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Heat On US Pharma Firms

It is astonishing that a 100-year-old product like insulin has seen prices rise steadily, to the point at which one study found that obtaining the life-saving drug was an extreme financial burden to a vast number of people — 14 per cent of Americans for instance, and over 40 million Indian diabetics.

Why? Partly, the drug companies are granted patents on treatments, essentially a temporary monopoly to let them recoup their R&D investments. Those temporary monopolies are very sweet, prompting lots of strategies to extend them through a variety of practices that have come under heavy criticism.

Paying for R&D

Manufacturers argue that they need high prices to pay for the R&D that creates miracle drugs in the first place. There are essentially no regulations around what a pharma firm can charge for a new drug, leading to eye-popping prices — Gilead Science charges $84,000 for a full course of its hepatitis medication, Sovaldi.

While that's pretty high, remember that the drug cured Hepatitis-C, preventing eventual liver transplants or other expensive treatments. Gilead argued that the high price was needed to recoup the investment they made to find the cure, and a curative drug is less lucrative than a drug that has to be taken on an ongoing basis. One may argue that the company was motivated by profits, rather than providing a relief to a greater number of patients suffering from Hep-C.

In the US, things are a bit weird. Just like the MRP in India, there is a “list price.” But, the pharma company then negotiates extensively with Pharmacy Benefit Managers (PBMs), who negotiate on behalf of insurers and payers. The PBMs are supposed to remove administrative burdens from insurers and the plan sponsors who actually pay for the whole system.

In reality, PBMs have become incredibly powerful, making much of their money on rebates that they negotiate. To appease them, many manufacturers raise the “list” price and offer a bigger rebate, which is unfortunate for those who actually do have to pay the list price. This is a totally different system from most developed countries, where national health systems do the negotiation.

And, in a uniquely American twist, when prescription drug benefits were added to Medicare under a 2003 law, Congress specifically forbade the two large public payers from negotiating, instead implementing a sort of “most favoured customer” clause. This clause effectively gave pharma companies an out when other players tried to negotiate hard, by saying they couldn't afford to offer discounts to the two biggest payers! The new Inflation Reduction Act in the US essentially ends the most favoured customer clause on a few drugs, granting the health ministry to negotiate prescription drug prices for Medicare patients.

Exclusivity period

But another shift, embedded in the Act, helps the government negotiate pricing for drugs after a window of exclusivity for nine years (for so-called small-molecule drugs that you typically take in pill form) and 13 years for large-molecule drugs (that have to be injected/infused). What that means is that the lifecycle during which a pharmaceutical company can enjoy a ‘monopoly’ is going to be truncated.

Will this make manufacturers look for products that face less impact by the Inflation Reduction Act? Plans and programmes with a shorter exclusive “expiry date” are likely to be de-emphasised by pharma decision-makers. A new challenge will come from payers like Caterpillar, which has been able to tame the growing cost of prescription medicines. This could create a watershed for payers, who seem to have the least amount of control over the system, despite footing the bill. McGrath is professor at Columbia Business School; Muneer is Fortune-500 advisor, startup investor and Co-Founder of the non-profit Medici Institute for Innovation. (Source: Business Line)

Indian Pharma Industry To Witness 11% Rise In Revenues, Propelled By Domestic And US Markets

The Indian pharmaceutical industry is poised for robust growth this fiscal, primarily because of active growth both in India and the US, new product launches, and a healthy product mix, according to the financial services firm, Sharekhan. The firm projects an 11% year-on-year (YoY) revenue increase to Rs 60,202 crore, Ebitda growth of 24% to Rs 14,971 crore, and PAT growth of 43% to Rs 9,174 crore for the industry.

Sharekhan estimates that Ebitda margins for pharmaceutical companies will rise by 252 basis points y-o-y to 24.9%, buoyed by a robust product mix and RM cost rationalisation. The Indian segment of the industry is estimated to grow by 10% to Rs 14,908 crore.

The firm also expects the US segment to register 12% YoY growth, propelled by product launches to Rs 17,451 crore. Top picks within the industry include leaders like Sun Pharma, Dr. Reddy's, and Cipla, among large caps. Mid-cap favourites are Sanofi, Strides Pharma, and Caplin Point, while Artemis Medicare tops the list among hospital stocks.

The fourth quarter of the fiscal year 2024 alone is expected to yield an impressive 11.4% YoY growth in sales for pharmaceuticals, with demand expected to rise in the chronics segment and new product launches. The Indian region is predicted to see a YoY growth of 10% while the US region is set to grow by 12%, driven by the launch of complex products.

Despite ongoing headwinds such as R&D expenditure and USFDA inspection, Indian pharmaceutical companies are well-positioned to take advantage of growth opportunities due to their global competitiveness and substantial market share.

