News Updates: January 9, 2014

OPPI

Publication: The Financial Express
Edition: National
Date: January 9, 2014
Headline: FDI in brownfield pharma stays, more power to FIPB

Story: *(Scan attached for your reference)*
DESPITE the department of industrial policy and promotion (DIPP) pitching for curbs on FDI in existing pharmaceutical units, the government on Wednesday announced continuation of the policy of allowing 100% FDI in the brownfield space, subject to approval from the Foreign Investment Promotion Board (FIPB).

A press note issued by the DIPP following an earlier Cabinet decision, however, said the non-compete clause would not apply for mergers and acquisitions involving FDI in the pharmaceutical space, except in cases where the FIPB feels it is needed. Analysts said the discretion given to the FIPB to vet the proposals and decide whether to invoke the non-compete clause could reduce potential FDI flows into the sector, which has seen a flurry of acquisitions of Indian units by foreign drug-makers in recent years.

FDI up to 100% is allowed in new (greenfield) ventures through the automatic route.

The DIPP had contended that FDI limit in companies making “critical” segments like oncology and vaccines be brought down to 49% through the approval route. It also wanted to enforce compulsory capacity creation by the foreign investor. Other riders recommended by DIPP included not allowing foreign investors to divest their manufacturing and R&D facilities in case of ownership transfer, and forcing them to put at least 25% of their total investment in research. The DIPP had also argued that acquisition of Indian pharma companies would lead to a paucity of essential medicines and a price spiral. This was refuted by analysts citing sufficient competition in the segment and alternative therapies available at low cost.

With the PMO, the finance ministry and Planning Commission voting against such a policy overhaul at a time when the country was liberalising foreign investment in various sectors and needed copious capital inflows, the DIPP’s views fell flat. The DIPP, however, could get the non-compete clause removed, contending that if a promoter sells one facility, he should not be barred from using all his knowledge and expertise to start a similar venture.

While the pharma industry is relieved by the government’s stand to continue with the policy, it is “worried” about the “conditional scrapping” of the non-compete clause.

The domestic industry fears that removing this clause would reduce its negotiating powers to get a high valuation, while foreign players are concerned that they (as buyers) would not be able to limit competition. Under a non-compete clause, existing promoters who sell out cannot re-enter the same line of business for a substantial number of years – or never in certain cases – limiting competition for the buyer.

“The industry needs non-discretionary and clear rules for investment. They (government) have granted discretionary powers to the FIPB which, for a fee, could be overridden,” said DG Shah, general secretary, Indian Pharmaceutical Alliance.

However, Ranjana Smetacek, director general of the Organisation of Pharma Producers of India, which represent foreign drug makers said a case-by-case review of the non-compete clause would encourage future deals.

Shah added that the move could also remove the leverage that Indian companies had to negotiate premium valuations. Abbott's agreement to buy Piramal Healthcare's domestic formulations business for $3.7 billion in 2010 prevents promoter Ajay Piramal from entering a similar business for eight years. Abbott had valued the Piramal unit at nine times annual sales.

Analysts say similar high-value deals in the pharma sector may take a beating due to the conditional use of non-compete clause. In 2008, Japan's drug major Daiichi-Sankyo paid $4.9 billion for a majority stake in Ranbaxy, valuing the company at over five times its annual sales of 2007. Last year, Nasdaq-listed Mylan Inc valued Agila Specialties at $1.6 billion or about 6.2 times annual sales.

FDI / Foreign Investment in Pharma / M&As in Pharma

Publication: The Economic Times
Edition: Online
Date: January 9, 2014
Headline: No non-compete clause in pharma mergers and acquisitions except in special cases, says government

Synopsis: The government has decided against a blanket ban on the incorporation of a 'non-compete' clause if an Indian pharma company is acquired by a foreign drug company. The ban was mooted by the Department of Industrial Policy and Promotion (DIPP) as a safeguard to ensure acquisition of Indian pharma companies does not lead to shortage of critical drugs. The government has decided to take up the issue on a case-by-case basis. The Foreign Investment Promotion Board (FIPB) could allow such a clause in special circumstances.

