

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: 4/11/2019

To,

All State/UT Drugs Controllers,

Sir,

Sub: Proton Pump Inhibitors associated Acute Kidney Injury - Reg.

Various formulations of Proton Pump Inhibitors like Pantoprazole, Omeprazole, lansoperazole, Esomeprazole, Rabeprazole etc are marketed in the country.

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 Proton Pump Inhibitors which were discussed by them in the 15th Signal Review Panel (SRP) meeting held on 21st August, 2019 at Indian Pharmacopoeia Commission, National Coordination Centre-Pharmacovigilance Programme of India (PvPI) with an objective to detect Signal/Prescribing Information Leaflet change from Indian data and promote patient safety.

In the meeting, the SRP has evaluated the drug Proton Pump Inhibitors -ADR on the basis of Individual Case Study Reports (ICSR) and recommended to PvPI that CDSCO be informed to take necessary steps to incorporate Acute Kidney Injury as an Adverse Drug Reaction into the PIL of the Proton Pump Inhibitors marketed in India.

Subsequently, the SRP-PvPI recommendations were deliberated in the Subject Expert Committee (SEC-Antimicrobial & Antiviral) meeting held on 10.10.2019

at CDSCO, New Delhi. After detailed deliberation the committee recommended that CDSCO should request the State Drugs Controllers to direct the manufacturers of Proton Pump Inhibitors to incorporate Acute Kidney Injury as an Adverse Drug Reaction in the package insert leaflet of the drugs.

The recommendation of the SEC has been considered by this office. Accordingly, you are requested to direct the manufacturers of formulations of Proton Pump Inhibitors under your jurisdiction to mention Acute Kidney Injury as an adverse drug reaction in the Package insert/Promotional Literature of the said drugs.

Action taken in this regard may be intimated to this office.

Yours faithfully,

V.G.S.

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.