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Govt may soon permit 100% FDI in brownfield medical device projects

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THE government is likely to soon permit 100% FDI in brownfield medical devices and equipment manufacturing projects through the automatic route.

Currently, 100% FDI is allowed in the pharmaceutical sector (including medical devices) in greenfield projects through automatic route, while Foreign Investment Promotion Board (FIPB) approval is needed for brownfield investments. Besides, there are riders while giving permission to brownfield investments, including that 'non-compete' clause would not be allowed except in special circumstances with FIPB approval. Also, FIPB has the discretion to incorporate conditions for foreign investment in all brownfield cases, at the time of granting approval.

These riders will continue only for brownfield investments in the drugs/cosmetics and pharmaceuticals sector, while medical devices will be exempt from it, official sources told *FE*. The new norms are likely to be in place before PM Narendra Modi's US trip by this month-end as many US companies and investors have evinced interest to enter the sector in India, they added.

Significantly, of the $5-6 billion-worth medical devices, equipments and technology market in India, 70% is catered to by imports. The government wants to reduce dependence on such imports through incentives to increase domestic manufacturing. "Foreign investors know that with labour costs in China going up, it will be cheaper to manufacture medical devices in India and make it a hub for exports to other parts of South Asia," an official said.

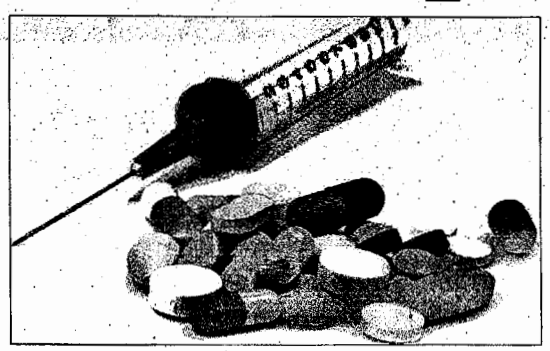
Currently, the government is empowered to include the needed riders in cases of FDI in brownfield pharma entities to ensure that post the brownfield investment, the level of manufacturing as well as investments in research and development in India does not shrink. In case of drugs and pharmaceutical companies, the government can also specify that that the items (eg: essential drugs), produced by the company that is acquired/getting FDI, should continue to be available post acquisition/investment at a reasonable price. "A separate carve-out will be done for medical devices so that they are treated differently with respect to brownfield investments. None of the current restrictions will be applicable to them," an official said.

Another factor that has led to increased imports and a fall in domestic manufacturing is the steady fall in gross customs duties to around a maximum of 11% currently (many items have even zero gross customs duty) from 27% five years ago, in turn resulting in several domestic manufacturers shutting shop and becoming traders, said Rajiv Nath, forum coordinator, Association of Indian Medical Device Industry. He said gross customs duty should be hiked or rationalised on many items.

Pointing out that many foreign investors are indulging in trading due to the current restrictions, he said the government should also bring in a condition that in cases of 100% FDI, 60% of turnover should come from manufacturing in India and not trading. Or else, FDI limit should be brought down to 40%, he added.

Discussions are on between the ministries of health and commerce on the treatment and regulation of medical devices under the Drugs and Cosmetics (Amendment) Bill. Once the health ministry comes out with a negative list of medical devices/equipments/technology that needs to be controlled (via FIPB approval in brownfield investments), the remaining items can then take advantage of the proposed FDI norms, they added. Pending parliamentary approval to the Bill, the commerce ministry wants the health ministry to find a via media – through notification or guidelines – to ensure separate treatment for FDI in brownfield medical devices/equipment projects.

AIMED has been of the view that the Bill must treat medical devices separately from drugs and cosmetics. It also wanted the Bill to incorporate international aspects of medical devices safety and performance.



RIDERS AND NORMS

- Now 100% FDI in the pharma sector (including medical devices) in greenfield projects through automatic route, 100% FDI in brownfield investments but through FIPB approval
- Many riders for permission of brownfield investments; FIPB given discretion to incorporate appropriate riders
- These norms to be applicable only for drugs/cosmetics and pharma sector, while medical devices to be exempt from it
- New norms before PM's US trip this month-end; many US investors interested to enter the sector

FDI