

RESERVE BANK OF INDIA
Foreign Exchange Department
Central Office
Mumbai- 400 001

Notification No.FEMA.334/2015-RB

Dated January 09, 2015

Foreign Exchange Management (Transfer or Issue of Security by a Person Resident outside India) (Amendment) Regulations, 2015

In exercise of the powers conferred by clause (b) of sub-section (3) of Section 6 and Section 47 of the Foreign Exchange Management Act, 1999 (42 of 1999), the Reserve Bank of India hereby makes the following amendments in the Foreign Exchange Management (Transfer or Issue of Security by a Person Resident outside India) Regulations, 2000 ([Notification No.FEMA 20/2000-RB dated 3rd May 2000](#)) namely:-

1. Short Title & Commencement:-

(i) These Regulations may be called the Foreign Exchange Management (Transfer or Issue of Security by a Person Resident Outside India) (Amendment) Regulations, 2015.

(ii) They shall come into force from January 21, 2015.

2. Amendment to Schedule 1

In the Foreign Exchange Management (Transfer or Issue of Security by a Person Resident outside India) Regulations, 2000 (Notification No.FEMA 20/2000-RB dated 3rd May 2000), the existing entry 17 in Annex B of the Schedule 1 shall be substituted by the following, namely:-

17	Pharmaceuticals		
17.1	Greenfield	100%	Automatic
17.2	Brownfield	100%	Government
17.3	Other Conditions:		
17.3.1	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 :		

	<p>i. FDI upto 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.</p> <p>ii. Medical device means :-</p> <p>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 :-</p> <p>(aa) Diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;</p> <p>(ab) diagnosis, monitoring, treatment, alleviation of, or assistance for, any injury or handicap;</p> <p>(ac) investigation, replacement or modification or support of the anatomy or of a physiological process;</p> <p>(ad) supporting or sustaining life;</p> <p>(ae) disinfection of medical devices;</p> <p>(af) control of conception;</p> <p>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;</p> <p>b) an accessory to such an instrument, apparatus, appliance, material or other article;</p> <p>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.</p> <p>iii. The definition of medical device at Note (ii) above would be subject to the amendment in Drugs and Cosmetics Act.</p>
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(B.P. Kanungo)
Principal Chief General Manager

Foot Note:-

The Principal Regulations were published in the Official Gazette vide G.S.R. No.406 (E) dated May 8, 2000 in Part II, Section 3, sub-Section (i) and subsequently amended as under:-

G.S.R.No. 158(E) dated 02.03.2001
G.S.R.No. 175(E) dated 13.03.2001
G.S.R.No. 182(E) dated 14.03.2001
G.S.R.No. 4(E) dated 02.01.2002
G.S.R.No. 574(E) dated 19.08.2002
G.S.R.No. 223(E) dated 18.03.2003
G.S.R.No. 225(E) dated 18.03.2003
G.S.R.No. 558(E) dated 22.07.2003
G.S.R.No. 835(E) dated 23.10.2003
G.S.R.No. 899(E) dated 22.11.2003
G.S.R.No. 12(E) dated 07.01.2004
G.S.R.No. 278(E) dated 23.04.2004
G.S.R.No. 454(E) dated 16.07.2004
G.S.R.No. 625(E) dated 21.09.2004
G.S.R.No. 799(E) dated 08.12.2004
G.S.R.No. 201(E) dated 01.04.2005
G.S.R.No. 202(E) dated 01.04.2005
G.S.R.No. 504(E) dated 25.07.2005
G.S.R.No. 505(E) dated 25.07.2005
G.S.R.No. 513(E) dated 29.07.2005
G.S.R.No. 738(E) dated 22.12.2005
G.S.R.No. 29(E) dated 19.01.2006
G.S.R.No. 413(E) dated 11.07.2006
G.S.R.No. 712(E) dated 14.11.2007
G.S.R.No. 713(E) dated 14.11.2007
G.S.R.No. 737(E) dated 29.11.2007
G.S.R.No. 575(E) dated 05.08.2008
G.S.R.No. 896(E) dated 30.12.2008
G.S.R.No. 851(E) dated 01.12.2009
G.S.R.No. 341 (E) dated 21.04.2010
G.S.R.No. 821 (E) dated 10.11.2012
G.S.R.No. 606(E) dated 03.08.2012
G.S.R.No. 795(E) dated 30.10.2012
G.S.R.No. 796(E) dated 30.10.2012
G.S.R. No. 797(E) dated 30.10.2012
G.S.R.No. 945 (E) dated 31.12.2012
G.S.R. No.946(E) dated 31.12.2012
G.S.R. No.38(E) dated 22.01.2013
G.S.R.No.515(E) dated 30.07.2013
G.S.R.No.532(E) dated 05.08.2013
G.S.R. No.341(E) dated 28.05.2013
G.S.R.No.344(E) dated 29.05.2013
G.S.R. No.195(E) dated 01.04.2013
G.S.R.No.393(E) dated 21.06.2013
G.S.R.No.591(E) dated 04.09.2013
G.S.R.No.596(E) dated 06.09.2013

G.S.R.No.597(E) dated 06.09.2013
G.S.R.No.681(E) dated 11.10.2013
G.S.R.No.682(E) dated 11.10.2013
G.S.R. No.818(E) dated 31.12.2013
G.S.R. No.805(E) dated 30.12.2013
G.S.R.No.683(E) dated 11.10.2013
G.S.R.No.189(E) dated 19.03.2014
G.S.R.No.190(E) dated 19.03.2014
G.S.R.No.270(E) dated 07.04.2014
G.S.R.No. 361 (E) dated 27.05.2014
G.S.R.No.370(E) dated 30.05.2014
G.S.R.No.371(E) dated 30.05.2014
G.S.R.No. 435 (E) dated 08.07.2014
G.S.R.No. 400 (E) dated 12.06.2014
G.S.R.No. 436 (E) dated 08.07.2014
G.S.R.No. 487 (E) dated 11.07.2014
G.S.R.No. 632 (E) dated 02.09.2014
G.S.R.No. 798 (E) dated 13.11.2014
G.S.R.No. 799 (E) dated 13.11.2014
G.S.R.No. 800 (E) dated 13.11.2014
G.S.R.No. 829 (E) dated 21.11.2014

**Published in the Official Gazette of Government
of India – Extraordinary – Part-II, Section 3,
Sub-Section (i) dated 14.01.2015- G.S.R.No.30(E)**