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RBI formalizes automatic 100% FDI in medical devices sector

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MUMBAI

Medical device manufacturers in India will be able to bring in foreign direct investment (FDI) up to 100% through the automatic route, the Reserve Bank of India (RBI) said on Monday, formalizing a government decision taken in this regard in January.

Until now, the medical devices industry has been considered part of the overall pharmaceutical sector, where 100% FDI is allowed through the automatic route in new projects; however, existing companies can do so only with permission from the Foreign Investment Promotion Board (FIPB), in what is called the approval route. The RBI clarification essentially carves out the devices industry from the pharmaceutical sector for regulatory purposes and opens it for 100% FDI through the automatic route.

In 2014, the government had reviewed the FDI policy for the pharma industry to restrict the 100% automatic approval route only for greenfield or new units and insisting on FIPB approval for existing units. This review was prompted by concerns that 100% foreign investment though automatic route in existing units would lead to increased inbound mergers and acquisitions in the sector, driving pharmaceutical manufacturing to the control of foreign companies.

On 6 January, the government said it will allow 100% FDI for medical devices manufacturing in India. All kinds of medical instruments, diagnostic tools and products, any technology and products including clinical implants were included in the category. It was also proposed that the FDI approval restrictions on the pharmaceutical industry will be removed for medical devices. Monday's RBI clarification mandates this policy recommendation.

Allowing 100% FDI in the medical devices sector is aimed at promoting local manufacturing of these products, as currently India meets at least 70% of its requirements through imports. Local industry, however, says automatic approvals may not necessarily result in boosting local manufacturing as many foreign companies may use this rule for setting up their local subsidiaries in the country to import and trade in products.

Policy.