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Elder Pharma to repay creditors by selling assets

OUR BUREAU
Mumbai, October 26

Troubled drug firm Elder Pharmaceuticals plans to repay its creditors and investors by raising funds through a combination of debt, equity and asset sale.

The company intends to sell its stake in its subsidiaries in the UK and Bulgaria.

Earlier this month, the Bombay High Court directed the company repay ₹155 crore to small investors who had invested in the company's fixed deposit in January.

In its appeal, the company said it has proposed to repay the entire amount which it said would come through a lender with whom the company has a term sheet. The company has to also pay a bunch of debenture holders ₹263 crore.

The ailing company also faces 24 winding up petition, including one by Tata Financials. The company was also restrained from creating any third party rights or to sell off its assets except in the natural course of business, without permission from the Court.

The company has been going through tough cash flow situations but is on the path of recovery and has substantial asset base to cover all its liabilities. Raising funds is a time consuming process and cannot be done overnight as the 'due-diligence' by investors takes up many months, said the company.

Due to numerous legal issues – coupled with a weak real estate market – the company has not been able to sell off its non-core assets at the right price. But the efforts continue to realise the best value for the non-core assets.

Company

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QUESTIONABLE BUSINESS

Is Valeant Pharmaceuticals the new Enron?

By Joe Nocera
feedback@livemint.com

Valeant Pharmaceuticals is a sleazy company.

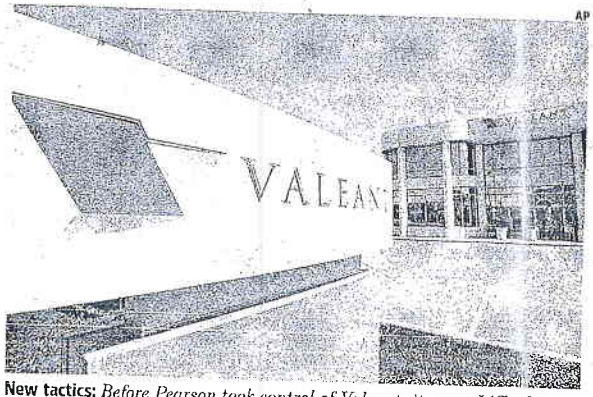
Although it existed before 2010, it did a deal that year that put it on the map. The deal was with Biovail, one of Canada's largest drug makers—and a company that had run afoul of the Securities and Exchange Commission (SEC).

In 2008, the SEC sued Biovail for "repeatedly" overstating earnings and "actively" misleading investors. Biovail settled the case for $10 million.

As it happens, 2008 was the same year that a management consultant named J. Michael Pearson became Valeant's chief executive. Pearson had an unusual idea about how to grow a modern pharmaceutical company. The pharma business model has long called for a hefty percentage of revenue to be spent on scientists who try to develop new drugs. The failure rate is high—but a successful new drug can generate over $1 billion in annual revenue, which makes up for a lot of failures.

Pearson didn't have much patience for research and development. While he certainly wanted moneymaking drugs, he didn't really need blockbusters to make his business model work. His plan was to acquire pharm firms, fire most of the scientists and jack up the drug prices. Biovail gave him the heft to put his plan in action. And so he has done, to the delight of Valeant's shareholders, and the dismay of most everyone else.

Before Pearson took control of Valeant, it spent 14% of its revenue developing new drugs. Last year, that number was under 3%.



AP

New tactics: *Before Pearson took control of Valeant, it spent 14% of its revenue developing new drugs. Last year, that number was under 3%.*

COMMENTARY

Meanwhile, Pearson has been ruthless about price hikes; in February, according to *The Wall Street Journal*, the company raised the price of one heart drug by 525% and another by 212%—on the very day it acquired the rights to the drugs. Complaints from patients, doctors and insurance companies have prompted investigations by federal prosecutors in Massachusetts and New York.

