

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-110002.

Dated:

To,

17 JUN 2019

All State/UT Drugs Controllers,

**Sub: Phenobarbital – Drug Rash with Eosinophilia & Systemic
Symptoms (DRESS) Syndrome - Reg.**

Sir,

Phenobarbital is approved by CDSCO and marketed in the country in various dosage forms.

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 Phenobarbital, which were discussed by them in the 14th Signal Review Panel (SRP) under the programme meeting held on 28.02.2019 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 drug Phenobarbital-ADR on the basis of Individual Case Study Reports (ICSR) and recommended CDSCO to take necessary steps to **incorporate Drug Rash with Eosinophilia & Systemic Symptoms (DRESS) Syndrome as an adverse drug reaction** in to the prescribing information leaflet (PIL) of the drug Phenobarbital marketed in the country.

Subsequently, the PvPI recommendations was deliberated in the Subject Expert Committee (SEC-Neurology & Psychiatry) meeting held on 15.05.2019 at CDSCO HQR, New Delhi. After detailed deliberation the Committee has

recommended that Drug Rash with Eosinophilia & Systemic Symptoms (DRESS) Syndrome should be incorporated as an adverse drug reaction in the package insert of the drug Phenobarbital as suggested by PvPI.

The recommendation of the SEC has been considered by this office. Accordingly, you are requested to direct the manufacturers of Phenobarbital formulations under your jurisdiction to mention Drug Rash with Eosinophilia & Systemic Symptoms (DRESS) Syndrome as an adverse drug reaction in the label/Package insert/Promotional Literature of the drug.

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

Yours faithfully,



Dr. S. Eswara Reddy
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.