File No. 4-01/2015-DC (Misc. 82)
Directorate General of Health Services
Office of Drugs Controller General (India)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated: 23 DEC 2015

To,

All State/UT Drugs Controllers

Subject: Potential Signal & Recommendation for the label change of certain medicinal product marketed in India -Regarding.

Sir,

Pharmacovigilance Programme of India (PvPI) informed this office that in view of the strong causal relationship and published literature, the Signal Review Panel (SRP) members recommended to insert the following adverse reactions to the corresponding package insert of following medicinal product:-

Sr No.	Name of Product	Adverse Reactions
1.	FDC of Piperacillin and Tazobactam	Hypokalaemia, Bronchospasm

The proposal for Potential Signal & Recommendation for the label change of certain medicinal product marketed in India was discussed by the SEC (Antimicrobial, Antiparasitic& Antifungal, Antiviral) committee in its meeting held on 26.10.2015. The committee recommended that all the manufacturers of above said FDC product should be instructed to include these two adverse reactions i.e. Hypokalaemia and Bronchospasm in their package insert as well as any other promotional litrature.

The recommendations of the SEC were considered by this Directorate and accordingly, you are requested to instruct all the manufacturers of the above said FDC product to include these two adverse reaction i.e. Hypokalaemia and Bronchospasm in their package insert as well as any other promotional literature for the said FDC. Action taken in this regard may be intimated to this office.

Yours faithfully,

(Dr. G. N. Singh)
Drugs Controller General (India)

Copy to:-

1. All Zonal/Sub Zonal Offices of CDSCO.
2. Drug Manufacturing Associations: IDMA/OPPI/IPA/CIPI/FOPE etc.