CLIFFORD CHANCE

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India tightens norms for pharma M&A

On 8 November 2011, the Indian government amended its foreign investment rules imposing a requirement to seek its approval for foreign direct investment ("FDI") in existing Indian pharmaceutical companies. FDI in greenfield pharmaceutical ventures can be made without the requirement of any such approval.

FDI in Indian companies is regulated by the foreign exchange laws administered by the Reserve Bank of India and by FDI policy statements issued by the Government of India ("**GOI**"). These laws and policy statements regulate aspects of FDI and identify circumstances where: approval of the GOI is required for the foreign investment ("**Government Route**"), where no such approval is required ("**Automatic Route**"), where foreign investment is limited to a certain percentage of the shareholding ("**Sector Limits**") and where FDI is completely prohibited.

100% FDI is permitted in the pharmaceutical sector. A number of medium and large Indian pharmaceutical companies were acquired by global pharmaceutical companies in the recent past:

Indian Target	Foreign Acquirer	Appx. Deal Value GBP(m)	Year
Matrix Laboratories Limited	Mylan Inc, U.S.	381.2	2006
Fresenius Kabi Ltd (formerly Dabur Pharma Ltd)	Fresenius SE & Co. KGaA, Germany	174.4	2008
Ranbaxy Laboratories Limited	Daiichi Sankyo Company Limited, Japan	2,797.4	2008
Orchid Chemicals & Pharmaceuticals Limited (certain business)	Hospira Inc, U.S.	245.9	2010
Piramal Healthcare Solutions business	Abbott Laboratories, U.S.	2,572.8	2010
JB Chemicals and Pharmaceuticals (certain brands)	Cilag AG, Switzerland	161.3	2011
Paras Pharmaceuticals Ltd	Reckitt Benckiser Group Plc	453.7	2011

[Source: Mergermarket]

These deals triggered a debate in India whether a stricter M&A environment is required to ensure availability of cheaper drugs manufactured by Indian generic drugs manufacturers. However no conclusive studies were carried out to establish a direct linkage between increased foreign ownership of Indian pharmaceutical companies and an increase in drug prices.

The GOI has now prescribed a stricter regime for foreign acquisitions. This regulatory tightening comes in the backdrop of the GOI proposing to modify its policy on drug price control by covering more than 60% (from current 10-20%) of the drugs available in the domestic market.

This new regime will be reviewed after a period of six months.

So as not to discourage FDI for generating new capacity in the Indian pharmaceutical sector, FDI, up to 100% continues to remain permitted under the Automatic Route.

The revised policy does not clarify whether it would impact contractual arrangements that were in place before 8th November 2011, including any share purchase or investment arrangements or joint venture arrangements between Indian and foreign entities.

The revised norms are silent about the basis on which the Indian Government will decide on granting or refusing to grant its approval for any FDI in an existing pharmaceutical company.

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This FDI policy reversal comes a mere few months after India introduced a merger control regime to regulate mergers and acquisitions, including those in the pharmaceutical sector. Thus, mergers and acquisition in the pharmaceutical sector in India are likely to require two sets of approval and could potentially result in creating conflicting environment for acquisitions by global pharmaceutical companies in the Indian pharmaceutical sector.