International Journal of Commerce and Management Research
www.managejournal.com
ISSN: 2455-1627
Received: 26-09-2025, Accepted: 25-10-2025, Published: 10-11-2025
Volume 11, Issue 11, 2025, Page No. 23-27

Challenges faced by State Governments in regulating public health hazard caused by alcoholic tinctures marketed in India as homeopathic remedies

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Abstract
The good starting point to explain this issue is the exceptionally complicated regulatory architecture under the Constitution for these alcoholic tinctures, which are liquid extracts of herbs dissolved in alcohol. As per Schedule VII of the Constitution, only States can enact legislation in relation to public health and the taxation of alcohol. The exception this rule of taxation is if the alcohol is meant for medicinal purposes, in which case, Entry 84 of List I allowed the Union to decide the rate of taxation.
A recent judgment of the Supreme Court of India, in Bhagwati Medical Hall Versus Central Drugs Standard Control Organization & others, has, once again, turned the impossible challenge faced by State Governments in regulating a significant public health hazard—that posed by alcoholic tinctures marketed in India as homeopathic remedies.
In the pre-Goods and Services Tax (GST) era, alcohol for medicinal preparation was taxed at a tiny 4% under the now repealed Medicinal and Toilet Preparations (Excise Duties) Act 1955. Nevertheless, the Union has prescribed an 18% tax slab for alcohol meant for medicinal purposes, which is still significantly lower that State taxes on alcoholic beverages.
Another aspect is that drugs are on the Concurrent list, which means that both Union and States can enact law but since the Drugs and Cosmetic Act, 1940 is the Union law laying down quality standards for homoeopathic products, States need presidential approval for State-specific amendments.
This complex regulatory architecture has meant that manufactures of these homoeopathic alcoholic tinctures have historically been immune from any form of quality regulation or taxation by States despite having a direct impact on public health which again is the responsibility of States, as per List II of Schedule VII.
Moreover, due to the difference in taxation rates for alcoholic tinctures is sold as homoeopathic remedies and alcoholic beverages, alcoholic tinctures manufactured by the homoeopathic industry are more affordable than alcoholic beverages. These alcoholic tinctures are the perfect substitute for alcoholic beverages especially since many of these tinctures contain a very high volume of alcohol.
The more important question is whether the law should permit the use of any alcohol in not just homoeopathic products but also ayurvedic products, especially when other countries are contemplating compulsory cancer warning on regular alcoholic beverages. It is one thing for these homoeopathic and ayurvedic products to not cure any ailments as claimed by their manufactures, but quite another for them to cause further harm to unsuspecting and poorly informed citizens. This paper reveals the importance of the notification of Central Drugs Standard Control Organization and challenges towards the affected society.

Keywords: Alcoholic tinctures, regulatory architecture, public health, taxation, homoeopathic remedies, Constitution of India

Introduction

A recent judgment of the Supreme Court of India, in Bhagwati Medical Hall Versus Central Drugs Standard Control Organization & others, has, once again, turned the spotlight on the impossible challenge faced by State Governments in regulating a significant public health hazard—that posed by alcoholic tinctures marketed in India as homeopathic remedies. Feeble attempts by the Union Government to tackle the problem have often been frustrated by ruthless lawfare conducted by the very formidable homeopathic industry.

The Bhagwati Medical Drugs Standard Control Organization case is a significant judgment related to the regulation of Ayurvedic medicines in India. The legal implication is that the decision provides clarity on the regulatory framework for Ayurvedic medicines emphasizing the need for manufacturers to comply with the Drugs and Cosmetic Act 1940. The court's decision to limit the alcohol content on Ayurvedic medicines to 10% v/v (volume by volume) aims to prevent misuse and ensure health and safety.

As far as industry impact is concerned the judgment increases the compliance burden on Ayurvedic medicines manufacturers, requiring them to reformulate their products and adhere to stricter regulatory standards.

The decision may impact the market for Ayurvedic medicines, potentially leading to a reduction in the availability of certain products or changes in their formulation.

