BioSpectrum
the business of Bi
24 years of leveraging the business of Bio
www.biospectrumindia.co

# High-risk drugs packs must carry prominent warnings

10 May 2018 | News

**The health ministry has made it mandatory for high-risk medicines to carry warnings prominently on drug packs from November 1**



In a move to enhance consumer awareness and accountability of pharma companies, the health ministry has made it mandatory for high-risk medicines to carry warnings prominently on drug packs from November 1.

The new rules will be applicable to medicines such as cancer drugs, narcotics analgesics, sedatives, tranquillisers, steroids and anti-depressants which have either a high risk of side effects or are to be used strictly under medical supervision.

The changes are part of the new labelling rules under the Drugs and Cosmetics (Fifth Amendment) Rules, 2018. According to the norms, the label of the innermost container of such drugs - categorised under Schedule G or Schedule H or Schedule H1 or Schedule X in - will bear a caution or warning in legible black-coloured ink in a red rectangular box. These medicines also include some antimicrobials, anti-epileptics and anticoagulants.

The new rules specify that if the medicine contains a drug substance specified in Schedule H, G or X, it will be labelled with symbol Rx, like cancer drugs, anti-depressants and steroids.

In case of substances specified under Schedule H1, which comes within the purview of the narcotic drugs and psychotropic substances Act, 1985, the packaging will be labelled with symbol NRx, in red colour with caution statement on the left top corner. This will cover mainly narcotics analgesics.

The government's move is aimed at bringing in transparency while also preventing sale of prescription drugs over the counter. Officials say the main objective is to help make consumers aware.

"Prominent warning will ensure that consumers are aware of the risk and side-effects attached with a medicine," an official said.

The Indian drug retail market is pegged at over Rs 1 lakh crore annually, of which 75-80% is prescription drugs.