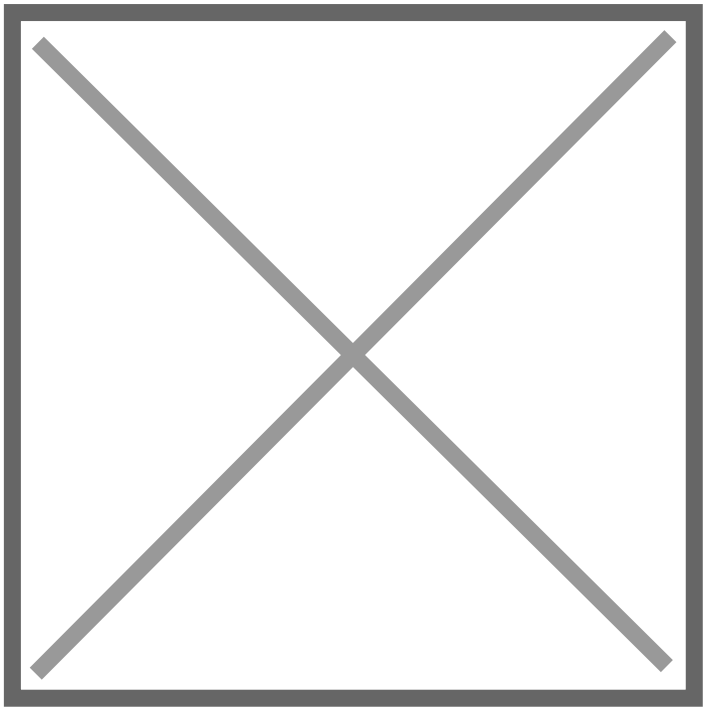
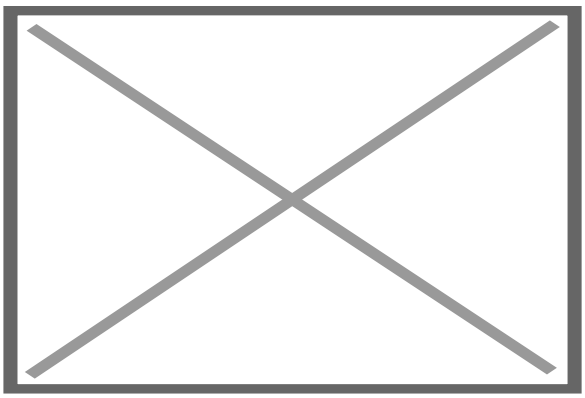
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FDI in Pharma: Does India require a policy revamp?

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There is a raging question on controlling foreign direct investment in India amidst worries that acquisitions of Indian pharma and biotech companies by foreign firms will make access to healthcare difficult BioSpectrum tries to find some answers



In the backdrop of foreign multinational companies (MNCs) taking over some major Indian pharma and biotech companies, there have been increased concerns over its effect on the price of generic drugs.

The Department Of Industrial Policy And Promotion (DIPP) that oversees the policy framework allowing or restricting foreign direct investment (FDI) in the country, under the Ministry Of Commerce And Industries, in July 2011, came out with a discussion paper inviting views on the rationale and relevance of putting a cap on FDI. Following this, the Department pushed for restrictions on foreign investments in the pharma sector.

Since 2006, as many as six big Indian pharma companies have been taken over by foreign firms. About $4.73 billion or 50 percent of the recorded FDI in the sector since the year 2000 has been in the form of mergers and acquisitions. In the year 2006, Matrix Lab was sold to the US-based company Mylan. In 2008, Dabur Pharma was bought by Singapore-based Fresenius Kabi. Again in the same year, Ranbaxy was taken over by the Japanese company, Diachii Sankyo. The year 2009 witnessed two major deals in which Shantha Biotech was taken over by the French major Sanofi Aventis and the US-based company Hospira took over Orchid Chemicals. The latest example is of Piramal Healthcare, which was bought in the year 2010 by the US multinational, Abbot Laboratories.

Earlier this year, the government set up a panel headed by Planning Commission member Mr Arun Maira to study a proposal to reduce FDI in the pharma sector from 100 percent to 49 percent and check whether it requires a policy intervention. Currently, there is 100 percent FDI in pharma under automatic route and the foreign companies only have to inform the Reserve Bank of India at the time of investing in India. They are allowed to invest 100 percent in India without the prior approval of the Foreign Investment Promotion Board (FIPB) .

Few critics argue that the government should utilize its agencies, such as Competition Commission of India (CCI) and National Pharmaceutical Pricing Authority (NPPA) efficiently to ensure the fair use of foreign investments instead of blindly limiting the investment.

