

M/s Bhagwati Medical Hall & Anr.
v.
Central Drugs Standard Control Organization & Ors.
(Civil Appeal No(s). 14735-14736 of 2024)
19 December 2024
[Vikram Nath and Prasanna B. Varale, JJ.]

Issue for Consideration

Whether District Magistrate's order prohibiting sale of 'aromatic tincture of cardamom' on the ground of it containing a high level of alcohol was correct and in accordance with the statutory framework of Drugs & Cosmetics Act, 1940.

Headnotes[†]

Drugs and Cosmetics Act, 1940 (D&C Act) – District Magistrate (DM), Agra issued orders prohibiting sale of “alcohol mixed tinctures” – Drug Inspector acted on said orders and prevented Appellants from selling “aromatic tincture of cardamom” on the ground that it was an alcohol mixed tincture – Appellants, being licensed distributor of “aromatic tincture of cardamom” under D&C Act objected to such prohibition and challenged said actions of Respondents before High Court – Dismissed; review petition also dismissed by High Court – Appellants approached Supreme Court:

Held: The Court held that under D&C Act, power to ban or categorize any drug as prohibited article in public interest vests solely with the Central Government under Section 26A of the D&C Act – Such legislative scheme of centralised decision-making is deliberate to prevent fragmentation of drug regulatory regime in India and to ensure uniformity and avoid inconsistent local measures. [Paras 7-9]

On facts, the Court found no notification issued by Central Government prohibiting / restricting trade of “aromatic tincture of cardamom” – It also referred to the list of prohibited drugs issued by the Ministry of Health and Family Welfare through their gazette notifications that was attached as Annexure P17 with the special leave petition. [Para 10]

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Thus, the directions issued by the DM was held to be against the legislative scheme of D&C Act. – Respondents' reliance on Section 22(1)(d) of D&C Act to justify their actions was rejected by the Court for the reason that the said provision was procedural in nature and was limited to inspecting, sampling, seizing non-compliant drugs, and in all enforcing the existing statutory framework and could not be a substitute for Central Government's prerogative under Section 26A of D&C Act. [Para 11]

The Court found that High Court failed to appreciate the distinction between general regulatory authority and the special, centralized power to prohibit drugs under D&C Act; that also adversely impacted the rights of the Appellants in this case who were a duly licensed trader. [Para 13]

List of Acts

Drugs & Cosmetics Act, 1940; Constitution of India.

List of Keywords

Prohibited article; Aromatic Tincture of cardamom; Alcohol mixed tincture; Restriction; Sale; Ban; prohibition; Public interest; Medicine; Section 26A and Section 22 of Drugs & Cosmetics Act; Central government; Local authorities.

Case Arising From

CIVIL APPELLATE JURISDICTION: Civil Appeal No(s). 14735-14736 of 2024

From the Judgment and Order dated 12.07.2022 and 22.09.2022 of the High Court of Judicature at Allahabad in WRITC No. 13134 of 2022 and CMRA No. 355 of 2022 respectively

Appearances for Parties

Nikhil Goel, Sr. Adv., Ms. Parul Shukla, Ms. Shubhangi Pandey, Saday Mondol, Advs. for the Appellants.

K M Nataraj, A.S.G., Samar Vijay Singh, Ms. Sabarni Som, Fateh Singh, Keshav Mittal, Dr. Sukhdev Sharma, Venkatesh Rajput, Santosh Kumar, Sharath Nambiar, Vinayak Sharma, B K Satija, Annirudha Sharma- II, Amrish Kumar Sharma, Gurmeet Singh Makker, Advs. for the Respondents.

Supreme Court Reports**Judgment / Order of the Supreme Court****Order**

1. Leave granted.
2. These appeals, by the Appellants, challenge the correctness of the orders dated 12.07.2022 and 22.09.2022 passed by the High Court of Judicature at Allahabad in Writ C No.13134 of 2022 and Civil Misc. Review Application No.355 of 2022, respectively. By the impugned orders, the High Court dismissed the writ petition as well as the review petition preferred by the Appellants, thereby upholding the actions taken by the Respondent authorities restricting the sale of a medicinal preparation known as “aromatic tincture of cardamom” at the Appellants’ medical shops.
3. The factual background giving rise to the present appeals are as follows:
 - 3.1. The Appellants are proprietors of medical firms/shops engaged for several decades in the wholesale and retail sale of drugs and medicines at Agra, Uttar Pradesh. They hold valid and subsisting licenses under the Drugs & Cosmetics Act, 1940 (hereinafter, “D&C Act, 1940”) and the rules framed thereunder, permitting them to sell, stock, and distribute various drugs, including a herbal medicinal preparation commonly referred to as “aromatic tincture of cardamom.”
 - 3.2. The said tincture, as stated by the Appellants, is a non-prescription, licensed medicine recognized under the D&C Act, 1940. It is used for treating mild ailments such as indigestion, flatulence, stomach pain, nausea, and vomiting. The tincture is manufactured by licensed manufacturers who are approved by the Indian Government, and the Appellants procure their supplies from such recognized sources, including the British Pharmacopoeia-approved suppliers.
 - 3.3. The Appellants submit that, despite the lawful nature of their business, the Respondent authorities—comprising officers from the Drug Control and Excise Departments of the State—subjected their shops to repeated inspections, abrupt closures, and harassment.