Publication: The Economic Times
Edition: National
Date: January 9, 2014
Headline: Government retains 100 per cent FDI in existing pharma units

Synopsis: Government today decided to retain the policy of allowing 100 per cent foreign investment in the existing pharma firms, brushing aside concerns about non- availability of affordable drugs in view of MNCs takeovers. The Department of Industrial Policy and Promotion (DIPP) said however that as far as the contentious issue of non- compete clause is concerned, the Foreign Investment Promotion Board (FIPB) will take a view on it on case-by-case basis.

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The Indian Express: Pharma FDI Non-compete clause only in special cases *(Link not available)*
The Asian Age: India won't stop Pharma MNCs *(Link not available)*

Publication: The Financial Express
Edition: National *(Opinion)*
Date: January 9, 2014
Headline: Delayed release medicine

Synopsis: Though the Department of Industrial Policy & Promotion (DIPP) lobbied hard, both during and after the Mylan purchase of Agila Specialties for $1.8 billion, to restrict the buyouts of Indian pharmaceuticals units by foreign firms, the government has done well to stick to the status quo. Which is that foreign firms require no permission to invest up to 100% in setting up greenfield pharmaceutical units in the country, but they need the approval of the Foreign Investment Promotion Board (FIPB) if they are to buy existing units (brownfield pharma). While foreign firms can currently buy up to 100% of brownfield pharma units subject to FIPB approval, DIPP wanted to cap this at 49%—it also wanted lock-in clauses before such firms could be re-sold and wanted to fix the proportion that had to be invested in research activities.

FDA / Drug Regulatory / DCGI / Pharma Policy

Publication: Reuters
Edition: Online
Journalist: Bill Berkrot
Date: January 9, 2014
Headline: FDA approves AstraZeneca type 2 diabetes drug

Synopsis: U.S. health regulators on Wednesday approved an AstraZeneca drug from a new class of medicines to treat type 2 diabetes after previously rejecting it over safety concerns. The Food and Drug Administration's approval had been expected after an outside advisory panel of medical experts voted by a wide margin in December to recommend its approval, saying the benefits of the drug, dapagliflozin, outweighed its safety risks. It will be sold in the United States under the brand name Farxiga. The medicine was co-developed by Bristol-Myers Squibb Co and AstraZeneca. AstraZeneca late last year bought out Bristol's stake in their diabetes joint venture for more than $4 billion, including upfront and sales-related milestone payments. Farxiga, which has already been available in Europe, belongs to a class of diabetes drugs called SGLT-2 inhibitors that work by blocking reabsorption of glucose by the kidney and increasing its excretion through urine to lower levels of blood sugar.

Publication: The Financial Express
Edition: New Delhi
Journalist: Pallavi Ail
Date: January 9, 2014
Headline: Despite high-profile Ranbaxy alerts, US FDA finds India okay

Synopsis: Has the US Food and Drug Administration (FDA) become fastidious in its scrutiny of Indian pharmaceutical plants registered with it? Information received by FE from the USFDA making use of that country's Freedom of Information Act (the US equivalent of India's Right to Information Act) shows that although the FDA has been rigorous and frequent with its inspections of Indian units over the last few years, only a tiny fraction of these inspections has escalated into serious adverse actions like issuance of warning letters to the Indian firm concerned or the more damaging import alerts.

