DCA
DRUGS CONTROL ADMINISTRATION
TELANGANA

# GOVERNMENT OF TELANGANA
# DRUGSCONTROLADMINISTRATION

## Public Notice

**Rc. No. 01/09/DG-Peshi/DCA/2024** **dated: 03-09-2024**

**Sub:** Sale of Formulations containing Pregabalin - Restrictions - Reg.

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The drug 'Pregabalin' has been approved in India by the Drugs Controller General (India) for the following indications: the treatment of peripheral neuropathic pain in adults (such as diabetic neuropathy), and the management of fibromyalgia syndrome, either as a single-ingredient formulation or in a fixed-dose combination with Methylcobalamin, Alpha-lipoic Acid, Pyridoxine, and Folic Acid.

Products containing 'Pregabalin' are being manufactured and supplied by most pharmaceutical manufacturers with a **boxed caution** on the product label, including the primary pack (strip) and carton, stating: **'CAUTION: Not to be sold by retail without the prescription of a Registered Medical Practitioner.'**

Based on reports received by the Drugs Control Administration, Telangana regarding the abuse potential of the drug Pregabalin, and considering drug literature, including several case reports and epidemiological studies, concerns have been raised about the abuse potential of Pregabalin, the use of which has increased substantially over the last decade.

In light of the reports concerning the abuse potential of Pregabalin, the Drugs Control Administration, Telangana, instructs all stakeholders, including retail outlets and hospital-attached pharmacies, that **Pregabalin formulations must be sold only with a prescription from a Registered Medical Practitioner.**

The details of Pregabalin sales must be recorded in the **Prescription Register** at the time of supply, and the serial number of the register entry must be noted on the prescription.

The following particulars shall be entered in the 'Prescription Register' for the sale of formulations containing Pregabalin:

(a) Serial number of the entry

(b) Date of supply

(c) Name and address of the prescriber

(d) Name and address of the patient

(e) Name of the drug and the quantity

(f) Name of the manufacturer, batch number, and date of expiry of potency

(g) Signature of the registered pharmacist who supplied the medicine or under whose supervision it was supplied

The above instructions shall be strictly adhered to. Failure to comply with these instructions will attract punishment under the Drugs and Cosmetics Act, 1940, and the Rules made thereunder.

**DIRECTOR GENERAL**

**To:**

All Stakeholders

**Copy to:**

- All Drugs Inspectors in the State, to circulate this notice to all retail outlets, including hospital-attached pharmacies, for widespread publicity regarding restrictions on the sale of Pregabalin, with instructions to verify compliance through inspections.
- All Assistant Directors, to ensure strict compliance.
- The Joint Director and Deputy Directors, to monitor compliance.