years. Teva and Sun Pharma have the highest withdrawals of drug applications.

The reason is the shift in focus to complex generics and molecules that are difficult to make and more profitable. While the base business will continue to face pricing pressure as has been the case in Q2, incremental specialty launches should help reduce overall impact.

What should also aid generic players is the resolution of regulatory issues at various plants, especially with respect to launch of limited competition drugs in the US.

Following updates from the management after Q2 analysts expect resolution and clearance by the US FDA for Lupin's Unit II (Pithampur, Indore) and Goa unit by mid 2019. Both had received a warning letter in November 2017.

While Dr Reddy's regulatory resolution may take time, any resolution—especially of its Duvvada oncology formulation unit at Visakhapatnam where inspection began last month—is expected to be positive for the stock.

Second, consolidation among generic manufacturers increases their bargaining power. While there has been consolidation among distributors, which has increased their bargaining power (top three distributors account for 90 percent of sourcing), generic manufacturers are fragmented, with the top ten accounting just over 55 percent of the generic spends in the market. This is expected to drive consolidation of generic players at attractive valuations as evident when Aurobindo acquired some generic assets of Sandoz for \$900 million at less than one time sales.

The low average of large Indian generic players (most are sitting on cash) — less than half their international peers — should help them acquire assets in the US and other geographies at reasonable valuations. This will lead to lower competition in the sector on the manufacturing side and thus improve pricing, say analysts.

With various positives are likely to play out over the second half of the current fiscal, analysts believe earnings growth for larger generic players should be upwards of 15 percent, over FY18-20. This should reverse the cycle of poor performance resulting in decade low operating profit margins in FY18 due to pricing/regulatory pressure in the US.

Brokerages prefer Aurobindo, Sun Pharma and Dr Reddy's—given the diversified portfolio, a differentiated pipeline, R&D and execution capability. (Source: Business Standard)

In Six Years, Oral Cancer Cases Rise by 114% in India: Study

Researchers have discovered that a particular drug combination may have a more significant effect against melanoma, a type of cancer that typically occurs in the skin, than other medications.

According to recent studies, one of the best ways of blocking melanoma is by administering protein kinase inhibitors, which prevent the action of certain specialized enzymes.

The main downside of treating people with this type of cancer with protein kinase inhibitors is that



they often acquire resistance to the drugs, making them ineffective.

However, researchers from the Massachusetts Institute of Technology in Cambridge, believe they may have found a way to boost the effect of protein kinase inhibitors and prevent resistance to them.

The specialists suggest that combining protein kinase inhibitors with ribonuclease drugs could improve melanoma treatment.

Ribonucleases can "unravel" RNA, a molecule that helps to encode and decode genes, as well as regulate gene expression. They also put up a "shield" against viral RNA, which is the genetic material of certain aggressive viruses.

"We discovered that this ribonuclease drug could be paired favourably with other cancer chemotherapeutic agents, and not only that, the pairing made logical sense in terms of the underlying biochemistry," explains Prof. Ronald Raines, senior author of the new study.

(Source: Medical News Today)



*RP : RepTrak Points

*RepTrak® poin dihitung dari 2,608 peringkat individual yang masing-masing mempertimbangkan 7 kriteria: produk dan pelayanan, inovasi, tempat bekerja, tata kelola, negara asal perusahaan, kepemimpinan dan performa keuangan perusahaan. Dari 22 perusahaan farmasi, Sanofi merupakan perusahaan farmasi memiliki reputasi paling baik.

*RepTrak® points are calculated from 2,608 individual ratings on seven areas : product and services, innovation, workplace, governance, citizenship, leadership, and financial performance. These contribute to companies "RepTrak" score. Overall, of the 22 pharma companies ranked, Sanofi was number one.

Sumber/Source : <http://www.businessinsider.com/pharmaceutical-company-reputation-rankings-2018-6>

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In Six Years, Oral Cancer Cases Rise by 114% in India: Study

The number of cancer cases countrywide has gone up in the last six years by 15.7%. Data shared by Indian Council of Medical Research's National Institute of Cancer Prevention and Research on Wednesday showed that 11.5 lakh cancer cases were reported across the country this year, as against 10 lakh in 2012.

Experts from Tata Memorial Hospital said the increase was not alarming as it can be explained with factors such as increased population and better diagnostic techniques. As per the new data, cancer-related deaths also increased by 12%. While 7 lakh Indians died of cancer related complications in 2012, the number increased to 7.8 lakh this year.

ICMR cancer centre director Dr Ravi Mehrotra said lip and oral cavity cancers increased by a whopping 114% in the six-year period. Breast cancer, emerging as a disease linked to urban lifestyle, increased by almost 11% from 1.4 lakh in 2012 to 16 lakh in 2018.

The numbers are estimates provided by web-based Globocan programme that was developed by international Agency for Research on Cancer among Indian women. Globocan data showed a 21% fall in cervical cancer cases, from 1.23 lakh in 2012 to 96 in 2018.

Dr Mehrotra said, "An increase in awareness, better screening and treatment facilities, later age of marriage, fewer pregnancies and improved hygiene leading to fewer infections are some key factors contributing to this decline in cervical cancer cases.

Dr Rajesh Dikshit, who heads Tata Memorial Centre's epidemiology department said the incidence of cervical had started decreasing in Mumbai many years back. 'A decade back, the incidence in Mumbai was 127 cases for every 100,000 population, but the incidence has now dropped to 8 per 100,000 in Mumbai," he said.

ICMR officials said as 18 % of the world's population lived in India. It was important to understand the disease burden of cancer in every state of India. ICMR released an elaborate state-wise data of cancer along with medical journal, 'The Lancet', last month. (Source: Times of India)

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For feedback and query

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