F. No. 29/Misc./4/2016-DC(101)
Government of India
Director General of Health Services
Central Drugs Standard Control Organisation
O/o DCG (I)

FDA Bhawan, Kotla Road
New Delhi-110002
Date:

29 DEC 2016

NOTICE

SUB: Import of Radiopharmaceutical Products -Regarding.

Radiopharmaceutical and Radio Immunoassay diagnostic products for therapeutic and diagnostic use are regulated under the provisions of Drugs & Cosmetics Act 1940 and Rules, 1945 thereunder. These products are required to be made available to the cancer & other patients in the hospitals before the short expiry. Atomic Energy Regulatory Board (AERB) issues NOC to the Institutes/ hospitals to import and receive radiopharmaceuticals.

A meeting of stakeholders alongwith experts was convened on 07.11.2016 at CDSCO, HQ to discuss the issues relating to import of such radiopharmaceutical products. A transition time of 45 days has been given to the importers to fulfill the requirements which has expired on 21 Dec. 2016. Therefore, all the importers require to obtain necessary permission under the provisions of Drugs and Cosmetics Act 1940 & Rules made thereunder.

It has been decided in consultation with the Ministry of Health and Family Welfare that no concession will be given in respect of regulatory requirements under the Drugs and Cosmetics Rules beyond 21.12.2016. This may be noted by all concerned for strict compliance.

(Dr. G. N. Singh)
Drugs Controller General (India)