

F. No. 12-01/18-DC (Pt-337)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi
(New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi,
Date: 04 JUL 2022

To

All State/UT Drugs Controllers,

Sub: Prescribing Information Leaflet change for "Olanzapine" marketed in the country- Reg.

Sir,

The National Co-ordination Centre for Pharmacovigilance Programme of India (NCC-PvPI), functioning at IPC, Ghaziabad has forwarded their recommendation based on ADR reports on Olanzapine which was discussed by them in the 20th Signal Review Panel (SRP) under the programme meeting held on 11.03.2022 with an objective to detect Signal/Prescribing Information Leaflet change from Indian database and promote patient safety.

In the meeting, PvPI has evaluated the reported ADRs for Olanzapine on the basis of Individual Case Study Reports (ICSRs) and recommended CDSCO to take necessary steps to incorporate **Hyponatraemia** as an adverse effect in the Prescribing Information Leaflet (PIL) of Olanzapine marketed in the country.

Subsequently, PvPI recommendations was deliberated in the Subject Expert Committee (SEC-Neurology & Psychiatry) meeting held on 21.06.2022 at CDSCO (HQ), New Delhi.

After detailed deliberation, the committee recommended that CDSCO should request the State Drugs Controllers to direct the manufacturers of the drug to include **Hyponatraemia** as an adverse effect in the package insert of the drug as suggested by PvPI.

The recommendation of the SEC has been considered by this office.

Accordingly, you are requested to direct the manufacturers of Olanzapine under your jurisdiction to incorporate **Hyponatraemia** as an adverse effect in the package insert/promotional literature of the drug.

Action taken in this regard may be intimated to this office.

Yours faithfully,



Dr. V.G. Somani
Drugs Controller General (India)

1. Copy for information & follow-up:

All Zonal / Sub Zonal offices of CDSCO.

2. Copy for information:

JS(R), Nirman Bhawan, MoHFW, New Delhi-110002.