In the seven years Pearson has run the company, Valeant has done more than 100 deals. Its growth has been supercharged, and so has its stock price. Pearson has become a billionaire.

Fast forward to 19 October. During a conference call with investors, Valeant disclosed a relationship with a specialty pharmacy called Philidor RX Services, a relationship in which Philidor seemingly does business with no one besides Valeant, and that is so close that Valeant consolidates Philidor's financials while holding Philidor's inventory on its books. During the call, Valeant also disclosed that it had paid $100 million for an option to buy Philidor, though it had not actually made the purchase—a very strange deal indeed.

It made these disclosures because Roddy Boyd, a former *New York Post* reporter who now runs the Southern Investigative Reporting Foundation, had found out about the Philidor relationship and begun asking questions. So had several Wall Street critics of the company, including John Hempton of Bronte Capital.

Valeant's disclosures last week—along with subsequent allegations by Citron Research that Valeant was cooking the books—as well as stories by Boyd and several others have caused the stock to tank.

On Monday, Pearson and his executive team held a lengthy conference call with investors in which they insisted Valeant had complied with "applicable law". But Valeant also announced that a committee of the board would probe the ties with Philidor. And it urged the SEC to probe Citron. This was also a tactic Biovail once used to silence its critics; it backfired spectacularly when the SEC concluded that the critics were the ones who had it right.

It is difficult, if not impossible, to understand all the implications of the Philidor-Valeant relationship, or whether anything genuinely illegal has taken place. But the whole thing looks pretty, well, sleazy.

As *The New York Times'* Andrew Pollack pointed out last week, Valeant uses Philidor to keep patients from getting generics instead of its high-priced drugs. Philidor negotiates directly with the insurance firms, and saving patients from the feeling the sticker shock their price hikes would otherwise cause. The copay is often waived, which only adds to the allure of using Philidor.

The evidence strongly suggests that Philidor is controlled by Valeant, even though it is supposed to be an independent company. *The Wall Street Journal* reported that certain Valeant employees work at Philidor using fake names. But why? And why did Valeant fail to disclose the relationship for so long? If there was really nothing wrong, why did Valeant keep it a secret? Why, even now, are there more questions than answers?

Maybe it will all turn out to be innocent. But I remember another company that Wall Street once swooned over, a company that had eye-popping growth, but also had secrets, which eventually destroyed it. You probably remember that company, too. Its name was Enron.

Company

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Russia keen to share liquid waste treatment technology with India

Consul- General sees scope for ties in pharma, auto sectors too

OUR BUREAU
Hyderabad, October 27

Russia could offer various technologies, including assembly lines for treatment of liquid waste to India, according to Sergey Kotov, Consul-General of the Russian Federation to the Republic of India.

Addressing members of the Federation of Telangana and Andhra Pradesh Chambers of Commerce and Industry here on Tuesday, Kotov said: "For India, this may be big interest along with water management, among others."

There was also scope for improving business ties in sectors such as pharma and automobile, he added.

Consul-General of the Russian Federation, Sergey Kotov at a business meet organised by the Federation of Telangana and Andhra Pradesh Chambers of Commerce and Industry in Hyderabad MOHAMMED YOUSUF

While responding to a comment by a member that the customs regime was complex in Russia, he said it was simplified to some extent in the recent past and was "slightly changed for the better."

"You don't ask for too much from Russia. We are not Soviet Union. We are working reviving economy after the undue influence of west in 1991. Russia is still bleeding," he said.

At present, India's trade with Russia is just $6 billion, which is less than 1 per cent of the country's total foreign trade.

Miscellaneous

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Antibiotics overuse: 'India must be part of solution'

Emerging markets doing well in study of anti-microbial resistance: economist O'Neill

VIDYA RAM
London, October 26

The Indian generic drugs industry and diagnostic companies will have a major part to play in global attempts to reduce the inappropriate use of antibiotics, which threatens to create a health crisis globally, said Jim O Neill, economist and chair of a major review of anti-microbial resistance.

