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Finally approval to 100% FDI in medical devices

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In a review of the policy on Foreign Direct Investment (FDI) in pharmaceutical sector to carve out separate set of rules exclusively for medical devices, the union cabinet chaired by the Prime Minister, Mr Narendra Modi, on December 24 gave its approval to amend the existing policy. The policy on the pharma sector covers `medical devices` since this area is not separately covered. It is expected to boost the sector that has so far failed to attract much domestic capital.

As per the extant FDI policy for pharma sector, FDI up to 100 percent is permitted subject to specified conditions. While FDI for green-field projects is under automatic route, brown-field projects are placed under government route.

Since medical devices are part of the Drugs & Cosmetics Act, 1940 and fall under the Pharmaceutical sector, all the conditions of the FDI policy on the sector, including the condition relating to `non-compete clause`, apply on brownfield investment proposals of medical devices industry.

As per National Industrial Classification (NIC) Code 2008, sector code of `Manufacture of pharmaceuticals, medicinal chemical, and botanical products` is 2100 while sector code of `Manufacture of medical and dental instruments and supplies` is 3250. Medical devices will fall under the category of `medical and dental instruments and supplies`. Therefore, drugs and pharmaceuticals and medical devices are two different industrial activities. The condition of `non-compete` was imposed so that the Indian manufacturers can continue manufacturing generic drugs and catering to the needs of the large number of people in the country and in other developing countries who cannot afford branded and patented drugs. This condition is not relevant to `medical devices` industry of the country where the country is substantially import dependent and the sector is adversely impacted because of the lack of adequate capital and required technology.

Therefore, the Cabinet approved the following proposal to amend the relevant paragraphs of the extant FDI policy as contained in the Consolidated FDI Policy Circular 2014.

In simple terms, a medical device means any instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specially for human beings or

animals for one or more of the specific purposes of diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder.

Easing of norms for medical devices industry by creating special carve out in the extant FDI policy on pharma sector will encourage FDI inflows in this area.