



KAMARAJ IAS ACADEMY
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Centre Amends Drugs Rules, 1945 to Strengthen Regulation of High Alcohol-Containing Drug Formulations

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The Ministry of Health and Family Welfare (MoHFW) has amended the Drugs Rules, 1945 to strengthen regulation of medicinal formulations containing high levels of ethyl alcohol.

Under the amendment, medicinal formulations containing more than 12% v/v ethyl alcohol in pack sizes exceeding 30 mL will no longer be exempt under Schedule K of the Drugs Rules, 1945.

These products will now require licensing under the Drugs and Cosmetics Act, 1940 and have been brought under Schedule H1, making them prescription-only medicines with stricter monitoring and record-keeping requirements. The move aims to curb misuse of such formulations while ensuring their availability for genuine therapeutic use.

Key Amendments:

Withdrawal of Schedule K Exemption:

Medicinal formulations containing more than 12% v/v ethyl alcohol in packs exceeding 30 mL will no longer enjoy licensing exemption under Schedule K.

Inclusion under Schedule H1:

These formulations will now be classified as Schedule H1 drugs.

Sale only on the prescription of a Registered Medical Practitioner (RMP).

Pharmacies must maintain a separate sales register and preserve records.

Kamaraj IAS Academy

Plot A P.127, AF block, 6 th street, 11th Main Rd, Shanthi Colony, Anna Nagar, Chennai, Tamil Nadu 600040

Phone: **044 4353 9988 / 98403 94477** / Whatsapp : **09710729833**

Licensing Requirement:

Manufacturers and sellers must obtain licences under the Drugs and Cosmetics Act, 1940.

Objective:

Prevent misuse of high alcohol-containing medicinal formulations as intoxicants.

Ensure safe and regulated therapeutic use.

Why was the Amendment Needed?

Certain medicinal preparations such as tincture of cardamom, tincture of ginger, and other aromatic tinctures contain 80–90% v/v ethyl alcohol.

These products were earlier exempt under Schedule K, making them vulnerable to misuse.

Several State Governments reported misuse and diversion of such products for intoxication.

Drugs and Cosmetics Act, 1940:

Principal legislation regulating the import, manufacture, distribution, and sale of drugs and cosmetics in India.

Ensures the safety, efficacy, and quality of medicines.

Empowers the Central Government to frame the Drugs Rules, 1945.

Drugs Rules, 1945:

Framed under the Drugs and Cosmetics Act, 1940.

Prescribe rules relating to:

Licensing

Manufacture

Storage

Distribution

Sale

Labelling

Prescription requirements for drugs.

About Schedule K:

Lists specified drugs and medicinal preparations exempt from certain licensing provisions under defined conditions.

The latest amendment removes this exemption for specified high alcohol-containing formulations.

About Schedule H1:

Introduced to regulate medicines with a high risk of misuse.

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Key features:

Sale only on prescription.

Mandatory maintenance of sales records by pharmacies.

Helps prevent misuse and promotes rational use of medicines.

Exam Focus Points:

Ministry: Ministry of Health and Family Welfare (MoHFW).

Law: Drugs and Cosmetics Act, 1940.

Rules Amended: Drugs Rules, 1945.

Alcohol Threshold: More than 12% v/v ethyl alcohol.

Pack Size Covered: More than 30 mL.

Schedule Affected: Schedule K (licensing exemption withdrawn).

New Classification: Schedule H1.

Prescription Requirement: Mandatory prescription by a Registered Medical Practitioner (RMP).

Objective: Prevent misuse of high alcohol-containing medicinal formulations while ensuring therapeutic use.