

FILE No. DCG(I)/MISC/2017(11)
DIRECTORATE GENERAL OF HEALTH SERVICES
OFFICE OF DRUGS CONTROLLER GENERAL (INDIA)
(IMPORT & REGISTRATION)

ORDER

Date 01.05.2017

WHEREAS, in terms of sub clause (1) of clause (b) of section 3 of the Drugs and Cosmetics, Act 1940, import, manufacture and sale of drugs is regulated with a view to ensure their safety, efficacy and quality;

AND WHEREAS Rules 23 to 27(A) of the Drugs and Cosmetics Rules, 1945 specify the provisions for grant of Registration Certificate and Import License for import of Drugs including Radiopharmaceuticals;

AND WHEREAS vide letter No. 1/RIA(NOC)/2003-DC dated 6th Feb. 2006, it was clarified that this Directorate had no objection for importing various Radioimmuno assay Kits and tracers so far as the provisions of the Drugs and Cosmetics Act, 1940 and rules thereunder were concerned, subject to the condition that before importing these kits, the importer would obtain NoC from BARC for the end user and the same shall be submitted to the Customs Authorities at the time of import;

AND WHEREAS in response to the clarification sought by the CDSCO Port Office, CDSCO Hqrs vide letters No. Import/Misc./78/2016-DC dated 12th Sept. 2016 and 13th Oct. 2016, informed all port offices of CDSCO that Radiopharmaceutical products or Radioimmunoassay Kits are required to be regulated under provisions of the Drugs and Cosmetics Act and Rules thereunder and that no consignment of such products may be released without import license;

AND WHEREAS aggrieved by the decision, a number of representations were received by CDSCO and, thereafter, a meeting of importers and experts in the field of nuclear medicines was convened on 7th Nov. 2016 in DCG(I)'s chamber to resolve issues pertaining to import of such products;

AND WHEREAS vide letter No. 29/Misc/4//2016-DC(101) dated 29.12.2016, stakeholders were informed that a transition period of 45 days has been given to importers to submit application for grant of import license;

And whereas some applications were received through the online portal and after scrutiny of the applications, the deficiencies were pointed out and queries sent to the applicants;

AND WHEREAS the applicants have failed to submit the requisite clarifications despite lapse of a considerable time;

AND WHEREAS issues relating to import of radiopharmaceutical products/ radio-Immuno assay kits for (in-vivo or in- vitro) diagnostics use had been further examined in the light of the provisions of the Act and Rules thereunder and it had been decided that:

- i. For those in-vivo radiopharmaceutical products, which do not have indigenous manufacturing facility, Form -10 license may be granted after approval of the Central Government, without Registration Certificate under Rule 24 (2) second proviso.
- ii. Those in-vivo radiopharmaceuticals for which indigenous manufacturing facilities are available, import registration and license in Form 10 will have to be obtained as per provisions of the Drugs and Cosmetics Rules, 1945 and such products shall be tested for their quality at the time of import.

AND WHEREAS it has subsequently been informed by the importers that Radiation Medicine Centre of BARC or Institute of Nuclear Medicines & Allied Sciences (INMAS), Delhi have not accepted the samples for testing and also stated that necessary permission may also be required from AERB for transporting such samples to the testing centres;


AND WHEREAS various representations have been received from importers stating that they have stopped import of Technetium 99 Generators as they are not able to comply with the condition relating to testing stated in the Notice No. DCG(I)/Misc/2017(21) dated 20.02.2017;

AND WHEREAS representations have also been received from different Associations of Physicians stating that various directions issued by CDSCO should not result in disruption of routine functioning of Nuclear Medicine Centers and also suggested to have dialogue with Radioactive import vendors and Nuclear Medicine physicians to find a lasting solution to this problem;

NOW, THEREFORE, after careful examination of the matter and to facilitate an un-interrupted supply of Technetium 99 Generators and noting that these generators have continued to be imported for quite some time, it has been decided:

- i. to permit import of Technetium 99 Generators by importers, whose applications are under active consideration of this Directorate for grant of registration Certificate for a further period of 45 days from the date of issue of this order as these products are to be used in the diagnosis of cancer and cardiovascular diseases and their inadequate availability could hamper public health.
- ii. that the importer shall voluntarily make a sample of Technetium 99 Generator available for test and analysis by Radiation Medicine Centre of BARC or Institute of Nuclear Medicines & Allied Sciences (INMAS) from out of the samples imported within 10 working days of this order in respect of each manufacturer.
- iii. that necessary permission may be sought by importers from AERB to transport the sample of Technetium 99 Generators to testing centre.
- iv. that in cases, where the samples fail in test/analysis, no imports from the manufacturer shall be permitted and stocks already imported or in transit shall be disposed of or re-exported in the prescribed manner.
- v. in other cases, import shall be permitted pending completion of all formalities for registration for a period not exceeding 45 days from the date of this order subject to the condition that the sample manufactured by the manufacturer concerned has been submitted within the stipulated timeframe for testing.

- vi. In case of non-submission of sample for testing/manufacturing within 10 working days by the importer in respect of the product or a manufacturer, no import shall be allowed.
- vii. No import shall be allowed after 45 days from the date of this order without valid registration.


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

To,

1. All concerned importers
2. All port offices of CDSCO

CC:

1. The Director, Radiation Medicine Centre of BARC, Mumbai
2. The Director, Institute of Nuclear Medicines & Allied Sciences (INMAS), Delhi
3. PPS to DG(DGHS), Nirman Bhavan, New Delhi
4. PPS to JS(KLS), Nirman Bhavan, New Delhi