Sharekhan anticipates the industry will sustain its performance owing to 8-10% growth in the domestic branded business and a focus on complex product launches. The sector forecasts are further bolstered by companies' increasing investment in R&D, with potential medium and long-term growth driven by factors such as rising Loss of Exclusivity (LOE) opportunities, increasing preference towards specialty and complex generics, and emerging opportunities due to the China+1 factor in the Active Pharmaceutical Ingredients (API) space. (Source: Business Today)

Indian Private Hospitals' Revenue Growth Set To Continue, Reaching 11-12% in FY25: CRISIL

Indian private hospitals' revenue growth set to continue, reaching 11-12% in FY25: CRISIL Private hospitals in India are predicted to witness a robust 11-12% growth in revenue in the fiscal year 2025, credit rating agency CRISIL said on Tuesday.

This comes on the heels of an estimated 14% growth in the fiscal year 2024, primarily fuelled by healthy occupancy levels and a consistent rise in average revenue per occupied bed (ARPOB).

"Healthy demand for healthcare services, increased awareness of lifestyle treatments, rising medical tourism, and increasing health coverage will ensure bed occupancy is sustained at 60-62% even on significantly enhanced capacities in fiscal 2025," said Anuj Sethi, Senior Director, CRISIL Ratings.

Medical tourism, accounting for 10-12% of revenue, is expected to grow at nearly double the overall rate in the mid-term, driven by affordable treatment costs, world-class facilities, and skilled medical personnel, the agency said. The preponderance of medical tourists is seen to come from South-East Asia and the Middle East.

Moreover, the rising trend in health insurance coverage, growing at over 20% in the last two fiscal years, is making quality treatment more affordable and accessible. Demand for healthcare services is also expected to increase due to the rising occurrence of lifestyle diseases and an ageing population.

CRISIL has predicted that in response to this demand, hospital chains will add 2,000-2,500 beds in fiscal 2025, following an estimated addition of 2,000 beds in fiscal 2024.

Poonam Upadhyay, Director, CRISIL Ratings, suggested the growing revenue and healthy operating margins will "ensure strong cash accrual, which will help fund more than 65% of the total planned capex of Rs 4,500 crore by private hospitals in fiscal 2025." However, despite these promising business prospects, CRISIL warned that the sustainability of high occupancy levels and any potential impact of regulations on private hospitals should be closely watched. (Source: Business Today)

Indian Pharma Gets A US Booster Shot

Indian pharma's US business is back on strong footing again. In the 9MFY24, the US segment grew by an average of 22 per cent across the top five companies against a 7 per cent YoY increase last year. There have been structural shifts behind the performance which is reflected in the stock returns as well. The sector indices (Nifty Pharma or BSE S&P Healthcare) have returned more than 60 per cent in the past year with a valuation premium at 20 per cent (one-year forward PE against past five-year average). There are two primary drivers of the re-rating. Plants exiting US FDA's heightened scrutiny of last three years and complex product profile developed in that period. The two drivers, being structural in nature with impact extending to several more years, valuations have also expanded in tandem.

Plants approvals drive products

By the middle of 2023, plant inspection outcome started turning favourable for Indian companies which started the turnaround for the sector. Only in 2020-22, Aurobindo, Sun Pharma, Lupin, Cipla and Zydus Lifesciences had plants in warning letters or import alerts. Fast forward to 2024, Lupin has cleared three of the five plants under observation, Aurobindo also reported four of its plants receiving favourable outcomes in 2023.

Similarly Zydus Lifesciences, Torrent Pharma and others, reported a positive improvement. This has led to a strong growth in product launches. Aurobindo and Lupin for instance have launched 50 and 30 per cent more products in last two years compared to their previous three years. Dr. Reddy's which had its main plant's approval earlier than others.

Astrong launch calendar in FY23 itself. Plant approvals translating to product approvals has a first order impact on the return metrics. Investments made on the plant, personnel and more importantly on R&D and filing expenses (which are significant for US ANDA approvals) have been utilized by way of launches with apparently very low levels of product write offs. Even with plants getting the go-ahead, analysts had expected delayed approvals to impact its relevance in the market, which has not been the case. Secondlyhigh.

The approval rate is crucial for pharma companies with a sizeable portfolio of more than $1 billion. Earlier rounds of buyer consolidation in US generics markets has forced high teens price erosion every year in legacy portfolio. New product launches ranging above 15-20 products would deliver an additional revenue of $120-200 million per year (assuming $8-10 million per launch), in order to overcome a 10 per cent price decline in base portfolio and drive growth. The renewed launch calendar also coincided with softening of price decline in US generics which is currently facing shortages and had to scale back on price discounts.

