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Import/Misc./09/Import of Norgestimate-2013 DC
DIRECTORATE GENERAL OF HEALTH SERVICES
CENTRAL DRUGS STANDARD CONTROL ORGANISATION
OFFICE OF DRUGS CONTROLLER GENERAL OF (INDIA)

FDA Bhawan, Kotla Road,
ITO, (near Balbhavan), New Delhi

Dated: 13 FEB 2014

Office Memorandum

Subject: Special conditions under which the permission for import of drug with residual shelf life less than 60% is allowed – reg.

As per Rule-31 of Drugs & Cosmetics Rules, 1945 Standard for Imported drugs is laid down which states that "No drug shall be imported unless it complies with the standard of strength, quality and purity, if any", provided that the licensing authority shall not allow the import of any drug having less than sixty per cent residual shelf-life period as on the date of import. However, in exceptional cases the licensing authority may, for reasons to be recorded in writing, may allow, the import of any drug having lesser shelf-life period, but before the date of expiry as declared on the container of the drug. The issue of import of such drugs by the importers in our country holding valid Import License has been examined by the office of DCGI in consultation with the Ministry of Health and Family Welfare.

The special conditions/ circumstances under which the permission for import of drug with residual shelf life less than 60% may be considered are as follows:

1. For charity purpose (it should be ensured that the drug is used within the shelf life).
2. The drugs which are required under the National Health Programs/ schemes or for use in emergency situations where there is no substitute available.
3. The drugs required for treatment of diseases which are specific to be of Indian origin.
4. The drugs which are imported only for the testing/ analysis purposes.
5. Orphan drugs for rare diseases.
6. Drugs required for control of sudden outbreak of diseases.
7. Import of unapproved/approved new drug/banned bulk drugs for manufacturing of formulation exclusively for export.

It is required for importers who would import such drugs shall give proper justification for the import. The application for import of the drug with residual shelf life of less than 60% should be made to the DCG(I) for necessary No Objection Certificate.

The above procedure is being issued with the approval of the Ministry of Health and family Welfare.

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

Copy to: All Zonal/sub-Zonal/Port Offices of CDSCO