FIPB TO CLEAR BROWNFIELD INVESTMENTS IN PHARMA COMPANIES

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In October, an inter-ministerial group headed by the prime minister decided to make the Competition Commission of India ("CCI") the approving body for foreign investments in the pharma sector. At the meeting it was also decided that the Foreign Investment Promotion Board ("FIPB") would approve investment proposals for an interim six-month period, which ended in April, 2012. However, the guidelines authorizing CCI to act as the approving body have still not been finalized. Meanwhile, the FIPB has stopped clearing foreign investment proposals on the grounds that specific conditions for considering cases of brownfield foreign investment in the pharma sector were under formulation. The matter got further complicated by the fact that the FIPB's six-month window for considering foreign investment proposals in this sector expired. To end this confusion, the department of pharmaceuticals has mooted a proposal to allow the country's foreign investment approving body to continue clearing stake purchases by foreign firms in Indian drug companies.

PSA view – Though it seems that eventually brownfield investments will be approved by the CCI, it is best if FIPB permanently remains the controlling body for such approvals. As reported in PSA flash dated April 20, 2012 the move to allow CCI to handle brownfield foreign investment has been heavily criticized by the industry, ministry of finance, pharmaceutical and the planning commission. The guidelines authorizing CCI as the approval body were to come into effect in April 2012. The failure to finalize the guidelines has resulted in confusion as to which body is at present authorized to approve brownfield investments. This in turn has lead to the stalling of applications by (a) Mauritius-based Ambrose Private Ltd's to buy 40% stake in Sutures India for INR 2 billion, (b) Spain's Chemo Group's plans to buy a 100% stake in Ordain Healthcare Global for INR 580 million, (c) Ankur Drugs' plans to raise about INR 400 million from NRIs and (d) Plethico Pharma's plans to raise INR 4.9 billion by diluting 22% stake via foreign currency convertible bond.

Irregularities in CDSCO

The parliamentary standing committee has pointed out huge irregularities in the functioning of the Central Drugs Standards Control Organisation ("CDSCO") in its report. The parliamentary panel has pointed out in its report that around 33 drugs were allowed to be sold in India during 2008-10 without conducting trials on Indian patients, and there was no scientific evidence to show that these drugs were "really effective and safe" for use. To look into this report, the Union Health Minister has announced a three-member committee which would examine the issue and submit its report in two months. The committee would comprise of Indian

Council of Medical Research, Director-General V.M. Katoch, National Brain Research Centre, President P.N. Tandon, and Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, Former Director S.S. Aggarwal.

The committee shall examine the validity of the scientific and statutory basis adopted for approval of new drugs without clinical trials, outline appropriate measures to bring about systemic improvements in the processing and grant of statutory approvals, and suggest steps to institutionalise improvements in other procedural aspects of functioning of the CDSCO. The committee shall also examine the charge levelled by the parliamentary panel regarding an apparent nexus between drug manufacturers and experts, whose opinion matters so much in the decision making process at the CDSCO.

PSA view – Serious revelations have been made in the parliamentary committee report about the way CDSCO functions. It is crucial that these revelations are enquired upon and the functioning of CDSCO tightened. Enquiry regarding the organizational structure and strength of CDSCO, approval of new drugs, banning of drugs, approval of fixed dose combinations, pharmacovigilance and spurious/sub-standard drugs are crucial to identify the problem and then work upon to improve the situation and outline appropriate measures to bring systemic improvements in the processing and grant of statutory approvals.

Rise in spurious drugs prompts CDSCO to run random check

As per the CDSCO, the number of spurious drugs being marketed in the previous fiscal year has shown an increase. According to the statistics provided by the health ministry, the number of spurious drugs being sold increased from 95 to 113 during the last fiscal year, calling in the need for more random checks to be run by the CDSCO. In addition to this, investigations have been initiated against 211 persons involved in marketing of spurious drugs.

PSA view – It appears that the increase in spurious drugs has revealed a serious lack in enforcement of drug manufacturing and quality legislations. While there are manufacturing guidelines in place, it appears the standardization and implementation needs a rigorous check. It would be beneficial to deter future marketers and manufacturers of spurious drugs by imposing exemplary penalties on the guilty parties, since marketing spurious drugs can jeopardize lives.

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