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: 20 SEP 2022

To,

All State/UT Drugs Controllers,

Sub: Incorporation of Piperacillin + Tazobactuam associated acute generalized exanthematous pustulosis (AGEP) in the prescribing Information Leaflet - reg.

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Sir/Madam,

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 **Piperacillin + Tazobactuam** which were 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, the PvPI has evaluated the **Piperacillin + Tazobactuam -ADR** on the basis of Individual Case Study Reports (ICSR) and recommended CDSCO to take necessary steps to incorporate **Piperacillin + Tazobactuam associated acute generalized exanthematous pustulosis (AGEP)** as an adverse drug reaction in to the prescribing information leaflet (PIL) of the drug **Piperacillin + Tazobactuam** formulations marketed in the country.

Subsequently, the PvPI recommendations was deliberated in the Subject Expert Committee (SEC-Antimicrobial & Antiviral) meeting held on 26.08.2022 at CDSCO (HQ), New Delhi. After detailed deliberation, the committee recommended that CDSCO should request the State Drugs Controllers to direct the manufacturers to

include **Piperacillin + Tazobactuam associated acute generalized exanthematous pustulosis (AGEP)** as ADR in the corresponding PIL of the drugs.

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

Accordingly, you are requested to direct the manufacturers of **Piperacillin + Tazobactuam** formulations under your jurisdiction to mention **acute generalized exanthematous pustulosis (AGEP)** 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.