

F. No. 12-01/19-DC (Pt-09)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(New Drugs Division)

FDA Bhavan, Kotla Road,
New Delhi

Dated: 15/12/19

NOTICE

Concerns have been raised from time to time regarding sale of medicines without prescription. Recently one representation has been received regarding sale of anti psychiatric medicines without any prescription. This office has sensitized all the concerned from time to time about the concerns of sale of drugs with prescription.

This office is again advising the supply chain system in India to follow strict requirements of Schedule H, H1 and X for sale of medicines, which are appended below

1. Schedule H: If it contains a substance specified in Schedule H be labelled with the symbol Rx and conspicuously displayed on the left top corner of the label and also be labelled with the following words-

‘Schedule H drug-Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only’

2. Schedule H1: If it contains a substance specified in Schedule H1, the drug formulation shall be labelled with the symbol Rx which shall be in red and conspicuously displayed on the left top corner of the label, and also be labelled with the following words in a box with a red border-

"SCHEDULE H1 DRUG - WARNING:

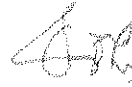
- It is dangerous to take the preparation except in accordance with the medical advice.
- Not to be sold by retail without the prescription of a Registered Medical Practitioner."

3. Schedule X: If it contains a substance specified in Schedule X, be labelled with the symbol XR_x which shall be in red and conspicuously displayed on the left top corner of the label and also be labelled with the following words-

‘Schedule X drug-Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only’

The stakeholders are hereby advised for strict compliance of the requirement of the Drugs and Cosmetics Act and Rules made thereunder by

- (i) Taking strong policy measures including stringent regulatory action on the over the counter (without prescription) sale of drugs included in the above Schedules.
- (ii) Raising awareness through Consumer Associations about the side effects of taking medicines without prescription for patient safety, their well being and protection of their health.



(Dr. S. Eswara Reddy)
Drugs Controller General (India)

To,

1. All State/UT Drugs Controllers
2. All Zonal/sub-zonal offices of CDSCO
3. Pharma/Consumer Associations