

**GOVERNMENT OF INDIA  
MINISTRY OF HEALTH AND FAMILY WELFARE  
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**LOK SABHA  
UNSTARRED QUESTION NO. 3494  
TO BE ANSWERED ON 21<sup>ST</sup> MARCH, 2025**

**ILLEGAL EXPORT OF UNLICENSED OPIOIDS AND REGULATORY  
OVERSIGHT**

**3494. SHRI AZAD KIRTI JHA:**

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) whether the Government is aware of reports alleging that Indian Pharmaceutical Companies, including Aveo Pharmaceuticals, have been illegally manufacturing and exporting unlicensed opioid-based drugs to West African countries, contributing to a major public health crisis and if so, the details thereof;
- (b) the steps taken/proposed to be taken by the Government to investigate these allegations and hold the responsible entities accountable;
- (c) whether the loopholes in the existing regulations on pharmaceutical exports have enabled the continued export of such unlicensed and harmful drugs, if so, the details thereof;
- (d) the measures taken/proposed to be taken by the Central Drugs Standard Control Organisation (CDSCO) to ensure stricter enforcement and monitoring of pharmaceutical exports, particularly in the case of opioid-based medications; and
- (e) whether the Government has conducted any inspections or audits of pharmaceutical manufacturers engaged in the export of opioid-based drugs and if so, the details thereof?

**ANSWER  
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND  
FAMILY WELFARE  
(SMT. ANUPRIYA PATEL)**

(a) to (e): In order to assess the regulatory compliance of drug manufacturing premises in the country, the Central Drugs Standard Control Organization (CDSCO), in collaboration with state regulators, initiated risk-based inspections of drug manufacturing and testing firms in December 2022. As of now, 905 units have been inspected, resulting in 694 actions being taken. These actions include Stop Production Orders (SPO), Stop Testing Orders (STO), license suspensions/cancellations, warning letters, and showcause notices, depending on the severity of non-compliance.

Based on a media report relating to M/s Aveo Pharmaceuticals, a joint team from CDSCO and the State drugs regulatory authority conducted a comprehensive audit of the firm between 21st and 22nd February 2025. The findings from the audit led to the issuance of a stop activity order, halting all operations at the company's premises.

With regard to export of opioid drugs, CDSCO has a system of issuing export NoC for new drugs and drugs not approved in India based on submission of customer details, quantity and country specific purchase order alongwith regulatory approval of the product in importing country.

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