

F No. 18-13/2018-DC (Part-1)
Directorate General of Health Services
Central Drugs Standard Control Organization
FDA Bhawan, Kotla Road, New Delhi
(O/o DCG (I))

Dated: **22 JUN 2018**


PUBLIC NOTICE FOR COMMENTS ON PROPOSED NOTIFICATION

Subject: Proposal to include all implantable medical devices and other high end equipment under the purview of Section 3 (b) (iv) of the Drugs and Cosmetics Act, 1940 as Medical Devices-regarding.

In pursuance of sub-clause (iv) of clause (b) of Section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940), Drugs Technical Advisory Board (DTAB) in its 79th meeting held on 16.05.2018, deliberated and recommended for the proposal to specify the following medical devices under the definition of drug.

- 1) All implantable medical devices
- 2) CT scan equipment
- 3) MRI equipment
- 4) Defibrillators
- 5) Dialysis machine
- 6) PET equipment
- 7) X-Ray machine
- 8) Bone marrow cell separator

This will be notified in the official Gazette of India and it will come into force after a period of twelve months from the date of its publication. All the stakeholders are requested to forward their comments/suggestions within 21 days of issue of this notice prior to finalization of the notification, through email at dcj@nic.in and dcctab@cdsco.nic.in or in hard copies to the O/o DCG(I), CDSCO, FDA Bhawan, Kotla Road, New Delhi-110002.


22/6/18

(Dr. S. Eswara Reddy)

Drugs Controller General (India)

CC: ppsto JS (CR)