

**GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

LOK SABHA
UNSTARRED QUESTION No. 3342
TO BE ANSWERED ON THE 17th December, 2021

Verification of Imported Raw Pharma Materials

3342. SHRI GNANATHIRAVIAM S.:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

- (a) whether import of cheap pharmaceutical raw materials and vaccines from some countries is allowed without physically verifying the compliance of its regulatory requirements or the equivalent international standard;
- (b) if so, the details thereof and the reasons therefor; and
- (c) whether there is a need of regulatory norms to be complied for import of pharmaceutical raw materials and vaccines and if so, the details thereof and the steps taken by the Government to ensure transparency in the system?

ANSWER

MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS

(Dr. MANSUKH MANDAVIYA)

(a), (b) & (c): Import of Drugs including vaccines is regulated under Chapter III of Drugs & Cosmetics Act 1940 & Rules thereunder. For import and marketing of any drug including vaccine the overseas manufacturing site and drug/ vaccine are required to be registered and import licence is required to be obtained from CDSCO under the rules.

In case of New Drugs including Vaccines, import permission is also required from CDSCO under the New Drugs and Clinical Trials Rules, 2019.

The imported consignments are cleared through notified port offices. There is a provision under Rule 40 of the Drug Rules 1945 that If the Customs Collector has reason to doubt whether any drugs comply with the provisions of Chapter III of the Act and Rules thereunder he may, and if requested by an officer appointed for this purpose by the Central Government shall, take samples of any drugs in the consignment and forward them to the Director of the laboratory appointed for this purpose by the Central Government and may detain the drugs in the consignment of which samples have been taken until the report of the Director of the said laboratory or any other officer empowered by him on this behalf, subject to the approval of the Central Government, on such samples is received.

All the imported drugs including vaccines are required to comply with standards mentioned under Second Schedule of the Drugs & Cosmetics Act 1940.

Further sampling for drugs is carried out based on defined risk based criteria whereas 100% sampling is carried out for vaccines for imported consignments, at Port offices.

Application related to import of Drugs including Vaccines are cleared by port officers as and when referred through Indian Customs and Central Excise Electronic Commerce/Electronic Data Interchange Gateway (ICEGATE) system maintained by Customs.

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