**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: 04 FEB 2022

To,

All State/UT Drugs Controllers,

Sir,

**Sub: Incorporation of drug associated ADRs in Prescribing Information Leaflet of some medicinal products marketed in India- Reg.**

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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 with an objective to detect Signal/Prescribing Information Leaflet change from Indian database and promote patient safety.

The PvPI has evaluated the reported ADRs of 11 drugs namely Ranitidine IV, Ceftriaxone, Azithromycin, Cloxacillin, Itraconazole, Ibuprofen Amoxicillin/Clavulanate, Ciprofloxacin, DPP4 Inhibitor, Doxycycline and Tinidazole on the basis of Individual Case Study Reports (ICSRs) and recommended CDSCO to take necessary steps to incorporate the reported adverse drug reaction in to the Prescribing information leaflet (PIL) of the drugs marketed in the country.

Subsequently, the PvPI recommendations was deliberated in the respective Subject Expert Committee meeting held at CDSCO HQR, New Delhi. After detailed deliberation, the Committee has recommended that above drug associated ADRs should be incorporated in the package insert of the drugs as suggested by PvPI.

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

Accordingly, you are requested to direct the manufacturers of the following below drug formulations under your jurisdiction to mention the respective drug associated adverse drug reaction in the Package insert/Promotional Literature of the marketed drug in the country as follows: -

1. **Ranitidine IV medicinal product induced Cardiac arrest**
2. **Ceftriaxone Induced Stevenson Johnson Syndrome (SLS)**
3. **Azithromycin induced Acute generalized Exanthematosus Pustulosis (AGEP)**
4. **Cloxacillin induced Acute generalized Exanthematosus Pustulosis (AGEP)**
5. **Itraconazole induced Photosensitivity**
6. **Ibuprofen induced Stevenson Johnson Syndrome (SJS)/ Toxic Epidermal Necrosis (TEN)**
7. **Amoxicillin/Clavulanate induced Stevenson Johnson Syndrome SJS/Toxic Epidermal Necrosis (TEN)**
8. **Ciprofloxacin induced Stevenson Johnson Syndrome SJS/Toxic Epidermal Necrosis (TEN)**
9. **Dipeptidyl Peptidase-4 (DPP4) Inhibitors like Sitagliptin, Vildagliptin, Saxagliptin etc. induced Arthralgia**
10. **Doxycycline associated Fixed Drug Eruption (FDE):**
11. **Tinidazole associated Fixed Drug Eruption (FDE)**

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.