US debt crisis to hit India's life sciences exports

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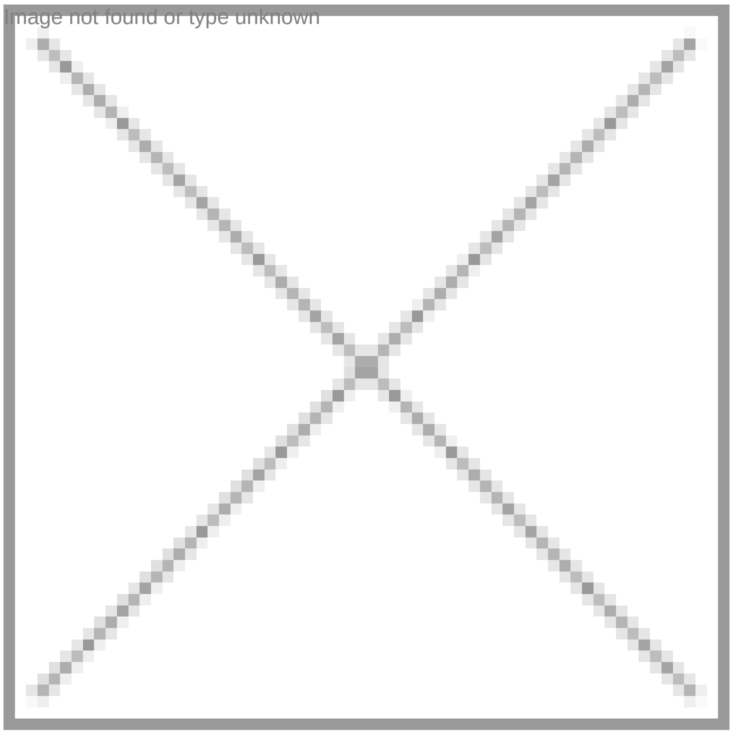

However, the sovereign debt crisis in the US could lead to the creation of a much-anticipated US biosimilars pathway

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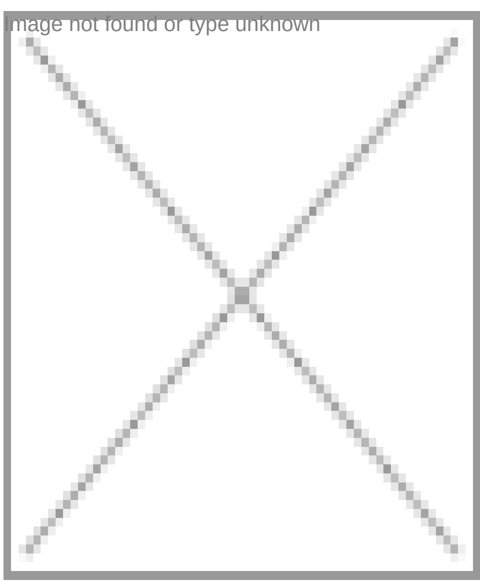

Standard and Poor's historic downgrading of the US credit rating to AA+ from a AAA towards the beginning of August 2011 did not just make the US policymakers and economists jittery, but also upset investors across the world. As chaos hit the financial markets across the world, Indian investors too hit the panic button wary of the consequences on industries, especially in the export-oriented sectors like IT, d biotechnology.

The debt crisis could spell bad news for companies involved in export businesses to the regulated markets of the world. The US, by far, is the largest market for exports for the Indian life sciences industry. â€œThe anxiety is palpable given the fact that the US is not only the largest customer for Indian pharma exports, but also one of the most profitable and fastest growing markets in terms of value,â€? said Mr VN Saravanan, assistant vice president â€“ Research, Unifi Capital. According to estimates by the same firm, out of the total pharma exports of $11.6 billion in 2010, 22 percent relates to the US, followed by 16 percent to Africa and eight percent to

The Indian life sciences industry derives substantial revenues from exports especially from APIs and finished dosage forms. Biocon, for example, exports around 80 percent of its statins and APIs and commands over 20 percent global market share. It derives over one-third of its revenues from this business. Today, it caters to regulated markets like the US and Europe and is one of the largest exporters of Lovastatin to the US.

Vaccine major Serum Institute of India exports its products to around 140 countries across the world. Concord Biotech, the largest producer of penicillin-G amidase enzyme exports to a number of companies in China, Europe and the US. Concord also produces and exports lovastatin and tacrolimus. For biotechnology enzyme company, Advanced Enzyme Technologies, exports constitute above 50 percent of its total revenues with the US being the largest market for the company. A volatility in these markets could hit their export revenues.