Scaling up on complexity

Sun Pharma and Cipla, have not witnessed a turnaround in product approval rate (Halol for Sun and Goa for Cipla are under observation). But the revenue growth has matched that of the sector, as the two companies' complex and speciality portfolios, respectively, have delivered strongly. Even amongst others, without a stark uptick in complexity of portfolio, a slow march towards product differentiation is well underway. Lupin with its extensive respiratory portfolio has transformed a bulk of its revenue base to complex portfolio.

There are now injectable, metered sprays, solutions, creams and extended release or delayed release capsules as part of the base portfolio for other players as well. On patent complexity, most of the leading players have got access to gRevlimid, which should deliver until FY26 before competition sets in. Large patent expiries in diabetes and ARV's are expected in next few years, which can support the momentum.

Pharmaceutical companies though are not uniform and have to be analysed by their pipelines. A large turnaround in US business has supported the current segment momentum. The upside in shares and index already reflect these. But going ahead, product approvals, favourable price erosion and large one-time opportunities will have formed part of the base. Growth from such high base will determine each companies' outlook. (Source: Business Line)

Pharmacies Journey Through Litigations and Another Election

Over a fortnight ago, a key association representing chemists across the country wrote to BJP President JP Nadda, calling for a few pharma trade-linked features to be included in the party's election manifesto. One of their asks was to ban e-pharmacies.

Rekindling a long simmering and contentious debate, the All India Organisation of Chemists and Druggists' (AIOCD) letter said, online medicine businesses "posed a serious threat to public health, serving as a gateway to counterfeit medicines in the country." Representing over 12 lakh chemists across the country, the AIOCD also drew attention to, what they called, "predatory pricing" and deep discounts offered by online pharmacies. "We advocate for regulations to curb deep discounting, safeguarding small businesses and local economies from monopolistic practices that harm competition and consumer choice," it said.

A draft notification (August 2018) outlining governance of the online pharmacy segment, saw litigation and subsequently went onto the back-burner. Five years on, the policy needle has not quite moved. The AIOCD's call for a ban is not a new one, although it comes at a time when the Centre is pushing full steam ahead with its digital health initiatives. Significantly now, it comes just ahead of the general elections, when political parties make promises to their business constituencies, as well.

JS Shinde, AIOCD President, says they are not against the digital initiative. But there needs to be a regulatory framework within which online pharmacies operate, he says, calling for a system to be able to track and ensure that the doctor prescriptions used to buy medicines online are authentic, the medicines are being given by pharmacists and so on. The policy needs to be in place and that includes a revision of the Drugs and Cosmetics Act, which is still to be done, says Shinde. He adds, their own network of chemists are also being trained on digital initiatives.

Discount Boards

Pointing to the deep discounts offered by online chemists, Shinde alleged, medicines were being sold at over 25 per cent discount, skewing the pitch for the neighbourhood chemist who was bound by the D&C Act, that did not allow for such promotional activity. "Placing discount boards or advertising discounts in a price-controlled commodity like drugs and medicines, where doses or quantities are strictly regulated by prescription — goes against the standards of the pharmacy profession," the AIOCD said. Retailers have their margins fixed at 16 per cent on scheduled drugs and 20 per cent on non-scheduled drugs, an offline chemist said, indicating it was not a level playing field. Even as AIOCD soldiers on for the retail chemist, the online pharmacy world has been gathering momentum, with the Covid-19 pandemic providing the wind in its sails.

Major corporates are on the bandwagon, including Tatas (1 mg), Reliance (Netmeds) and Amazon, to name a few. PharmEasy went against the tide when it bought out diagnostics player, Thyrocare. In fact, online pharmacies bundle multiple services into their platforms including diagnostics and scheduling doctor interactions — they act like an e-marketplace bringing service and customer together, says an industry-insider. Online pharmacy representatives defend their tribe saying, they play an "essential services" role, especially in times of emergency. Countering allegations of prescription abuse and easy access to MTP (medical termination of pregnancy) pills, psychotropic drugs and so on, another representative says that online sales, in fact, leave an electronic footprint that prevents the misuse of prescriptions.

The way forward is to take global best practices, so both segments of industry can co-exist, rather than one at the expense of the other, says Sujay Shetty, PwC's Global Health Industries Advisory Leader. Especially so, since there are access concerns when it comes to the elderly and others who may not be digitally savvy, he points out. With the Centre's plan of having an unmistakable digital backbone, it is unlikely that the Government would dial back on its approach, says an industry-watcher. However, there are issues to be ironed out on both sides, and they need to be tackled, he adds.

Retail pharmacy's journey over the last several years has been punctuated with litigations and deliberations. Now with Elections 2024 just days away, the industry will be closely following if the next team at the Centre will resolve the impasse, or kick the can further down the road. (Source: Business Line)