



THE ALL INDIA ORGANISATION OF CHEMISTS & DRUGGISTS®

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Press Note

Date : 16.06.2026

AIOCD Welcomes Government's Move to Amend Schedule K; Calls for Comprehensive Review in Consultation with Stakeholders

The All India Organisation of Chemists and Druggists (AIOCD) has welcomed the notification issued by the Ministry of Health and Family Welfare, Government of India vide G.S.R. 477(E) dated 9 June 2026, whereby the word "Syrups" for Cough has been omitted from Item (7) under Serial No. 13 of Schedule K of the Drugs Rules, 1945.

AIOCD has consistently been raising concerns before the Government regarding the misuse of Schedule K provisions by certain entities, including online pharmacies and others, for the sale and supply of medicines without adhering to the safeguards envisaged under the Drugs and Cosmetics Act and Rules. The organisation has repeatedly demanded a comprehensive review of Schedule K to prevent misuse and to strengthen patient safety.

As per the provisions of the Drugs and Cosmetics Act, 1940 and the Rules framed thereunder, as amended from time to time, the pharmaceutical retail sector in India has witnessed exceptional growth over the years. In view of the substantial increase in the number of licensed chemist shops across the country, there is an urgent need to rationalise and significantly restrict the stocking and dispensing of medicines under the provisions of Schedule K by doctors and clinics. Therefore, a comprehensive review and immediate amendment of Schedule K is required to prevent misuse, ensure a level playing field, and safeguard public health.

Welcoming the amendment, AIOCD President J. S. Shinde and General Secretary Rajiv Singhal stated that this decision is a positive and significant step towards ensuring responsible distribution of medicines and curbing regulatory loopholes that have been exploited in recent years.

The leaders further stated that while this amendment is a good beginning, there is still an urgent need for a detailed review of Schedule K. They urged the Ministry of Health and Family Welfare to undertake a comprehensive revision of Schedule K in consultation with all stakeholders, including regulators, healthcare professionals, pharmacists, chemists and druggists, patient groups, and industry representatives.

AIOCD believes that any exemption under the Drugs Rules must be aligned with the paramount objective of patient safety and public health. The organisation remains committed to working with the Government to ensure that medicines are dispensed through proper channels and in compliance with applicable laws and regulations.

In view of the latest amendment, AIOCD has also issued an advisory to all its member associations across the country to ensure strict compliance with statutory provisions governing the sale of medicines and to exercise utmost caution while dispensing cough syrups and other prescription medicines.

Thanking You,

For The All India Organisation of Chemists & Druggists

(J. S. Shinde)
President

(Rajiv Singhal)
Hon Gen Secretary

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 9th June, 2026

G.S.R. 477(E).— Whereas a draft of certain rules further to amend the Drugs Rules, 1945 were published as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) *vide* notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 927 (E), dated the 29th December, 2025 published in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), dated the 30th December, 2025 inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public:

And whereas, copies of the said Official Gazette were made available to the public on the 30th December, 2025;

And whereas, objections and suggestions received from the public on the said draft rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the said Act, the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs Rules, 1945, namely: —

1. (1) These rules may be called the Drugs (Fifth Amendment) Rules, 2026.
(2) They shall come into force on the date of their publication in the Official Gazette.
2. In the Drugs Rules, 1945, in Schedule K, in the column, under the heading Class of Drugs, against serial number 13, in item number (7), the word "Syrups," shall be omitted.

[F. No. X.11014/11/2025-DR]

HARSH MANGLA, Jt. Secy.

Note: The Drugs Rules, 1945 were published in the Official Gazette *vide* notification No. F. 28-10/45H(1), dated the 21st the December, 1945 and last amended *vide* notification number G.S.R. 444(E), dated, 1st June, 2026.

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- pure, skimmed or malted, fortified with vitamins and minerals or otherwise.
- (ii) Farex, Oats, ²¹[***] and all other similar cereal preparations whether fortified with vitamins or otherwise excepting those for parenteral use.
- (iii) Vitrol, Bovril, Chicken essence and all other similar predigested foods.
- (iv) ²²[Ginger, Pepper, Cumin, Cinnamon and all other similar spices and condiments unless they are specially labelled as conforming to the standards in the Indian Pharmacopoeia or the Official Pharmacopoeia and official compendia of drug standards prescribed under the Act and Rules made thereunder.]

²¹[11.***]

²²[12. Substances intended to be used for destruction of vermin or insects which cause disease in human beings or animals, viz. Insecticides and Disinfectants.]

The provision of Chapter IV of the Act and Rules thereunder, which require them to be covered by a sale licence ²³[subject to the condition that provision of condition (17) of Rule 65 of the Drugs and Cosmetics Rules, 1945 are complied with by the person stocking or selling such substances.]

²³[13. The following household remedies, namely-

- (1) ²⁴[Aspirin tablets.]
- (2) ²⁵[Paracetamol Tablets.]
- (3) Analgesic Balm.
- (4) Antacid preparations.
- (5) Gripe Water for use of infants.
- (6) Inhalers, containing drugs for treatment of cold and nasal congestion.
- (7) Syrups, lozenges, pills and tablets for cough.
- (8) Liniments for external use.
- (9) Skin ointments and ointments for burns.
- (10) Absorbent cotton wool, bandages, absorbent gauze and adhesive plaster.
- (11) Castor Oil, liquid Paraffin and Epsom Salt.
- (12) Eucalyptus Oil
- (13) Tincture Iodine, Tincture Benzoin C. o. and Mercurochrome in containers not exceeding 100 ml.
- (14) Tablets of Quinine Sulphate I.P.
- (15) Tablets of Iodochlorohydroxy quinoline-250 mg.

The provisions of Chapter IV of the Act and the Rules thereunder which require them to be covered with a sales licence in Form 20-A subject to the following conditions—

- (a) The drugs are sold only in a village having population of not more than one thousand persons and where there is no licensed dealer under the Drugs and Cosmetics Act;
- (b) The drugs do not contain any substance specified in ²⁷[Schedules G, H or X];
- (c) The drugs are sold in the original unopened containers of the licensed manufacturers;
- (d) When the drugs are sold under clause (a) condition 3 under "Conditions of licence" of Form 20-B shall not apply.

²⁴[14. Mechanical Contraceptives

The provisions of Chapter IV of the Act and Rules thereunder, which require them to be

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²⁶[14A. Vaginal contraceptive pessaries containing Nonoxynol.

covered by a sale licence ²⁷[subject to the condition that the provisions of condition (17) of Rule 65 of the Drugs and Cosmetics Rules, 1945, are complied with by the stocking or selling mechanical contra- The provisions of Chapter IV of the Rules made thereunder which req to be covered by a sale licence suby condition that the provisions of clau Rule 65 of the Drugs and Cosmetic 1945 are complied with by the person stocking or selling this contraceptive.]

