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

FDA Bhawan, Kotla Road,
New Delhi.
Dated: 13 JAN 2020

To,

All State/UT Drugs Controllers,

Sir,

Sub: Lamivudine associated Hearing Loss - Reg.

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Lamivudine is 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 lamivudine which were discussed by them in the 12th Signal Review Panel (SRP) under the programme meeting held on 27th March, 2018 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 PPIs-ADR on the basis of Individual Case Study Reports (ICSR) and recommended CDSCO to take necessary steps to incorporate **Hearing loss** as an adverse drug reaction in to the Prescribing information leaflet (PIL) of the Lamivudine marketed in the country.

Subsequently, the PvPI recommendations was deliberated in the Subject Expert Committee (SEC-Antimicrobial & Antiviral) meeting held on 30.10.2019 at CDSCO HQR, New Delhi. After detailed deliberation, the Committee has recommended that **hearing loss** should be incorporated in the package insert of the drug Lamivudine as suggested by PvPI.

The recommendation of the SEC has been considered by this office. Accordingly, you are requested to direct the manufacturers of Lamivudine formulations under your jurisdiction to mention **hearing loss** 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.

3. Copy to: -
   PvPI, Indian Pharmacopeia Commission, Ghaziabad.