Alcoholic tinctures are a common form of preparation in homeopathy. Homeopathy mother tinctures are prepared by soaking plant material in a solvent, typically a mixture of water and ethanol (alcohol). The alcohol content in homeopathic tinctures can vary, but it's typically between 20% to 90% ethanol by volume. Alcohol acts as a preservative, helping to prevent the growth of bacteria and mold in the tincture. Alcohol helps to extract the active principles from the plant material, making them more bio available. Alcohol can help stabilize the active ingredients, preventing degradation or oxidation.

Some individuals may be sensitive to alcohol or have conditions that require avoidance of alcohol. Homeopathic practitioners should be caution while prescribing tinctures. Homeopathic tinctures are typically taken in very small doses, which minimize the risk of adverse effects from the alcohol content.

The regulatory maze

The good starting point to explain this issue is the exceptionally complicated regulatory architecture under the Constitution for these alcoholic tinctures, which are liquid extracts of herbs dissolved in alcohol. As per Schedule VII of the Constitution, only States can enact legislation in relation to public health and the taxation of alcohol. The exception this rule of taxation is if the alcohol is meant for medicinal purposes, in which case, Entry 84 of List I allowed the Union to decide the rate of taxation.

In the pre-Goods and Services Tax (GST) era, alcohol for medicinal preparation was taxed at a tiny 4% under the now repealed Medicinal and Toilet Preparations (Excise Duties) Act 1955. Post the 101st Constitutional amendment which paved the way for the GST, the issue of taxation of alcohol meant for medicinal purposes is not clear since the exception created for alcohol meant for medicinal purposes is no longer mentioned in Entry 84. Nevertheless, the Union has prescribed an 18% tax slab for alcohol meant for medicinal purposes, which is still significantly lower that State taxes on alcoholic beverages.

The third aspect of this regulatory architecture is that drugs are on the Concurrent list, which means that both Union and States can enact law but since the Drugs and Cosmetic Act, 1940 is the Union law laying down quality standards for homoeopathic products, States need presidential approval for State-specific amendments.

This complex regulatory architecture has meant that manufactures of these homoeopathic alcoholic tinctures have historically been immune from any form of quality regulation or taxation by States despite having a direct impact on public health which again is the responsibility of States, as per List II of Schedule VII. Moreover, due to the difference in taxation rates for alcoholic tinctures is sold as homoeopathic remedies and alcoholic beverages, alcoholic tinctures manufactured by the homoeopathic industry are more affordable than alcoholic beverages. For a less discerning consumer of alcohol whose sole aim is to get intoxicated, these alcoholic tinctures are the perfect substitute for alcoholic beverages especially since many of these tinctures contain a very high volume of alcohol. The Drugs and Cosmetic Act permits alcoholic tinctures for homoeopathy to contain 12% alcohol by volume. For comparison, the most popular varieties of "Strong beer" sold in India generally contain 7% alcohol.

State governments have viewed the issue primarily through the lens of revenue loss caused by citizens who consume homoeopathic alcoholic tinctures at a higher rate. This loss of revenues was one of the reasons for the administrative actions taken by the Government of Uttar Pradesh, Under Section 22 of the Drugs and Cosmetic Act, 1940 in the Bhagwati Medical Hall case, except, as correctly held by the Supreme Court, only the Union government can regulate the sale of homoeopathic tinctures.

"Section 26A: Power of Central Government to regulate, restrict or prohibit manufacture, etc, of drug and cosmetic in public interest: Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied, that the use of any drug or cosmetic is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed or purported to be claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do, then, that Government may, by notification in the Official gazette, (regulate, restrict or prohibit) the manufacture, sale or distribution of such drug or cosmetic"

Section 26A of the Drugs and Cosmetic Act, 1940 empowers the Central Government, if satisfied that the use of any drug involves risk to human beings or animals, or that it lacks the therapeutic value claimed, or that it contains ingredients in a quality for which there is no therapeutic justification, to regulate, restrict, or prohibit its manufacture, sale or distribution by a notification in the official gazette. This is the sole statutory mechanism through which a drug, previously permissible, can be effectively taken off the market or subjected to special conditions. The provision ensures that any decision to restrict a drug stem from a central, uniform and scientifically informed process guided by expert advice, safety evaluations, and considered policy determinations. This centralized approach is deliberate, aimed at preventing arbitrary or inconsistent local measures that would fragment the national drug regulatory regime.

