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: 09.04.19

To,

All State/UT Drugs Controllers,

Sir,

Sub: Cefixime – Acute generalized Exanthematous Pustulosis (AGEP) Adverse Reaction - Reg.

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Cefixime 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 Cefixime which were discussed by them in the 13th Signal Review Panel (SRP) under the programme meeting held on 21st August, 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 drug Cefixime-ADR on the basis of Individual Case Study Reports (ICSR) and recommended CDSCO to take necessary steps to **incorporate acute generalized exanthematous pustulosis (AGEP) as an adverse drug reaction** in to the Prescribing information leaflet (PIL) of the drug Cefixime marketed in the country.

Subsequently, the PvPI recommendations was deliberated in the Subject Expert Committee (SEC-Antimicrobial & Antiviral) meeting held on 16.01.2019 at CDSCO HQR, New Delhi. After detailed deliberation the Committee has

recommended that acute generalized exanthematous pustulosis should be incorporated in the package insert of the drug Cefixime as suggested by PvPI.

The recommendation of the SEC has been considered by this office. Accordingly, you are requested to direct the manufacturers of Cefixime formulations under your jurisdiction to mention acute generalized exanthematous pustulosis 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. S. Eswara Reddy
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.