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Health Ministry Ends Licensing Exemption for High-Alcohol Medicines

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WHY IN NEWS

In (effective on or around **July 10***), the* **Union Ministry of Health and Family Welfare** *ended the long-standing* **licensing exemption** *for medicinal formulations containing* **more than 12 per cent ethyl alcohol**. *Such formulations now require a* **licence under the Drugs and Cosmetics Act, 1940**, *and can be* **sold only against a prescription**. *The move is aimed at curbing the misuse of certain medicinal syrups and tinctures as cheap intoxicants.*

WHAT HAS CHANGED

For decades, a category of medicinal preparations with a high alcohol content, including several traditional and Ayurvedic tinctures and certain syrups, could be manufactured and sold **without a drug licence** because they fell within an exemption. That exemption is now withdrawn for any formulation carrying **more than 12 per cent ethyl alcohol** by content.

The consequence is twofold. First, a manufacturer of such a formulation must now hold a **manufacturing licence** and comply with the quality and labelling discipline of the drug law. Second, the product moves behind the pharmacy counter: it can be **dispensed only on a registered medical practitioner's prescription**, and its sale must be recorded.

The public-health logic is direct. In several states, low-cost, freely available high-alcohol "medicines" had become a substitute for liquor, especially where alcohol is prohibited or heavily taxed. Sold without a prescription and without a sales record, they were consumed as intoxicants rather than as medicine. Bringing them under licensing converts an unregulated retail product into a controlled pharmaceutical.

THE GOVERNING FRAMEWORK

The Statute and the Rules

The **Drugs and Cosmetics Act, 1940** and the **Drugs and Cosmetics Rules, 1945** together regulate the **import, manufacture, distribution and sale** of drugs and cosmetics in India. The Act is the parent legislation; the Rules carry the operational detail, including the schedules that classify drugs by the degree of control they need.

The Regulator

The **Central Drugs Standard Control Organisation (CDSCO)**, under the Health Ministry, is the **national drug regulator**. It is headed by the **Drugs Controller General of India (DCGI)**. CDSCO sets standards, approves new drugs and clinical trials, and coordinates the regulatory system, while **State Drug Controllers** handle much of the on-ground licensing and enforcement.

The Schedules

The Rules place drugs into schedules according to how tightly their sale must be controlled.

CATEGORY	WHAT IT MEANS
Schedule H	Prescription-only drugs
Schedule H1	Drugs requiring a prescription **and** a maintained sale record (includes certain antibiotics and habit-forming drugs)
Schedule X	Narcotic and psychotropic drugs needing the strictest controls
Prior exemption	Allowed certain high-alcohol traditional and other preparations to be sold **without a drug licence**

The July 2026 decision effectively pulls high-alcohol formulations out of that last row and into the discipline of the prescription regime.

WHY IT IS A GOVERNANCE QUESTION

The measure sits at the intersection of **public health, federalism** (https://ujiyari.com/terms/federalism/) **and enforcement capacity**, which is what makes it a GS2 issue rather than a purely medical one.

Health is a State subject, drug standards are shared. Drug **manufacturing licences are issued by State licensing authorities**, so a rule tightened at the Centre only bites when States enforce it uniformly. A formulation blocked in one State can still be manufactured across a border and trafficked back, which is precisely how the misuse spread in the first place.

Access versus control. Some of the affected tinctures have genuine therapeutic use. A prescription requirement must not put legitimate medicine out of reach of poorer patients even as it shuts the door on misuse. Calibrating that balance, rather than a blanket ban, is the harder policy craft.

Enforcement is the binding constraint. India's drug inspectorate is thinly staffed relative to the scale of the retail pharmacy sector. A rule is only as strong as the inspection and prosecution that back it, and here the record has historically been weak.

WAY FORWARD

The reform is sound in principle: an intoxicant masquerading as medicine should not enjoy an exemption designed for genuine remedies. Its success now depends on **Centre-State coordination** so that licensing is applied consistently across borders, on **strengthening the drug inspectorate** so that the prescription requirement is actually policed, and on **protecting legitimate access** for patients who need these formulations. Regulation on paper closes the loophole; only enforcement closes the trade.

UPSC RELEVANCE

GS Paper 2: Government policies and interventions for development in the health sector, issues relating to the regulation of substance misuse, Centre-State coordination in a federal subject, and the role of regulatory bodies.

Prelims pointers:

- The **Drugs and Cosmetics Act, 1940** and the **Drugs and Cosmetics Rules, 1945** regulate the import, manufacture, distribution and sale of drugs and cosmetics in India.
- The **CDSCO** is the national drug regulator, headed by the **Drugs Controller General of India (DCGI)**.
- **Schedule H1** lists drugs that require a prescription **and** a maintained sales record.
- Drug **manufacturing licences are issued by State licensing authorities**, making this a shared Centre-State function.
- The 2026 measure applies to formulations with **more than 12 per cent ethyl alcohol**, ending their earlier licensing exemption.

Mains question: "The withdrawal of the licensing exemption for high-alcohol medicinal formulations shows how a public-health objective depends on federal coordination and enforcement capacity. Discuss the challenges of regulating substance misuse in India while safeguarding legitimate access to medicines." (15 marks, 250 words)

FACTS CORNER

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Measure: July 2026, the Health Ministry ended the licensing exemption for medicinal formulations with more than 12 per cent ethyl alcohol; now licensed and prescription-only.

Aim: curb misuse of high-alcohol syrups and tinctures as intoxicants.

Statute: Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945 regulate import, manufacture, distribution and sale of drugs and cosmetics.

Regulator: CDSCO, headed by the DCGI, is the national drug regulator.

Schedule H1: prescription plus a maintained sales record.

Federalism: manufacturing licences are issued by State licensing authorities.

Sources: Ministry of Health and Family Welfare (https://mohfw.gov.in/), Central Drugs Standard Control Organisation (https://cdsco.gov.in/), The Hindu (https://www.thehindu.com/)

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