O'Neill, former Chief Economist at Goldman Sachs and who coined the "BRIC" acronym, spoke to *BusinessLine* about the crucial role that Indian generic drug makers and diagnostic companies could play in meeting the global challenge.

Latest finding

The review, commissioned by the British government, but drafted by working with governments and NGOs globally, had launched last year.

It published a series of reports relating to the abuse of antibiotics. The latest report, published last week, focuses on the importance of developing cost-effective and speedy diagnostic tools to ensure that conditions are diagnosed properly, and the most appropriate narrow spectrum antibiotic is given.

It recommends the development of a global research and development fund for anti-microbial resistance (AMR), part of which will go towards new research on diagnostics globally.

It also recommends setting up of a second fund to reward diagnostic tools with subsidies and incentives, to make it easier to tackle the costs of diagnostics.

The review estimates that as many as 10 million people globally could die by 2050 because of growing resistance to antibiotics, that has resulted from the over use and inappropriate prescribing of antibiotics, which had become a major problem globally in the developed and developing world.

O'Neill, said the review recognised the particular challenge in

Jim O'Neill, economist.

BRIC nations, where many lacked even basic access to antibiotics.

"We don't suggest that people shouldn't get the right antibiotics. In many parts of the world, there is a huge need for the right kinds of antibiotics to preserve and lengthen people's lives — we want to be clear that it should happen more and better, but in order to help that, we need to have better objective indications as to when they are really necessary rather than used, because they might be of some benefit."

Indian firms

O'Neill said that Indian diagnostic firms were likely to play an important role, citing the example of SRL Ltd, whose Managing Director Sanjeev Chaudhry is an advisor to the review.

"The firm stands as one of the important things we've come across—even here in the UK, two of the top British hospitals send blood samples to its laboratories in India for tests because of better technology and affordability." He also expects the generic drug industry to play an important role, with Yusuf K Hamied, Chairman of Cipla, recently joining as an advisor.

"People would rightly say he has personally been responsible for saving millions of lives through generics, and we think there is a huge role for that to be a central part of the solution.

"It is part of the challenge because a lot of big western pharma companies want to focus on drugs that they are protecting from competition for as long a time as possible and at a higher charge. But for something that is a public and global good, we need to find the right set of incentives and rewards to help them behave and think differently. The way Cipla has approached life is a fantastic example and something we want to endorse."

Study estimates about 10 million people globally could die by 2050 because of growing resistance to antibiotics resulting from over use and inappropriate prescription of antibiotics

Faulty prescriptions

While much of the data in the report focuses on western markets, including the US — where according to one study in the report, as many as 27 million of the 40 million people given antibiotics for respiratory conditions annually were wrongly prescribed — there was a "strong suspicion" that in emerging markets it was a major problem, said O'Neill.

"We've had some success calling for funding of greater data surveillance; how evidence is collected by health authorities. Having state-of-the-art surveillance techniques so you can make judgments about aspects of AMR, is important."

O'Neill had led a visit by the AMR review team to India in March. "The question is: can you get India to be at the centre of finding a solution, along with other parts of the emerging world, rather than being carried along by what the developed world tells it to do? It's an important bias of mine to ensure emerging countries play a central role."

He said he welcomed growing signs that BRIC nations were looking to coordinate work on the challenge of drug resistance, particularly in areas such as TB, HIV and malaria.

"India is travelling in the right direction with Prime Minister Modi's focus on the Clean India campaign — it's an important part of the puzzle, and we are trying to pose the AMR challenge in India in the context of that campaign.

"I believe that ahead of his trip to the UK, the specific focus on AMR is rising as a policypriority."

Miscellaneous

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Drug e-store Netmeds gets $50m funding

Chennai: Online pharmacy marketplace Netmeds.com has bagged $50 million in a second round of funding since its launch in June this year. The latest round was led by OrbiMed, a healthcare-focused investment firm, along with Pradeep Dadha, CEO, Netmeds.com, through the family investment fund and boutique investment bank MAPE Advisory Group.

