FDI In Pharma Stays At 100% But With Certain Restrictions (INDEPTH)

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Current (FIPB) & proposed (CCI) approval requirements may act as a speed breaker for potential foreign investors.

The pharma and healthcare sector in India has been benefiting from 100 per cent foreign direct investment (FDI) under the automatic route, i.e., without the need for approval of the Foreign Investment Promotion Board (FIPB). In recent times, however, certain ministries and non-governmental organisations (NGOs) have recommended restricting FDI to 49 per cent in Indian companies. This recommendation arose as a result of some acquisitions of Indian pharma companies (including generic companies) by foreign pharma companies. It was felt that such acquisitions would lead to a significant rise in the cost of the drugs in India. Further, it was felt that if most of the generic companies are acquired by foreign companies, the option of compulsory licensing available under the Indian Patents Act, 1970, may not be availed by such companies.

Having given due consideration to the concerns raised by all, the Prime Minister of India convened a meeting of a high level committee involving certain ministries and government agencies on October 11, 2011.

This high level committee, headed by the Prime Minister, concluded that FDI in the pharmaceuticals sector would continue to stay at its previous level of 100 per cent, but with certain restrictions. It was decided that the FDI, in all brownfield projects in the pharma sector, will henceforth be scrutinised by the FIPB as an interim measure until the government comes up with a comprehensive policy to regulate such investments. However, the government has exempted FDI in greenfield projects from any prior FIPB approval requirement.

It is also proposed that in future, all Brownfield investments will be scrutinised and approved by the Competition Commission of India (CCI).

It seems that the current (FIPB) and the proposed (CCI) approval requirements may act as a speed breaker for potential foreign investors as they may have to show that their intention is not to collude or undertake predatory pricing or any such anti-competitive practice. Bringing in the CCI and FIPB approvals collectively for brownfield projects may burden the foreign pharma companies with certain pre-conditions to be observed in undertaking their business ventures, which the FIPB/CCI may impose upon them, such as divestiture of product line or division of business, if the approving authority finds that the proposed arrangement may lead to concentration. However, the industry has welcomed the move by the government to continue to allow 100 per cent FDI in the pharma sector and not restricting it to 49 per cent.

Upcoming Guidelines/Regulations In Clinical Trials Sector

India has been a preferred destination for conducting clinical trials in order to test the safety and efficacy of various drugs before they are approved for launching in the market. The authorities in India have been expressing concerns over the adverse reactions, injury or death of patients

participating in such clinical trials and compensation provided to them or their relatives by a sponsor pharma company that has conducted the trials. To constantly regulate and streamline the clinical trials sector, conscious efforts are made to either amend the existing regulations or introduce specific new regulations/guidelines.

To this effect, the Drugs Controller General of India (DCGI) has recently issued draft guidelines on reporting serious adverse events occurring in clinical trials in order to streamline the process of reporting such events to the drugs authorities in India. These guidelines propose to serve as a guidance document for the pharmaceutical industry to achieve consistency and completeness in the data submitted to the drugs authorities.

Moreover, when it comes to compensating the victims of clinical trials (in instances of injury or death of the study subjects), the law in India is pretty much silent on the specific obligations of stake holders, especially the sponsor companies in clinical trials. The law does not specifically obligate the sponsor to voluntarily provide compensation, in the absence of a claim against the sponsor. The Indian Council for Medical Research's (ICMR) Ethical Guidelines for Biomedical Research on Human Participants, 2006, had issued draft guidelines for 'compensation to participants for research-related injuries' some years ago, but these guidelines were, eventually, not implemented. In the absence of clear guidelines, there is no uniformity in the amount of compensation and the sponsor companies follow different parameters in deciding such amounts payable. This has led to dissatisfaction on the part of the study subject or his/her relatives. At the same time, several NGOs have raised concerns over the incidences of injury and death to the study subjects.

The Drugs Technical Advisory Board (DTAB), under the chairmanship of the Director General of Health Services (DGHS), who is the ex-officio chairman of the board in a meeting held recently, concluded that guidelines need to be issued in connection with the compensation to the study subjects. Consequently, DTAB has directed DCGI to issue guidelines on providing proper compensation to the victims of the trials. The proposed guidelines are expected to include various norms and conditions, as well as specific procedures, to decide on the amount of compensation that will be payable. The proposed guidelines would apply to all clinical research, irrespective of who has sponsored them.

Additionally, the DTAB has also decided that the independent ethics committee (IEC) involved in clinical trials will have to be registered with the drugs authority mandatorily. The DCGI is expected to issue guidelines in this regard as well. It may be recalled that a couple of years ago, the DCGI had made it mandatory for all clinical trials being conducted in India to be registered with the Clinical Trials Registry.

Normally, institutions which are involved in the conduct of clinical trials are required to have the IEC in place. The IEC has been conferred with certain powers under law to monitor clinical trials. However, there have been instances recently when the authorities have received several complaints against such IECs raising concerns in respect of the independent nature of the IECs and the manner in which they grant approvals for the trials. Mandatory registration of the IEC is likely to bring about transparency in the conduct of clinical trials and help in increasing the confidence of the public at large.

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