The Supreme Court held that the action taken by the Respondent lacked any "sustainable reasoning." The Bench stated that Section 26A of the Act is the sole statutory mechanism through which a drug, previously permissible, can be effectively taken off the market or subjected to special conditions. "The provision ensures that any decision to restrict a drug stem from a central, uniform, and scientifically informed process, guided by expert advice, safety evaluations, and considered policy determinations. This centralized approach is deliberate, aimed at preventing arbitrary or inconsistent local measures that would fragment the national drug regulatory regime," it remarked. Consequently, the Court held, "The Respondent authorities, if genuinely concerned on misuse, may intensify lawful regulatory oversight, ensuring strict compliance with licensing conditions and quality standards. However, they cannot assume the power to declare the product banned or treat it as such in the absence of a notification under Section 26A of the D&C Act, 1940. The statutory scheme envisions uniformity, predictability, and legal certainty— values that would be undermined if local authorities could unilaterally impose prohibitions contrary to the nationally determined regime.

The court held that restriction placed upon the use of containers for sale of homeopathic medicines with more than 12% alcohol content in the same is a reasonable restriction and is intended to prevent misuse of such preparations by those who purchase the same across the counters. The experience of such preparations having been misused in the past leading to loss of valuable human lives was, in our view, sufficient for the rule making authority to act in public interest and regulate the sale of such medicines by stipulating that they would not be sold in containers more than 30 ml capacity. The rule, it is noteworthy, does not require such small containers to be used in case the supply is meant for hospitals and dispensaries in which event the packing of bottles could be of 100 ml also. Having regard to the purpose sought to be achieved by the Act and the Rules

framed there under, the restriction contained in Rule 106B qua homeopathic medicine with more than 12% alcohol content cannot be said to be either unreasonable or otherwise violating of the right guaranteed to the petitioners under Article 19 (1)(g) of the Constitution.

The State Legislation

As per the Kerala Excise Act 1968 and the Kerala Excise Rules, 1972 pharmacies and medical stores must obtain a license from the Excise Commissioner to sell alcohol for medicinal purpose. Alcohol for medicinal purposes can only be sold on the production of a valid prescription from a registered medical practitioner. The quantity of alcohol that can be sold for medicinal purposes is restricted to a maximum of 100ml per prescription. Tinctures containing not more than 20% alcohol by volume are permitted for medicinal purposes. Mixtures containing not more than 10% alcohol by volume are permitted for medicinal purposes.

Relevance of Entry 84 of List I

Entry 84 of List I (Union List) of the Seventh Schedule to the Consititution of India deals with "Duties of excise on the following grounds manufactured or produced in India, namely:- (g) medicinal and toilet preparations containing alcohol".

This entry gives the Central Government the poser to levy excise duties on medicinal and toilet preparations containing alcohol. However, the state governments have the power to regulate the sale and distribution of these preparations. In the context of medicinal preparations containing alcohol, this entry is relevant because it allows the Central Government to regulate and tax these preparations, while also giving state governments some regulatory powers.

Central Government Power under Entry 84

The Central Government has the power to levy excise duties on medicinal and toilet preparations containing alcohol. The central government can regulate the manufacturers of these preparations to ensure quality and safety standards

State Government Power Under Entry 84

The state Government have the power to regulate the sale and distribution of medicinal and toilet preparations containing alcohol. State Government can issue license and permits for the sale and distribution of these preparations.

Conflict between Central and State Government under Entry 84

The Central Government and State Governments have conflicting claims over taxation jurisdiction, leading to disputes over revenue sharing. There is an overlap between the central governments regulatory powers over manufacture and the state government's regulatory powers over sale and distribution. Dispute arises over the classification of medicinal and toilet preparations and containing alcohol, affecting taxation and regulation.