Netmeds.com is promoted by the Dadha family, which has been in pharmaceutical business for over 100 years. The family ran Tamil Nadu Dadha Pharmaceuticals and Pradeep Drug Company earlier. Dadha said, "Most of the funds will go towards building a network of information between wholesalers and retailers to provide greater availability. We plan to use about $10 million immediately for backend development and to augment our logistics." TNN

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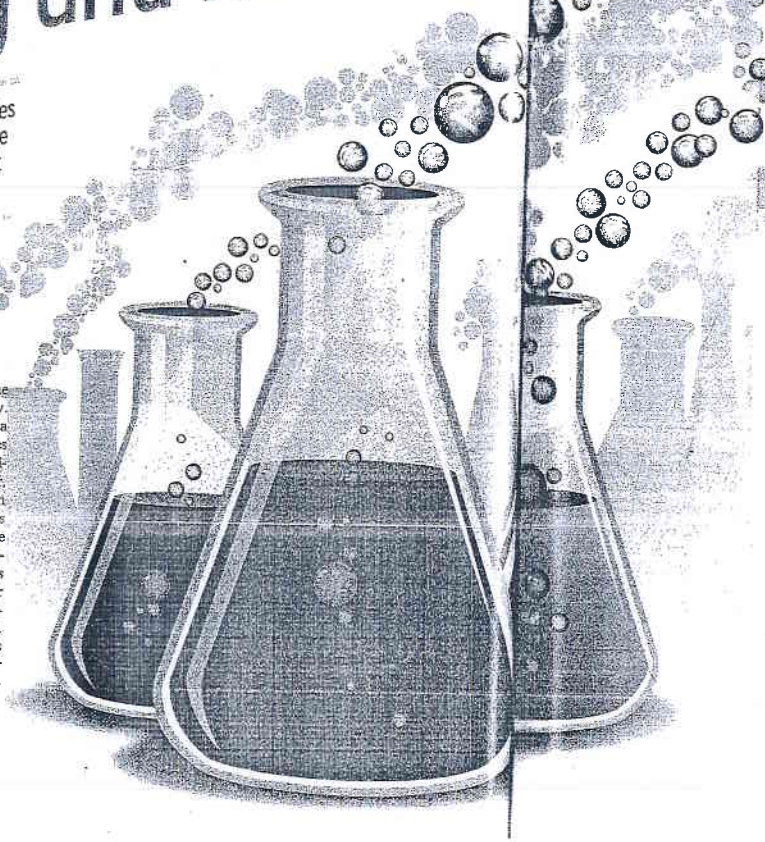
BT500
INDIA'S MOST VALUABLE COMPANIES
PHARMA

Strong and Healthy

All the major pharma companies are showing growth, both in the all-important US market and at home. By E. KUMAR SHARMA



AJAY THAKUR

Big is getting bigger in the global pharma industry. Israeli giant Teva Pharmaceutical Industries acquired the generics business of leading US player, Allergan, for $40.5 billion in July. Mylan N.V., which is now domiciled in the Netherlands with operational headquarters still out of the US, is pushing for a $33-billion hostile takeover of Ireland-based Perrigo, a maker of over-the-counter cough and allergy remedies. There have been a number of other M&As among US-based pharmacy chains or pharmacy benefit managers – intermediaries between drug companies and insurers – in the last few years. Will such consolidation impact the strength and influence of other players in the long term, especially Indian pharma companies operating in global markets?

