7-5/2025-MISC-002

Government of India

Directorate General of Health Services Central Drugs Standard Control Organization (International Cell)

FDA Bhawan New Delhi Date: 21.02.2025

To

All State/UT Drugs Control Authorities

Subject: Immediate withdrawl of the permission to manufacture all combinations of Tapentadol and all combinations of Caresoprodol- regarding

Sir/Madam,

This is in connection with a recent article from BBC whereby, it has been written that the combination drug Tapentadol and Carisoprodol has significant abuse potential and this combination is being exported to West African Countries form India.

Looking in to the potential of drug abuse and its harmful impact on population, it is requested to immediately withdraw all Export NOCs and permission to manufacture issued for combination of Tapentadol and Carisoprodol.

It is also requested to withdraw all Export NOCs and permission to manufacture issued for all the combinations of Tapentadol and all combinations of Caresoprodol which are not approved by importing country.

This is for implementation with immediate effect.

Thank you

Dr. Rajeev Singh Raghuvanshi Drugs Controller General (I)

Copy to:

- All Zonal and Sub Zonal offices of CDSCO
- 2. All port offices of CDSCO
- Customs offices at all the notified ports under Drugs Rules with a request to route all shipments of above products through the office of ADC(I), Concerned port.