The conflict between the Central government and state government regarding Entry 84 List I stems from overlapping taxation and regulatory powers. Judicial precedents have attempted to clarify the jurisdictional boundaries, but disputes persist. A clear demarcation of powers or a constitutional amendment may be necessary to resolve the conflict.

In Union of India V. Delhi Chemicals and Pharmaceuticals (1975) The Supreme Court held that the central government has exclusive power to levy excise duty on medicinal preparations containing alcohol. In State of Tamil Nadu V. M.K. Kandaswami (1975): The Supreme Court ruled that state governments have concurrent power to regulate the sale and distribution of medicinal preparations containing alcohol.

The Supreme Court of India has made a significant decision regarding Entry 84 of List I, which deals with the taxation of alcohol for medicinal purposes, in a recent judgment, a 9 judge bench ruled that states have the power to tax both alcoholic beverages and industrial alcohol, overturning its previous judgment in Synthetics & Chemicals Ltd.V State of Uttar Pradesh (1989).

This decision is a milestone in the history of alcohol regulation in India and has significant implications for fiscal federalism. The court held that the term "intoxicating liquor" in Entry 8 of the State List includes not just potable liquor but also any liquid containing alcohol that can be used to the detriment of public health. The judgment is expected to enhance state revenues, as excise duties on alcoholic drinks are a significant source of income for state governments. In fact, it's estimated that 15% to 30% of states revenue comes from liquor sales. This decision has been seen as a victory for states' rights and a boost to fiscal federalism in India. The court's ruling has clarified the powers of state governments to regulate and tax alcohol, and is expected to have a significant impact on state finances.

Health concerns, industry lawfare

The taxation story however pales in comparison to the public health nightmare posed by these alcoholic tinctures, since states have no ability to regulate alcoholic tinctures; they are required to permit the sale of these products even if the State law prohibits the sale of alcoholic beverages, as in Gujarat and Bihar. Both states have reported a string of deaths of those who consumed homoeopathic remedies containing spurious alcohol. In effect, the public health objectives of these State prohibitions on alcohol have been frustrated by a Union law. Technically, they can enact a State-specific amendment to the Drugs and Cosmetics Act 1940 but that requires presidential assent.

The larger public health hazard of these alcoholic tinctures are unsuspecting citizens who consume these products on the assumption that they are going to be cured of their ailments without being fully aware of the alcoholic content in these products. Except that consuming such products containing high levels of alcohol, on a daily basis, can cause serious illnesses such as alcoholic hepatitis in patients who are otherwise perfectly healthy. Indian doctors have been presenting an increasing amount of anecdotal data of such patients presenting symptoms consistent with those demonstrated by alcoholics.

The Union government has been aware of the public health hazards posed by these alcoholic tinctures and introduced Rule 106B of the Drugs and Cosmetic Rules, 1945 in 1994 after a tragedy took many lives. This new rule, which appears to lack any scientific basis, allows the homoeopathy industry to sell in the retail market, alcoholic tinctures containing 12% of alcohol in a bottle of maximum 30 ml. larger bottles of 100 ml can be sold only by hospitals. The rule mandates that the label of an Ayurvedic, Siddha, or

Unani medicine should include the full description of the medicine. The rule also specifies the packaging requirements for these medicines, including the use of tamper-evident packaging and child - resistant packaging, where applicable. Rule 106B aims to protect consumers by ensuring that they have access to accurate and essential information about the medicine they are using. The rule helps manufactures and marketers of Ayurvedic, Siddha, and Unani medicines to comply with regulatory requirements, which in turn helps to maintain the quality and safety of these medicines.