It is a difficult question to answer, but there are no such signs yet. On the contrary, most leading Indian pharma players have been growing in the all important US market – for many, their largest source of revenue. Around 47 per cent of Dr. Reddy's Laboratories' revenues in 2014/15, for instance, came from the US, as did 45 per cent of Lupin Ltd's. (Only about 20 per cent of the revenues of leading Indian pharma players come from the domestic market.) Indian pharma companies have succeeded in holding their own so far mainly because they have moved up the value chain in time. They have long had a global reputation for making cheap generic drugs, but many have since moved beyond plain vanilla generics. "The migration of Indian companies to higher, value added generics has made a difference," says G.V. Prasad, Co-chairman and CEO, Dr. Reddy's Labs. "The US remains a major growth driver." Value added or complex generics are those which are difficult or expensive (or both) to manufacture, with some even requiring clinical trials. They have limited competition and thereby provide scope for higher margins.

AROUND 47% OF DR. REDDY'S LABS REVENUES IN 2014/15 CAME FROM THE US

One of the companies, Sun Pharma, has even gone beyond generics. It pulled off the one big merger that has taken place in India too in recent times, completing its $4 billion takeover of Ranbaxy Laboratories in April last year (2014) to become the country's largest pharma company. To add to its proprietary knowledge and strengthen its US presence, it is also acquiring US-based InSite Vision, Inc. for $48 million through one of its subsidiaries. InSite Vision focuses on specialty ophthalmic products, and currently has three such in advanced stages of development. In June, Sun Pharma inlicensed Xelpros, preservative-free eye drops for glaucoma patients, developed by its own research organisation, Sun Pharma Advanced Research Co (SPARC) for the US market. But the company is yet to get the US Food and Drugs Administration (USFDA) approval.

Other Indian companies have made acquisitions in the US too this year, though these have remained in the traditional generic segment. In July, Lupin announced the acquisition of US-based GAVIS Pharmaceuticals – a niche generic drug specialist – for $880 million, its sixth acquisition in 18 months. And in September, Cipla Ltd acquired two US generics companies, InvaGen Pharmaceuticals and Exelan Pharmaceuticals, for $550 million.

Brokerage firm CLSA's report on Indian pharma in August 2015 singles out Sun Pharma and Dr. Reddy's for special praise. "Complex product launches by Sun Pharma and Dr Reddy's over the past three years have delivered strong results, indicating that

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BT 500

INDIA'S MOST VALUABLE COMPANIES
PHARMA

Indian players can move up the value chain," says author Alok Dalal. "The US differentiated-product contribution to Sun Pharma's sales and profit is eight per cent and 16 per cent (respectively), which could rise to 16 per cent and 26 per cent by 2019/20." Sun Pharma acquired a majority stake in US-based Taro Pharmaceutical in 2010 and took over another US company, DUSA Pharmaceuticals, in 2012.

The report predicts that the three together could emerge as a strong force in the US's dermatology and complex injectables markets. "We expect the company to launch its novel psoriasis drug Tildrakizumab (specialty product) in the US in 2017/18 with sales of $200 million by 2019/20," it adds.