â€œOur company has almost two-third sales in global market. We do have some favorable development from the above crisis since the Japanese Yen has reached historically high. Yet sales are a bit affected in the US and Europe. Over all, we may lose few percent growth. Yet we are working on mitigating this risk,â€? says Dr CL Rathi, CEO, Advanced Enzyme Technologies

Positive impact on US biosimilar

Heavy debt burden could see huge cost cutting measures by the US government. With mounting pressure on the government towards cutting down its federal budget for healthcare, reduction of drug prices is but an eventuality. This, in turn, could be a boon for generic pharmaceutical companies and could also push the envelope towards the creation of the much-anticipated biosimilars pathway in the US. â€œThe positive impact of these government actions could be higher penetration of generics in the pharmaceutical market (especially in the EU) and publishing of biosimilar approval pathway by USFDA (in order to reduce prices of expensive biopharmaceutical products),â€? said Mr KV Subramaniam, president, Reliance Life Sciences.

Opening up of the US biosimilar market could mean huge business for biotech companies in India. Between 2012-19, the US market will see patent expiry of blockbuster biotech drugs to the tune of $60 billion. Amgen is likely to be most hard hit with the patent expiry of three of its blockbuster drugs during that period. Amgen's blockbuster drug for anemia Epogen, which had a sale of about 11,600 crore ($2.5 billion) in 2008 will lose its patent in 2013. Other blockbuster drugs such as Neupogen will lose its patent in 2013, while arthritis drug, Enbreal, will lose its patent in 2012. Epogen, Neupogen and Enbrel together account for half of Amgen's total revenue.

Indian companies like Dr Reddy's Laboratories, Biocon, Intas Biopharmaceutical, Shantha Biotech, Ranbaxy, RelianceLife Sciences and Wockhardt are already proactive in this space. Cipla has entered into a 50:50 joint venture with a Chinese company for biosimilars.

â€œAny price collapse in the US and EU for generic products would significantly impact bottom lines of all industry players as these two markets constitute 75 percent of the global market for pharmaceuticals. The pharmaceutical industry is facing a number of challenges today from several USFDA failed inspections and this is impacting product supplies to developed markets. This crisis may cripple some companies that are hoping to regain the USFDA approval and thus recovering some of the lost grounds,â€? says Mr Subramaniam.

Further, any adverse movement of the Rupee against US dollar would impact profitability in case the import/export commitments are not hedged properly.

Mr Navroz Mahudawala, managing director, Candle Partners, said few large companies with regulated market sales wouldbe affected. â€œWe would continue to witness contract research and manufacturing services (CRAMS) as a sector being an under-performer. However, most Indian pharma companies have a diversified business model with exposure to several ROW countries (including emerging markets); importantly majority of profits still coming from India. Thus effect would be minimal,â€? he said.

On the subject of CRAMS, Mr Saravanan had a different take. â€œWith respect to CRAMS segment, the outsourced manufacturing model is not at risk because US-based innovator companies will need to access quality and cost-effective emerging markets to drive economies of scale and protect their eroding profitability due to entry of generic drug.â€?

Universal outlook positive

Like the global downturn of 2008, it is highly unlikely that life sciences would be hard hit by this crisis considering that the demand for medicines and healthcare will never diminish. â€œPharma is insulated from such volatility as demand for medicines and care is generally not discretionary, and as a result the pattern of cash generation via medicine sales and cash deployment due to setting up of capacity and access is not cyclical,â€? says Umang Vohra, senior vice president and chief financial officer, Dr Reddy's Laboratories. â€œOn the demand side, within the regulated and emerging markets prices for most medicines adjust rather rapidly post the patent expiration. Also at the moment, most pharma companies are not highly leveraged to be unduly concerned about borrowing and their costs.â€?

Analysts also predicted that given the current economic condition in the matured markets, emerging markets like India would see a decent inflow of funds from foreign investors, especially into sectors like healthcare and life sciences.

â€œWith the economic conditions worsening in the US and EU again, investors will be wary of putting money in those economies. The emerging market economies, especially India, are in far better shape and their growth targets are not likely to be impacted considerably by the turmoil,â€? says Mr Vishal Gandhi, vice president of life sciences and technology, YES Bank. â€œWe believe that global investors will increase capital flows to India in the near term. As the outlook for healthcare and life sciences in India is very positive, and the sector attracts around five percent of overall PE/funds to India and that is unlikely to change.â€?

Nayantara Som in Mumbai