



ALL INDIA ORGANISATION OF CHEMISTS & DRUGGISTS[®]

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No.DCG (I)/Misc./2017 (05)
Central Drugs Standards Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare
(Office of DCGI)

FDA Bhavan, Kotla Road,
New Delhi-110002.

Dated: 16th January, 2017

NOTICE

It has reported by the Press that antimicrobial resistance has resulted in the death of a patient in India. To contain anti-microbial resistance, the office has been advising the supply chain system in India to follow strict requirements of Schedule H and H1 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 drug 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-

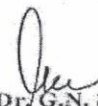
"SCHEDULE H1 DRUG, - WARNING;

- 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."

The stakeholders are hereby advised for strict compliance of the requirement of the Drugs & 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 high end antibiotics included in the above Schedules.
- (ii) Raising awareness through Consumer Associations about the side effects of taking antibiotics without prescription.

so that the antibiotic microbial resistance could be avoided for patient safety, their well-being and protection of their health.


(Dr. G.N. Singh)
Drugs Controller General (India)

To

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