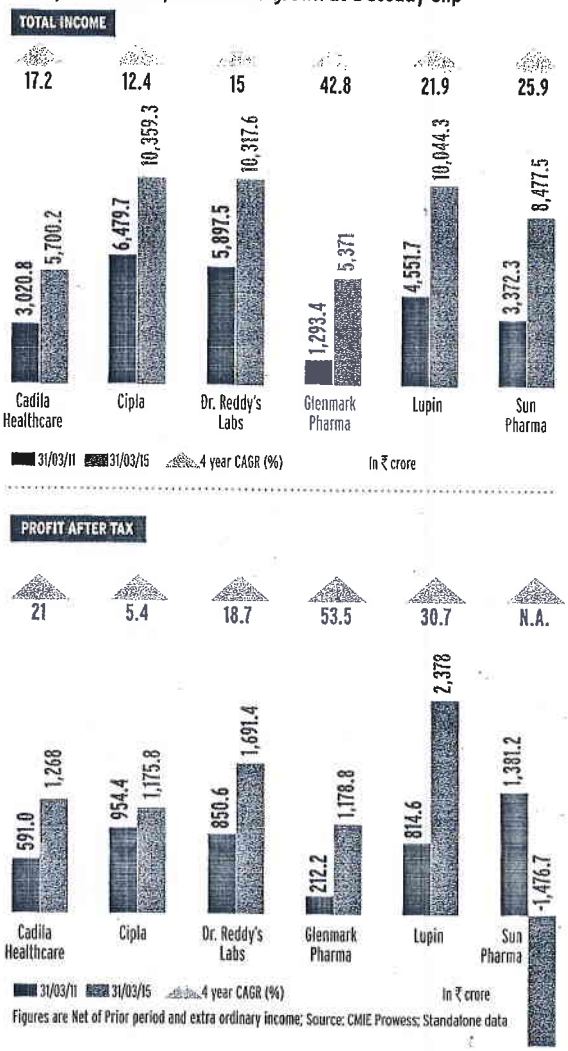
As for Dr. Reddy's, the report expects its differentiated products in the US market to contribute 33 per cent to its profit by 2019/20 from the current 13 per cent, with skin and central nervous system treatments as the main growth drivers. "We expect biosimilars to be a growth driver (for Dr. Reddy's) beyond 2019/20," it adds. About other pharma companies, Dalal is more restrained. He notes that Lupin has advanced through its acquisition of GAVIS, but maintains Cipla – which gets only eight per cent of its revenue from the US – has a long way to go. "We upgrade Cadila Healthcare from 'underperform' to 'outperform' as its differentiated products pipeline can generate long-term returns," he adds. Glenmark Pharmaceuticals too has filed three product approval applications in the US for immunosuppressants, apart from building on its niche strength in oral contraceptives, dermatology and oncology injectables.

Indian pharma companies have had their run-ins with the USFDA in the past, notably two years ago when the latter banned entry of drugs manufactured by leading companies such as Ranbaxy and Wockhardt Ltd at specified plants, claiming the plants fell short of its quality standards. But the situation seems to have vastly improved. A recent Bank of America Merrill Lynch report by Manoj Garg, research analyst, DSP Merrill Lynch (India), shows that there were 75 approvals of Indian drugs by the USFDA in the April to September15 period this year, against 75 in the entire financial year 2014/15. "Clearly, one of the reasons behind the recent growth has been an acceleration in product approvals by the USFDA," says Glenn Saldanha, Chairman and Managing Director, Glenmark Pharma. "Indian companies also now understand the US's market better, both the kind of compliance required and the filing and product quality needed."

The depreciation of the rupee since 2011, making Indian pharma products cheaper, has also worked to the industry's advantage, as the Bank of America Merrill Lynch report notes that a five per cent rupee movement would have a 2.4 to 5.6 per cent impact on pharma universe's earning per share. Another industry estimate maintains that for every one per cent fall in the rupee's value against the dollar, the EPS of lead-

A HEALTHY TREND

Most pharma companies have grown at a steady clip



Figures are Net of Prior period and extra ordinary income; Source: CMIE Prowess; Standalone data

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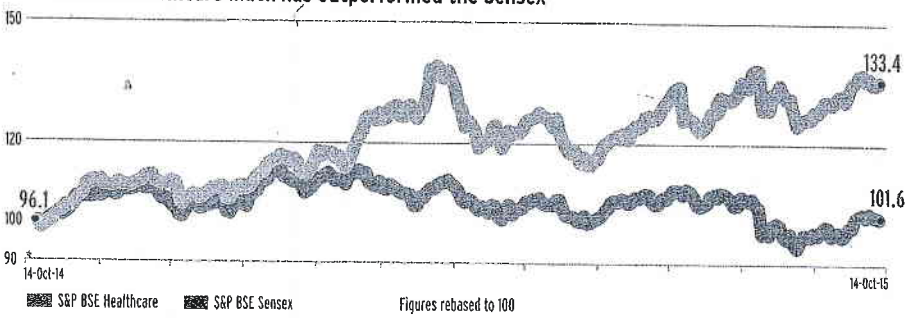
INDIA'S MOST VALUABLE COMPANIES: PHARMA

