

Annexure-1

About import and registration:

Registration & licensing system in India

- ❖ The import of Drugs into India is regulated under Chapter III of Drugs & Cosmetics Act 1940 & Part IV of Drugs & Cosmetics Rules 1945.
- ❖ The applications for registration certificate & import license of drugs are processed as per the requirements of Rule 24 (A) & 24 of Drugs & Cosmetics Rules 1945.

For this purpose drug|| includes—

- All medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes.
- Such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of [vermin] or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette.
- All substances intended for use as components of a drug including empty gelatin capsules.

In India import, manufacturing, sale and distribution of drug is regulated under Drugs and Cosmetics Act 1940 and Rules 1945. At present, bulk drug (Active Pharmaceutical Ingredients) and finished formulations are regulated under the said Act. Any substance falling within the definition of drug (Section 3b of the Act) required to be registered before import into the country. Not only drug but the manufacturing site needs to be registered for import. The application for Registration Certificate and import License can be made to the Licensing Authority under the Act i.e. to the Drugs Controller General (I) at CDSCO, FDA Bhawan, Kotla Road, Near Bal Bhawan, New Delhi by the Local Authorized Agent of the foreign manufacturer having either manufacturing or sale License or by the foreign manufacturers having a whole sale License in the country through online application system “SUGAM”.

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