

**GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**LOK SABHA
UNSTARRED QUESTION NO. 2151
TO BE ANSWERED ON 31ST JULY, 2026**

ETHYL ALCOHOL IN DRUGS

2151. SHRI V K SREEKANDAN:

Will the **Minister of HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) whether the Government has amended the rules to strictly regulate drugs formulations containing high level of alcohol in the country, if so, the details thereof;
- (b) whether it is also a fact that the Government has removed licensing requirements for formulations containing more than 12% of ethyl alcohol;
- (c) whether it is also a fact that some of these formulations contain highly potent concentrations of ethyl alcohol, in certain cases up to 80 to 90% v/v making them susceptible to misuse for intoxication, if so, the details thereof; and
- (d) whether it is also true that the Government has received urgent regulatory references and complaints from various State Governments in this regard, if so, the details thereof?

**ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY
WELFARE
(SMT. ANUPRIYA PATEL)**

(a) to (d): The Government received a representation from State Drugs Controller, Uttar Pradesh, stating the need for suitable amendments under the Drugs and Cosmetics Act, 1940 and Rules, 1945 to prevent misuse of tinctures/ alcoholic preparations.

The said matter was deliberated in 61st Drugs Consultative Committee (DCC) meeting held on 01.06.2023 and thereafter, in 90th meeting of Drugs Technical Advisory Board (DTAB) held on 25.01.2024. Subsequently, the Government has amended the Drugs Rules, 1945 vide notification G.S.R. 607(E) dated 08.07.2026. As per the said notification, all formulations containing more than 12% v/v ethyl alcohol, packed and sold in packings or bottles exceeding 30 mL, shall no longer be covered under the exemption provided to them under Schedule K of the Drugs Rules, 1945.

Consequently, all such oral formulations are now covered under Schedule H1 of the Drugs Rules, 1945, which mandates their sale against the prescription of a Registered Medical Practitioner, stricter record-keeping and requires to obtain the requisite licenses under the said rules. The said amendment shall come into force after six months of publication of these rules in the official gazette.