SURGING AHEAD

The BSE Healthcare index has outperformed the Sensex



ing pharma companies increases by 0.7 per cent. According to the report, Cadila Healthcare, Aurobindo Pharma and Lupin have been the biggest beneficiaries of depreciation. Strategic partnerships have also helped some companies – notably Cipla's tie up with Teva which made it sole supplier of the generic drug Nexium (esomeprazole magnesium) in the US.

In the $15 billion domestic market too, Indian pharma companies have been showing steady growth. There were many apprehensions when the National Pharmaceutical Pricing Authority passed a new Drug Price Control Order (DPCO) in May 2013, increasing the number of drugs under price control from 74 to 348, but these have been belied. The order itself took into account market realities, changing the formula for calculating drug prices from the former 'cost plus' approach to the more realistic 'market-based pricing' approach, and linking prices of the listed drugs to inflation, so companies would not have to seek government permission each time they needed to raise prices. Prices of some formulations did indeed have to be reduced, but this affected the MNCs operating in the country more than the wholly indigenous ones, since the former's prices are usually higher.

THE SIZE OF DOMESTIC PHARMA MARKET IS ABOUT $15 BN

Pharma companies have been growing within the country through select product acquisitions, marketing alliances and greater penetration. Dr. Reddy's has been particularly proactive in doing so – in April this year it finalised a ₹800 crore deal to buy up some of the brands of Belgian pharma giant UCB being distributed in India. The brands chosen will strengthen Dr. Reddy's presence in the dermatology, respiratory and pediatric segments. In May, it entered into a distribution agreement with the Indian arm of the UK-based AstraZeneca, to sell two of its trademark products, Riax and Riax M, within the country. In August, Dr. Reddy's announced a strategic collaboration with leading biotechnology company Amgen to market three of Amgen's drugs related to oncology and cardiology. The industry is also benefiting from a rapidly expanding market in certain chronic disease segments like diabetes, brought on by widespread lifestyle changes.

Despite the buoyant mood, a few concerns remain. A number of emerging markets such as Russia and its surrounding CIS countries, Venezuela, Brazil and South Africa are wracked by currency turmoil far greater than what the rupee faced. Most leading pharma companies have about 15 to 20 per cent of their revenues coming from these countries. Dr: Reddy's and Glenmark Pharma, for instance, have a good deal of exposure in Russia and the CIS countries as well as Venezuela. Analysts, however, maintain the companies concerned have imposed tight controls on their expenditure, taking the volatility into account. Future price regulation, be it in India, with more drugs being brought under the price control order, or in the US, is another worry. US Presidential hopeful Hillary Clinton's recent tweet, condemning the ill conceived attempt by US based Turing Pharmaceuticals to raise the price of one of its drugs by 5,000 per cent and vowing to oppose it, sounded ominous to some industry watchers.

But overall, most feel the good times will continue. "This is one industry that thrives on challenges," says D.G. Shah, Director-General, Indian Pharmaceutical Alliance (IPA). "It is creative not only in discovering treatments and cures, but also in getting out of tight corners." ◆

@EKumarSharma

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Drug disposal panels fail to hold timely meetings

High Court asks Principal Secy to file affidavit

SAURABH MALIK
TRIBUNE NEWS SERVICE

CHANDIGARH, OCTOBER 26

Taking cognisance of drug disposal committees' failure to meet at least once in two months for the disposal of drugs no more required as case property, the Punjab and Haryana High Court has asked Punjab Additional Chief Secretary/Principal Secretary (Home) to file his personal affidavit on the issue.

Justice Amol Rattan Singh asked the officer to specify the status of drugs required to be disposed of, but not done so, till November 15.

