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

FDA Bhawan, Kotla Road
ITO (Near Bal Bhawan)

Date: 28/04/2017

ORDER

In the light of requirements of Technitium 99 generator and other Radiopharmaceuticals by institution and patients, it is hereby directed that those institutions (hospitals etc) and patients apply offline or online to respective CDSCO, Zonal/ port offices in Form 12AA and/or Form 12A shall be issued the import licence in Form 11A and/or Form 12B within two hours of receipt of application.

Specific officer shall be designated to facilitate the process from the receipt to issue level in the respective office.

The action taken in this regard may be intimated to this office.

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

To,

All zonal/port offices of CDCSO

All stakeholders related to Radiopharmaceuticals

Website of CDSCO

[1][FORM 11A

(*See* rule 33A)

Licence to import drugs by a Government Hospital or Autonomous Medical Institution for the treatment of patients

Licence No ..... Date.....

Dr. .....Designation .....of .....

(Name of College/Hospital/Autonomous Institution)

is hereby licenced to import from M/s .....(name and full address) the drugs specified below for the purpose of treatment of patients for the disease (name of the disease) ..... at ..... or in such other places as the licensing authority may from time to time authorise.

2. This licence shall, unless previously suspended or revoked, be in force for a period of one year from the date of issue specified above.

3. Names of drugs to be imported:

Name of drugs	*Quantities which may be imported*

Place .....

Date .....

Licensing Authority
Seal / Stamp

Conditions of Licence

1. The licence shall be displayed in the Office of the Medical Superintendent of Government Hospital / Head of Institution of Autonomous Medical Institution.

2. The licensee shall store the drugs imported under this licence under proper storage conditions.

3. The drugs imported under this licence shall be exclusively used for the treatment of patients, and a record shall be maintained in this regard, by a registered pharmacist giving the full name(s) and address(es) of the patients, diagnosis, dosage schedule, total quantity of drugs imported and issued, and shall be countersigned by the Medical Superintendent of the Government Hospital or Head of the Autonomous Medical Institution which shall be produced, on demand by an Inspector appointed under the Act.]

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1. Subs. by G.S.R. 604(E), dt. 24.8.2001.

[1][FORM 12A

(*See* rule 36, Second Proviso)

Application for the issue of a permit to import small quantities of drugs for personal use

I, ...resident of .....by occupation..... hereby apply for a permit to import the drugs specified below for personal use from .....

I attach a prescription from a registered medical practitioner in regard to the need for the said drugs.

Name of drugs	*Quantities which may be imported*

Date..... *Signature*.....

[1][FORM 12B

(*See* rule 36, Second Proviso)

Permit for the import of small quantities of drugs for personal use

.....of ..... is hereby permitted to import from..... the drugs specified below for personal use.

2. This permit is subject to the conditions prescribed in the Rules under the Drugs and Cosmetics Act, 1940.

3. This permit shall, unless previously suspended or revoked, be in force for a period of six months from date specified below.

Name of drugs	Quantities which may be imported

Date..... *Licensing Authority]*

[1][FORM 12AA

(*See* rule 34A)

Application for licence to import small quantities of new drugs by a Government Hospital or Autonomous Medical Institution for the treatment of patients.

I ..... (name and designation) ..... of ..... (name of the Hospital/Autonomous Medical Institution) hereby apply for a licence to import small quantities of new drugs specified below for the purpose of treatment of patients for the disease ..... (name of the disease)..... ... . at.....(name and place of the hospital) and I undertake to comply with the conditions applicable to the licence and other provisions of the Drugs and Cosmetics Act, 1940 and the rules made thereunder, from time to time.

1. A fee of rupees ..... has been credited to Government under the Head of Account "0210-Medical and Public Health, 04- Medical and Public Health, 104- Fees and Fines" under the Drugs and Cosmetics Rules, 1945 - Central vide Challan No.....dated ..... (attached in original).

2. Name of new drugs to be imported:

Name of drugs	Quantities which may be imported

Place: .....

Date: .....

Signature.....

Name.....

Seal/Stamp.....

Certificate

Certified that the drugs specified above for import are urgently required for the treatment of patients suffering from and that the said drug(s) is/are not available in India.

Place.....

Date .....

Signature ....

Medical Superintendent of the Government Hospital / Head of Autonomous Medical Institution

Seal / Stamp.]