

File No. 18-9/2010-DC
Directorate General of Health Services
Central Drugs Standard Control Organization
FDA Bhawan, Kotla Road
New Delhi-110002

To,

1. All State/UT's Drugs Controllers
2. Zonal and sub-zonal offices
3. Manufacturers Associations
4. All India Chemist and Druggist Association

Dated:-19.03.2014

Subject:- Implementation of the Drugs and Cosmetics (Fourth Amendment) Rules, 2013 published under Gazette notification G.S.R. 588(E) dated 30.08.2013 regarding the inclusion of Schedule H1 under the Drugs and Cosmetics Rules, 1945 – clarifications thereon.


Sir,

The Drugs and Cosmetics Rules, 1945 were amended vide Drugs and Cosmetics (Fourth Amendment) Rules, 2013 published under Gazette notification G.S.R. 588(E) dated 30.08.2013 regarding the inclusion of Schedule H1 under the Drugs and Cosmetics Rules, 1945 containing certain antibiotics, anti-TB drugs and habit forming drugs. It was provided in the notification that these rules will come into force after six months of their publication in the official Gazette i.e. from 1st March, 2014.

Representations were received from the Drug Manufacturers Associations as well as Individual manufacturers that the chemists may not be able to sell the drugs covered under the Schedule H1 which are not labelled as per provisions of the amended rules even though these drugs at the time of their manufacture were labelled in accordance to the rules applicable to them.

The representations have been considered by the Ministry of Health and Family Welfare, Government of India and it has been decided that the drugs included in the Schedule H1 manufactured upto 28th February, 2014 without the labelling requirements specified in the said notification but labelled as per provisions applicable for them at the time of their manufacture, may continue to be sold even beyond 1st March, 2014. The Chemist, while selling the drugs included in Schedule H1, would, however, be required to comply with the requirements for the sale of drugs covered under the said notification in respect of requirements of sale of these drugs against the prescription of an RMP and maintenance of sale records as specified therein.

Yours faithfully,


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

Copy forwarded for information to:

1. Addl. Secretary & DG (CGHS), Ministry of Health and Family Welfare.
2. Joint Secretary (Regulation), Ministry of Health and Family Welfare.