The directions came during an appeal by Balbir Singh against the judgment of Nawanshahr Special Court Judge. Convicting him under the Narcotic Drugs and Psychotropic Substances Act, the Judge had sentenced him to 10 years of rigorous imprisonment and slapped a fine of Rs 1,00,000.

Allowing the appeal, Justice Amol Rattan Singh asserted that reports received in the High Court on administrative side from Sessions Divisions showed the presence of contraband in police stations' "malkhanas" due to its non-disposal in a timely manner by committees to be constituted vide standing order notified on June 13, 1989. "Hence, the chances of misuse of such contraband can obviously not be ruled out," he said.

Justice Amol Rattan Singh said that reports showed the presence of drugs in police stations' 'malkhanas' as these are not disposed of in a timely manner by these committees. "The chances of misuse of such contraband can obviously not be ruled out," he said.

Justice Amol Rattan Singh also observed poppy straw and other narcotic substances were to be disposed of under the supervision of Drug Disposal Committees to be constituted by the state governments, as per the notification. The committees were required to meet as frequently as possible, at least once in two months.

It was to examine the list of drugs to be disposed of. "After satisfying themselves that they are no longer required for legal proceedings and the approval of the court has been obtained for the purpose, necessary certificates are to be endorsed by the committees for disposal of such drugs..."

Justice Amol Rattan Singh added Additional Chief Secretary/Principal Secretary, Home, would file his personal affidavit after obtaining information on affidavit from the chairmen/presiding officers of the committees concerned on the current status of drugs.

The affidavit by the chairmen/presiding authorities is also required to spell out the reasons behind delay.

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फार्मा उद्योग पर सरकार गंभीर

अजीत पाठक .नई दिल्ली

देश में फार्मा उद्योग की स्थिति को सुधारने और नए व छोटे फार्मा व्यवसायियों को दिक्कतों से निजात दिलाने की दिशा में केंद्र सरकार गंभीरता से आगे बढ़ रही है।

औषधि विभाग के सचिव की अध्यक्षता में गठित एक उच्चाधिकार समिति टास्क फोर्स द्वारा दिए गए सुझावों और फार्मा उद्योग की तरक्की में बाधा डालने वाले कारकों को दूर करने की राह तलाश कर फार्मा उद्योग के सुनहरे भविष्य की पटकथा लिखेगी।

रसायन एवं उर्वरक मंत्रालय के एक वरिष्ठ अधिकारी ने बताया कि, टास्क फोर्स ने इस साल के मध्य में अपनी रिपोर्ट मंत्रालय को सौंप दी है। उसके सुझाव पर एक उच्च अधिकारी समिति गठित की गई है।

औषधि विभाग के सचिव की अगुवाई में गठित इस समिति में स्वास्थ्य एवं परिवार कल्याण मंत्रालय, पर्यावरण मंत्रालय, वाणिज्य मंत्रालय, औद्योगिक नीति बोर्ड, केंद्रीय प्रदूषण नियंत्रण बोर्ड, ड्रग कंट्रोलर अथॉरिटी व अन्य कई केंद्रीय संस्थानों को शामिल किया गया है।

टास्क फोर्स के सुझाव

बीते वर्ष दिसंबर में गठित टास्क फोर्स ने अपनी रिपोर्ट में जो प्रमुख सुझाव दिए हैं उनमें फार्मा उद्योग के नियंत्रण के लिए एकीकृत व्यवस्था पर जोर दिया है। नई व छोटी फार्मा कंपनियों को वित्तीय सहायता देने की भी अनुशंसा की है। टास्क फोर्स ने कंपनियों को आधारभूत संरचना उपलब्ध कराने, शोध और विकास कार्य पर जोर दिया है। फार्मा उद्योग की सुविधा के लिए सिंगल विंडो सिस्टम बनाने की सलाह दी है।

The Govt- is serious about Pharma industry.
Govt.