Divergent viewpoints

There seems to be a difference of opinion among the sections of the industry regarding this issue. The associations representing Indian and foreign drugs manufacturers also seem to be at loggerheads. Those against any strong measure by

the government point towards the fact that a dual policy cannot be followed when Indian companies can go abroad and acquire 100 percent stake in a company. According to them, attention must be paid to have enough regulations, such as compulsory licensing, that protect Indian firms.

The local drug industry fears that continuation of the 100 percent automatic approval policy will be perceived by foreign investors as the government's endorsement of takeovers by them. The apprehension prevalent within the domestic industry is that MNCs would soon come to monopolize the pharma sector in the country. The smaller companies competing with multinationals are against total monopoly and complete foreign ownership. They have recieved support from the Health Ministry that fears losing control over drug prices.

However, most of the industry leaders say that such a move would be detrimental to the country's image as an investment destination.

Ã¢â?¬Å?We strongly believe that this move will be a retrograde step in the financial reforms process of the country and would adversely affect the foreign investment not only in the pharmaceutical sector in India but possibly, far beyond it,Ã¢â?¬? the Organization of Pharmaceutical Producers of India (OPPI), which represents foreign drug makers in India, said in a note submitted to the Ministry in August 2011.

Ã¢â?¬Å?Policy decisions should always be based on facts and not on apprehensions,Ã¢â?¬? says Tapan Ray, director general of OPPI, which is also an affiliate of the International Federation of Pharmaceutical Manufacturers and Associations.

Speaking on the sidelines at the second annual meeting of BIO India International, Kiran Mazumdar Shaw, CMD, Biocon, said, Ã¢â?¬Å?This is a growing sector and attracts investment. Any measure to restrict FDI flow will be a regressive step and will devalue this sector.Ã¢â?¬?

Dr Rajeev Soni, CEO, Premas Biotech, which has 100 percent FDI and is not allowed to use government grant, says, Ã¢â?¬Å?Although it is important to safegaurd the interests of the domestic industry, I don't think the reduction in FDI will help. Moreover, though FDI is allowed in India, there are certain caps. For example, the companies that have 100 percent FDI are not allowed to have PPPs for government-funded projects.

Ã¢â?¬Å?On the one hand, the government enourages FDI and on the other it penalizes the companies by not allowing them to avail government grants. In my opinion, if the company is working on an innovative project of national importance, its case needs to be looked at differently. The blanket rules that discourage the entreprenuers in the industry need to be removed and handled on case-to- case basis,Ã¢â?¬? adds Dr Soni.

Mr Andrew Witty, CEO of GlaxoSmithKline, voicing his opinion on the issue of foreign ownership of Indian domestic companies, says, Ã¢â?¬Å?Don't see ghosts where they aren't any.Ã¢â?¬?

Mr Kamal Karanth, MD, Kelly Services, believes that Indian patients have benefitted from the latest discoveries faster by the presence of R&D-focused companies in India. Ã¢â?¬Å?We can't afford to lose this access. In fact, we need innovative pharma companies to invest further in India to focus on diseases unique to India. Foreign MNCs have always been present in India. Pharma acquisitions are not new for India and there aren't too many instances of irrational price rise," says Mr Karanth.

No reduction in FDI

The Maira Committee Report, submitted in early October 2011, recommended that in order to enhance scrutiny of pharma mergers and acquisitions, merger control thresholds should be lowered and the Competition Commission should be equipped better. The Commitee did not propose any change in the 100 percent automatic FDI policy. However, since the Health Ministry wanted more protection, the Cabinet on October 11, 2011, took a decision that 100 percent automatic FDI in Greenfield investments will continue but FDI in Brownfield investments would go through the FIPB clearance at least for the next six months. After that the requisite oversight will be done by the CCI entirely, in accordance with the Competition laws of the country.

Reacting to the same, Mr Sujay Shetty, leader, Pharma Life Sciences, Price waterhouse Coopers states, Ã¢â?¬Å?Some of the things that the FIPB may take cognizance of is the points raised by the Ministry of Health and that is whether enough jobs will be created, will there be more R&D, will manufacturing capacity go up, and assurances that supply will be continued, prices will not be raised, product portfolios would be such that they would not skew towards more expensive portfolios, that they will abide by law in the country, some of which could be around compulsory licensing.Ã¢â?¬?

With this decision, it seems that the question over the reduction of cap from 100 percent to 49 percent is settled for now.

Rahul Koul in New Delhi