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

FDA Bhawan, Kotla Road,
New Delhi.
Dated: 09 NOV 2021

To,

All State/UT Drugs Controllers,

Sub: Incorporation of Lamotrigine associated TEN/SJS in the Prescribing Information Leaflet - Reg.

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Sir/Madam,

Lamotrigine are approved by CDSCO and marketed in the country in various dosage forms.

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 certain medicinal products including **Lamotrigine** which were discussed by them in the 7th Signal Review Panel (SRP) under the programme with an objective to detect Signal/Prescribing Information Leaflet change from Indian database and promote patient safety.

In the meeting, the PvPI has evaluated the **Lamotrigine associated toxic Epidermal Necrolysis (TEN) & Stevens-Johnson Syndrome (SJS)** -ADR on the basis of Individual Case Study Reports (ICSR) and recommended CDSCO to take necessary steps to incorporate Lamotrigine associated toxic Epidermal Necrolysis(TEN) & Stevens-Johnson Syndrome(SJS) as an adverse drug reaction in to the prescribing information leaflet (PIL) of the drug lamotrigine formulations marketed in the country.

Subsequently, the PvPI recommendations was deliberated in the Subject Expert Committee (SEC-Neurology & Psychiatry) meeting held on 14.10.2021 at CDSCO HQR, New Delhi. After detailed deliberation the committee

recommended that CDSCO may request the State Drugs Controllers to direct the manufacturers of the drug to incorporate lamotrigine induced TEN/SJS in the PIL of the drug.

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

Accordingly, you are requested to direct the manufacturers of Lamotrigine formulations under your jurisdiction to mention **Epidermal Necrolysis (TEN) & Stevens-Johnson Syndrome (SJS)** as an adverse drug reaction 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 to: -
   JS(R), Nirman Bhawan, MoHFW, New Delhi-110002.