Government of India
Ministry of Commerce & Industry
Department of Industrial Policy & Promotion

Press Note No. 2 (2015 Series)

Subject: Review of the policy on Foreign Direct Investment (FDI) in Pharmaceutical Sector- carve out for medical devices.

1.0 Present Position:

1.1 Paragraph 6.2.18 of 'Consolidated FDI Policy Circular of 2014', effective from April 17, 2014, relating to Foreign Direct Investment policy in pharmaceuticals sector is as under:

6.2.18	**Pharmaceuticals**		
6.2.18.1	Greenfield	100%	Automatic
6.2.18.2	Brownfield	100%	Government
6.2.18.3	**Other Conditions:**		
	(i) 'Non-compete' clause would not be allowed except in special circumstances with the approval of the Foreign Investment Promotion Board. (ii) The prospective investor and the prospective investee are required to provide a certificate along with the FIPB application. (iii) Government may incorporate appropriate conditions for FDI in brownfield cases, at the time of granting approval.		

2.0 Revised Position:

2.1 The Government of India has reviewed the position in this regard and the policy will now be read as under:

6.2.18	**Pharmaceuticals**		
6.2.18.1	Greenfield	100%	Automatic
6.2.18.2	Brownfield	100%	Government
6.2.18.3	**Other Conditions:**		
	(i) 'Non-compete' clause would not be allowed except in special circumstances with the approval of the Foreign Investment Promotion Board. (ii) The prospective investor and the prospective investee are required to provide a certificate along with the FIPB application. (iii) Government may incorporate appropriate conditions for FDI in brownfield cases, at the time of granting approval. **Note: i.** FDI up to 100%, under the automatic route is permitted for manufacturing of medical devices. The abovementioned conditions will, therefore, not be applicable to greenfield as well as brownfield projects of this industry. **ii.** Medical device means- a. 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- (aa) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder; (ab) diagnosis, monitoring, treatment, alleviation of, or assistance for, any injury or handicap; (ac) investigation, replacement or modification or support of the anatomy or of a physiological process; (ad) supporting or sustaining life;		

	(ae) disinfection of medical devices; (af) control of conception, and which does not achieve its primary intended action in or on 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. an 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 or animals. **iii.** The definition of medical device at Note (ii) above would be subject to the amendment in Drugs and Cosmetics Act.

3.0 The above decision will take effect from 21.01.2015.

6/1/15

(Atul Chaturvedi)
Joint Secretary

D/o Industrial Policy & Promotion File No.: No. 1/16/2010-FC.I dated: 6th January, 2015

Copy forwarded to:

1. **Press Information Officer, Press Information Bureau**- for giving wide publicity to the above Press Note.
2. **Joint Secretary(I&C), Department of Economic Affairs, North Block, New Delhi**
3. **Reserve Bank of India, Foreign Exchange Department, Mumbai**

For suitably incorporating the policy changes in Foreign Exchange Management (Transfer or issue of security by a person resident outside India) Regulations, 2000 and the relevant schedules thereof.

4. **NIC Section in the Department of Industrial Policy and Promotion**- for uploading the Press Note on DIPP's website.
5. **Hindi Section, DIPP**- for providing Hindi version.