Union Health Ministry takes immediate action in response to concerns on export of unapproved drug combination of Tapentadol and Carisoprodol

Joint team of CDSCO and Maharashtra State Regulatory Authority conducts thorough audit of the drug manufacturing site

Stop Activity Order and Stop Production Order issued for the concerned drug combinations

CDSCO moves for immediate withdrawal of Export NOCs and Manufacturing Licenses for Tapentadol-Carisoprodol combinations

Posted On: 23 FEB 2025 8:23PM by PIB Delhi

The Ministry of Health and Family Welfare has taken immediate and decisive action following some news reports highlighting concerns regarding the export of unapproved combination drugs containing Tapentadol and Carisoprodol by Indian Pharmaceutical Manufacturer M/s Aveo Pharmaceuticals, Mumbai to certain countries in West Africa.

To ensure regulatory compliance across the pharmaceutical sector, 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 showcase notices, depending on the severity of non-compliance. This initiative has provided valuable insights into the ground reality of manufacturing practices and has led to relevant corrective actions, resulting in noticeable improvements in the regulatory framework.

During end Jan'25, CDSCO in collaboration with State Regulators had done focused audit of firms manufacturing and exporting NDPS drugs. Based on analysis of observations from the audit, important decisions were taken to strengthen regulatory oversight on export of NDPS drugs from India.

Regarding the specific issue at hand, both Tapentadol and Carisoprodol are individually approved by CDSCO in India. Tapentadol is approved in 50, 75, and 100 mg tablet forms, as well as 100, 150, and 200 mg extended-release tablets. However, the combination of Tapentadol and Carisoprodol is not approved in India. Neither of these drugs is included in the NDPS (Narcotic Drugs and Psychotropic Substances) list in India.

Actions taken by the Union Health Ministry:

1. **Audit and Inspection**: A joint team from the CDSCO and the State Regulatory Authority conducted a comprehensive audit of M/s. Aveo Pharmaceuticals 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.
2. **Seizure of Materials**: Following the audit, the investigation team seized all raw materials, in-process materials, and finished products. Approximately 1.3 crore tablets/capsules and 26 batches of APIs (Active Pharmaceutical Ingredients) of Tapentadol and Carisoprodol were detained to prevent further distribution of these potentially dangerous drugs.
3. **Stop Production Order**: The Maharashtra FDA issued a Stop Production Order to M/s. Aveo Pharmaceuticals on 22nd February 2025, effectively halting the manufacturing of the concerned drug combinations.
4. **Withdrawal of Export NOCs**: Communications have been sent to all State Drugs Control Authorities and Zonal Offices to immediately withdraw Export NOCs and Manufacturing Licenses granted for any combination of Tapentadol and Carisoprodol. The same communication has also been sent to all Customs offices at notified ports to route all consignments of referred products through CDSCO Port offices.
5. **Seizure of Export Consignment**: An export consignment of Tapentadol 125 mg + Carisoprodol 100 mg, destined for Ghana, has been put on hold at Mumbai Air Cargo pending further investigation.
6. **Updating Export NOC Checklist**: Going forward, CDSCO is updating the Export NOC checklist, to ensure that either the Product Registration Certificate from the importing country's National Regulatory Agency (NRA) or approval from the Indian Regulatory Authority (CDSCO) is required for all medicines being exported from India.

This updation of the checklist will address the root cause of the problem and settle the issue once for all. The Union Government will ensure smooth export operation for legitimate medicines to be used to support healthcare globally and strongly control these aberrations through swift and strong action as demonstrated through recent decisions and actions.

The Ministry of Health and Family Welfare, along with the CDSCO, remains committed to ensuring the safety and well-being of citizens in India and abroad. The steps taken in response to this issue reflect the Government’s zero-tolerance policy towards illegal or unethical export of unapproved and potentially harmful drugs.

India as a leading global supplier of pharmaceuticals, is dedicated to maintaining the highest standards of drug safety and regulatory compliance. The Union Health Ministry assures the public and global community that the Government will continue to monitor and regulate pharmaceutical exports to safeguard against any misuse of Indian-made medicines.

****

MV

HFW/Actions taken amid West Africa Opiod Crisis/23Feb2025/1

(Release ID: 2105672)