General Industry

Publication: The Economic Times
Edition: New Delhi
Date: January 9, 2014
Headline: Glenmark's anti-diabetes drugs halt Merck rally (Online Headline: Glenmark's anti-diabetes drugs shake up Indian anti-diabetes market)

Synopsis: Mumbai-based Glenmark Pharmaceuticals has shaken up India's Rs 3,000-crore lucrative anti-diabetes market dominated by multinationals with its new drugs, Zitamed and Zita. The drugmaker, which is locked in a bitter patent infringement battle with US drug firm Merck Sharp and Dohme's (MSD) over these drugs, has managed to rake in Rs 16 crore in just eight months since it launched them, according to data available with All India Organisation of Chemists and Association (AIOCD). What's more, Glenmark has priced these drugs 30 per cent cheaper than its competitors, a move that's likely to rattle this market in a big way in future, said analysts. Zita and Zitamet are the generic versions of Sitagliptin, a class of drugs known to fight the insulin levels better than the old-class of diabetes drugs.

Publication: The Economic Times
Edition: New Delhi
Journalist: Biswarup Gooptu
Date: January 9, 2014
Headline: Unitus Seed invests in healthcare company Commerzpoint

Synopsis: Global impact investment firm Unitus Seed Fund has invested in Bangalore-based Commerzpoint Networks, which owns and operates online healthcare-focused marketplace Medypal.com. While the terms of the transaction were not disclosed, Bangalore and Seattle-based Unitus has invested through its two flagship funds — Unitus Seed Fund and Unitus Seed Fund India (USF India), with the ticket size estimated at between $50,000 (Rs 31.10 lakh) and $150,000 (Rs 93.30 lakh).

Publication: Business Standard
Edition: National
Journalist: Reghu Balakrishnan
Date: January 9, 2014
Headline: Health care remains hot PE option, FMCG disappoints

Synopsis: The Indian health care sector is turning out to be a hot investment destination for private equity (PE) and venture capital (VC) investors across the globe. The past month, December 2013, has seen large PE investments in Gland Pharma, Medanta Medicity and Emcure Pharmaceuticals with three global PE giants - KKR, Carlyle and Bain Capital - investing $200 million, $158 million, and $114 million in the companies, respectively. Sujay Kotak, assistant vice-president at Mumbai-based boutique investment bank Singhi Advisors, said: "The sector once again substantiated the fact that it is a defensive bet for investors. It was probably the only sector that provided a decent exit, worth $500 million, to the investors."

Publication: Business Standard
Edition: National
Journalist: Sohini Das
Date: January 8, 2014
Headline: After Elder deal, Torrent pharma open to more buys

Synopsis: The acquisition of the domestic business of debt-ridden Elder Pharma last month could be a new beginning for the Ahmedabad-based drug major Torrent Pharmaceuticals.Torrent Pharmaceuticals has indicated it is open to more acquisitions in the future, both in domestic and overseas market, according to sources. “The company has a strong balance sheet and is aiming to grow inorganically. It is open to making strategic acquisitions,” a source said. Ranjit Kapadia of Centrum Broking said, “The company would take at least five to six quarters to settle down, and after that it could look for strategic acquisitions. However, even in that case, it would definitely be a much smaller acquisition, probably in the range of Rs 50-100 crore.”

Publication: Pharmabiz
Edition: Online
Date: January 9, 2014
Headline: Supply-demand gap for elderly care widening fast: KPMG-Assocham study

Synopsis: With the number of elderly is expected to rise to 315 million by 2050 from the current level of 90 million, 75 per cent of elderly population in rural areas will be in need of better geriatric care and facilities, according to a study. Life expectancy in India has increased from 42 years in 1960 to over 65 years at present, according to KPMG-ASSOCHAM Report, ‘Old age security: doing the right thing for our elders’, launched today. Longevity is laudable as an achievement in developing countries but it often leads to social and economic pressures on formal and informal care network along with the government, it says. While the demand for better healthcare for the elderly is expected to increase rapidly, lack of incentives for getting into elderly care is leading to an ever increasing gap between the supply and demand for elderly care. Disease management, as a concept, is relatively nascent in the country with healthcare being largely reactive in nature. The goal of disease management is to increase focus on preventive care to minimise the incidence of hospitalization and thereby reduce the overall pressure on the healthcare system, said the report.