

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: 06 FEB 2023

To,

All State/UT Drugs Controllers,

**Sub: Incorporation of Paracetamol associated Fixed Drug Eruption (FDE)
in the prescribing information leaflet- Reg.**

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 **Paracetamol** which were discussed by them in the 22nd Signal Review Panel (SRP) under the programme meeting held on 22.11.2022 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 reported ADRs for **Paracetamol** on the basis of Individual Case Study Reports (ICSR) and recommended CDSCO to take necessary steps to incorporate **Fixed Drug Eruption** as an adverse drug reaction in to the Prescribing information leaflet (PIL) of the **Paracetamol** marketed in the country.

Subsequently, the PvPI recommendations was deliberated in the Subject Expert Committee (Analgesic & Rheumatology) meeting held on 12.01.2023 at CDSCO (HQ), New Delhi. After detailed deliberation, the committee recommended that CDSCO should request the State Drugs Controllers to instruct the manufacturers of the drug to incorporate **Paracetamol** associated **Fixed Drug Eruption (FDE)** in the PIL of the drug marketed in the country.

The recommendation of the SEC has been considered by this office. Accordingly, you are requested to direct the manufacturers of **Paracetamol** formulations under your jurisdiction to mention **Fixed Drug Eruption** 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.