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# news flash

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## FOREIGN DIRECT INVESTMENT IN MEDICAL DEVICES SECTOR

### BACKGROUND

The terms and conditions pertaining to the Foreign Direct Investment ("**FDI**") in India are governed by the consolidated Foreign Direct Investment Policy ("**FDI Policy**") which is issued by the Department of Industrial Policy and Promotion ("**DIPP**") every year. Any amendments to the FDI Policy during the year are covered under the press notes released by the DIPP. The latest applicable FDI Policy was effective from 17 April 2014.

On 6 January 2015 the DIPP has issued Press Note No. 2 (2015 Series) ("**Press Note**") liberalising certain conditions for FDI in the business of manufacturing of "*medical devices*" under the Pharmaceuticals sector.

Pursuant to this Press Note, FDI up to 100% is permitted for manufacturing of medical devices under the automatic route in both greenfield and brownfield companies. The FDI Policy as applicable generally to the Pharmaceuticals sector provides that only investment in greenfield projects are under the automatic route but FDI in brownfield projects required specific approval from the Foreign Investment Promotion board (**"FIPB")**.

The term '*Medical Devices'* has been described as:

a. any instrument, apparatus, appliance, implant, material or other articles, whether used alone or in combination, including the software, intended by the manufacturer to be used specifically for human beings or animals for any one of the following purposes:
   i. diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;
   ii. diagnosis, monitoring, treatment or alleviation of, or assistance for any injury or handicap;
   iii. investigation, replacement or modification or support of the anatomy or of a physiological process;
   iv. supporting or sustaining life;
   v. disinfection of medical devices;
   vi. control of conception,

   and which does not achieve its primary intended action in or in the human body or animals by any pharmacological or immunological or metabolic means, but which may be assisted in its intended function by such means;

b. any accessory to such an instrument, apparatus, appliance, material or other article;

c. a device which is reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system whether used alone or in combination thereof intended to be used for examination and providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body of animals.

The Press Note clarifies that the definition of medical device is subject to the amendment in Drugs and Cosmetics Act, 1940 ("**Act**"). Presently, the Act does not have a specific definition of '*medical devices*'. The Drugs and Cosmetics (Amendment) Bill, 2013 ("**Bill**") introduced in the Rajya Sabha on 29 August 2013 proposed to introduce the definition of '*medical devices*', which not exactly similar to the definition under the Press Note. This Bill is still pending for approval before the Rajya Sabha. If and when the Bill is passed and if the definition of '*medical devices*' in the amended Act is different than the definition mentioned in the Press Note, the definition as per the amended Act will override the definition in the Press Note.

This Press Note can be viewed as an attempt by the Government to encourage FDI in manufacturing of medical devices as well as a move to further the "*Make in India*" campaign launched by the Prime Minister in September 2014.

## DISCLAIMER



For further clarification and details on the above, you may write to the Exchange Control team comprising of among others Mr. Aliff Fazelbhoy (Senior Partner) at afazelbhoy@almtlegal.com, Mr. Vaishakh Kapadia (Partner) at vkapadia@almtlegal.com, and Ms. Purti Minawala (Associate) at pminawala@almtlegal.com.

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