**IMP/141/2024-eoffice**
**Government of India**
**Directorate General of Health Services**
**Central Drugs Standard Control Organization**
**(Import and Registration Division)**

**CIRCULAR**

**Date:**

0 8 APR 2025

**Subject: - Transfer of Drugs (API/Formulations) from Special Economic Zone (SEZ) to Domestic Tariff Area (DTA)-Reg.**

For import of drug into India, Import registration and license are required to be obtained from CDSCO as per Drugs and Cosmetics Act and Rules made there under.

As per Schedule-D clause (6) of the Drugs Rules 1945, SEZ units are exempted from provisions of Chapter III of the Act and rules made there under for import of drugs for manufacture and export subject to the condition that these drugs shall not be diverted for sale in the country.

However as per provisio, such imported drugs may be permitted for sale and distribution to the domestic area, if they meet the requirements of standard procedure for import and registration as required under Chapter III of the Act and Rules thereunder.

In order to streamline the procedure for transfer ofdrugs manufactured in Special Economic Zone t o Domestic Tariff Area for sale and distribution, the matter was examined and it has been decided that the following procedure should be followed for the transfer to DTA to ensure that the drugs meet quality, safety and efficacy requirements as per the Act and rules there under.

1. The Banned drugs manufactured at Special Economic Zone for export purpose are not allowed for transfer to Domestic Tariff Area for any purpose.
2. In case of unapproved and approved new drugs manufactured in SEZ, the requirements specified for manufacturing of new drugs under NDCT Rules 2019 and Drug Rules 1945 are required to be complied with.
3. In case the drugs manufactured in SEZ do not fall under the category (i) & (ii) above, requirements specified for manufacturing of drugs under the Drugs Rules 1945 are required to be complied with.
4. In case, an API is imported to SEZ for manufacturing of its formulation and the formulation is proposed to be diverted to DTA for sale and distribution, Registration Certificate & Import License are required for that API.
5. The API/semi-finished/ finished dosage forms in bulk packs imported without Registration Certificate and Import License shall not be permitted for sale and

distribution to the DTA.

In this regard, all the port officers are directed to review the documents provided in ICEGATE portal for clearance of bill of entry pertaining to drugs manufactured in SEZ for sale in India by following the above mentioned procedures. Additionally, data on these bill of entry should be maintained and the details of such bills of entry should be intimated to the O/o DCGI as and when required.

**This is for information and compliance.**

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

**To:**

All Port, Zonal and Sub-Zonal offices of CDSCO.

**Copy to:** All stakeholders through CDSCO website.

**Copy for information to:** Under Secretary (Drugs), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.