**DCG (I)/Misc/2017 (21)**
**Directorate General of Health Services**
**Ministry of Health & Family Welfare**
**O/o Drugs Controller General (I)**

**FDA Bhawan, New Delhi**
**Dated:**

**Notice** 20 FEB 2017

**Sub: Import of Radiopharmaceutical Products/ Radio-Immuno Assay for (in vivo or in vitro) diagnostic use.**

In continuation to this office earlier notice dated 3.01.2017, certain issues relating to import of radio-pharmaceutical products / radio-Immuno Assay Kits for (in-vivo or in-vitro) diagnostic use has been examined and with the approval of Ministry of Health & Family Welfare, it has been decided that:

1) For those in-vivo radio-pharmaceutical Products, which do not have the indigenous manufacturer, the Form-I0 license may be granted, after approval of Central Government, without Registration Certificate under Rule 24 (2) second proviso, quoting it as an emergency due to use of these products on routine basis.

2) For those in-vivo radio-pharmaceuticals, for which there are indigenous manufacturer, it may not qualify as an emergency, for import of such products import registration and License in Form 10 are required to be obtained as per the provisions of Drugs & Cosmetics Rules. However, such products shall be tested for their quality at the time of import.

   As per information obtained, presently, only Technetium -99 is being manufactured locally. Therefore, the quality of Molybdenum & Vaccumtizer, which are imported for making Technetium -99 by end users by following a small process, it would be appropriate to test first five consignments & then decide about subsequent testing of these products (either all or on infrequent i.e reduced testing basis), based on the results.

   Testing of this can be under taken at:

   A) Radiation Medicine Centre of BARC at Tata Memorial Centre Annex, E-Borges Marg, Parel-Mumbai-400012 India Tele/Fax-022-24157098 (for those products which are imported through Mumbai port for Technetium-99).

   B) Institute of Nuclear Medicine & Allied Sciences ( INMAS), Lucknow Road, Timarpur, Delhi-llQ054 DRDO Email-director@inmas.drdo.in (for the products (Technetium-99) which are imported through Delhi port.

Contd.....

Further, the applicants for import of materials i.e. Molybdenum & Vaccumtizer for manufacturing of Technetium-99 shall be required to fulfill all the requirements for obtaining Registration & Form-I0 within 30 to 40 days. In case they do not fulfill the requirements, their applications shall be returned as incomplete & further import (even if the product passes testing of first five consecutive batches as mentioned above) shall not be allowed.

**(Dr. G. N. Singh)**
**Drugs Controller General (I)**

To:

All the Concerned Stakeholders

Copy to:

(1) All Port Offices of CDSCO

Copy for information to:

(1) PPS to DGHS

(2) PPS to Addl. Secretary (H)

(3) JS (R)