As soon as Rule 106B came into force, the homoeopathy industry unleashed a campaign of unmitigated lawfare against this rule because it wanted to sell tinctures with higher alcoholic content. In the first round of litigation, the homoeopathy industry challenged the constitutional validity of the rule on the grounds that it was an unreasonable restriction on its fundamental right to conduct trade and that the government lacked the power to make the rule. The industry lost before five High Courts and eventually the Supreme Court, except it took until 2014 for this litigation to be resolved. The very next year, in 2015, the homoeopathy industry launched a second round of lawfare by filing 13 law suits before seven different High Courts, on the ground that rule 106B was invalid since it was not placed before parliament for a period of 30 days, as required by Section 38 of the Drugs and Cosmetic Act. Since a statutory requirement was not met, at least four High Courts temporarily stayed the operation of the rule in 2015, restraining government from enforcing it until the legal challenge was disposed of.

The simplest solution to these law suits was for the Union Government to simply lay Rule 106B before parliament for 30 days thereby knocking out the basis of the legal challenge. Except, India's famed bureaucracy made the malicious decision to pursue the route of more litigation by filing a transfer petition in 2017 requesting for all 13 cases to be transferred to the Supreme Court. The court agreed to do so and transferred all 13 cases to itself in 2017, where the matter has since languished unheard. Delays of such nature before the Supreme Court, when it comes to regulations meant to protect public health, are nothing unusual and end up costing lives of citizens.

Challenges faced by State Government

Several challenges face by state government in regulating alcohol tinctures in medicine, which can impact public health. The following are the challenges

Regulatory Challenges

a. **Lack of Clarity:** Ambiguity in laws and lack of clarity on regulations regarding alcohol tinctures in medicine can lead to confusion and inconsistent enforcement.

b. **Overlapping jurisdictions:** The Central government's power to regulate medicinal preparations containing alcohol (Entry 84 of List I) can sometimes overlap with state governments powers to regulate public health (Entry 6 of List II) leading to conflicts,

c. **Inadequate infrastructure:** State governments may lack the necessary infrastructure, including laboratories and inspection facilities, to effectively regulate and monitor the quality of alcohol tinctures in medicine.

Public Health Challenges

a. **Alcohol abuse and addiction:** Easy availability of alcohol tinctures in medicine can contribute to alcohol abuse and addiction, particularly among vulnerable populations such as youth and those with mental health conditions.

b. **Adulteration and contamination:** Poor regulation and quality control can lead to adulteration and contamination of alcohol tinctures, posing serious health risks to consumers.

c. **Inadequate labeling and warnings:** Inadequate labeling and warnings on alcohol tinctures in medicine can lead to unintentional consumption or overdoes, particularly among children and the elderly.

Enforcement Challenges

a. **Limited resources:** State government may lack the necessary resources, including personnel and funding, to effectively enforce regulations and monitor the sale and distribution of alcohol tinctures in medicine.

b. **Corruption and illegal trade:** Corruption and illegal trade in alcohol tinctures can undermine regulatory efforts and pose significant public health risks.

c. **Public awareness and education:** State government may face challenges in raising public awareness and education about the risks associated with alcohol tinctures in medicine and the importance of responsible consumption.

Overcoming challenges

a. **Strengthening regulations and laws:** State governments can strengthen regulations and laws governing alcohol tinctures in medicine to ensure clarity and consistency

b. **Improving infrastructure:** State governments can invest in infrastructure and resources, including laboratories and inspection facilities, to enhance regulatory capacity.

c. **Enhancing public awareness and education:** Awareness and education can launch public awareness and education campaigns to raise awareness about the risks associated with alcohol tinctures in medicine and promote responsible consumption.

d. **Collaborating with stakeholders:** State governments can collaborate with stakeholders, including health care professionals, industry representatives and civil society organizations to develop effective regulatory strategies and promote public health.

Conclusion

The more important question is whether the law should permit the use of any alcohol in not just homoeopathic products but also ayurvedic products, especially when other countries are contemplating compulsory cancer warning on

regular alcoholic beverages. It is one thing for these homoeopathic and ayurvedic products to not cure any ailments as claimed by their manufactures, but quite another for them to cause further harm to unsuspecting and poorly informed citizens.

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