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- 3.4. On earlier occasions, the Appellants approached the High Court of Judicature at Allahabad, which, by an order dated 27.09.2021, directed that the State authorities shall not interfere with the running of the Appellants' business except in accordance with law.
 - 3.5. Further grievances arose when the District Magistrate, Agra, issued orders on 28.02.2022 constituting a joint team to curb the sale of "alcohol mixed tinctures," and the Drug Inspector thereafter, on 11.04.2022, purportedly directed the Appellants not to sell aromatic tincture of cardamom.
 - 3.6. Aggrieved by these actions, the Appellants filed Writ C No.13134 of 2022 before the High Court, seeking quashing of the impugned orders restricting their trade and an interim direction permitting them to continue their lawful business. The High Court, however, dismissed the writ petition on 12.07.2022, holding inter alia that "alcohol mixed tincture is a prohibited article," thereby upholding the actions taken by the Respondent authorities. The Appellants filed a Civil Misc. Review Application No.355 of 2022, but the review petition was also dismissed on 22.09.2022.
 - 3.7. The Appellants are before this Court challenging the aforesaid orders of the High Court and seek restoration of their right to carry on their business in accordance with their valid license and the statutory provisions.
4. The learned counsel for the Appellants, Shri Nikhil Goel, advanced the following arguments:
 - 4.1. The learned counsel for the Appellants contends that the High Court erred in categorizing aromatic tincture of cardamom as a "prohibited article." According to the Appellants, no such prohibition exists under the D&C Act, 1940, or any notification issued thereunder. Section 26A of the D&C Act, 1940 empowers only the Central Government to regulate, restrict, or prohibit the sale and distribution of any drug in the public interest. There being no notification prohibiting this particular tincture, the Respondent authorities have no jurisdiction to treat it as a banned substance.
 - 4.2. The Appellants argue that the impugned orders passed by the Respondent authorities and the High Court's endorsement of

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such actions infringe their fundamental right to carry on a lawful trade or business under Article 19(1)(g) of the Constitution of India. They stress that they possess a valid license and are in compliance with all applicable regulations.

- 4.3. The Appellants further submit that repeated inspections, arbitrary interference, and harassment by the Respondent authorities are motivated by extraneous reasons, including retaliation for complaints made against officials demanding bribes. The unlawful actions have resulted in closure of their shops, causing significant financial loss and damage to their reputation.
- 4.4. The Appellants emphasize that the tincture in question is a regulated drug, commonly used for minor digestive ailments, and does not figure in any list of prohibited or banned medicines. Multiple RTI responses from different governmental departments have confirmed that aromatic tincture of cardamom is a licensed medicine and does not require a doctor's prescription. In these circumstances, the restriction placed by the Respondent authorities is wholly unjustified and arbitrary.
5. In response, the learned counsel for the Respondent Authorities, Mr. Samar Vijay Singh, urged the following contentions:
 - 5.1. The Respondent authorities, while denying any mala fide intent, contend that aromatic cardamom tincture has extremely high alcohol content (around 84% to 87% v/v). According to them, the substance is being misused as a cheap substitute for country liquor by vulnerable sections of society, including daily-wage earners and rickshaw pullers. They argue that large quantities of this tincture are sold by the Appellants' shop without proper records or the presence of a registered pharmacist, and no other medicines are reportedly being sold.
 - 5.2. The Respondent authorities insist that the manner of sale and the demographics of the customers indicate that the tincture is effectively being used as an intoxicant rather than a medicinal preparation. They claim that its indiscriminate consumption poses serious health hazards and may lead to untimely deaths. They further submit that the misuse is causing substantial revenue losses to the State, as the tincture is replacing taxed country liquor.

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- 5.3. The Respondent authorities rely on the order of the District Magistrate and the joint team's inspections, which purportedly revealed the absence of necessary records and the availability of large stocks without any doctor's prescription. They contend that their actions are within the powers conferred under Section 22 of the D&C Act, 1940, which allows inspection and necessary steps to prevent offenses under the Act.
- 5.4. It is the Respondents' stance that, given the abuse and health ramifications, the High Court's observation treating the tincture as a prohibited article, at least for practical purposes, does not suffer from legal error. They maintain that public interest and health considerations justify the restrictions imposed on the Appellants' sale of the tincture, and no interference is warranted.
6. Having carefully considered the arguments advanced by both sides and upon a thorough examination of the materials on record, it is clear that the action taken by the Respondent authorities lacks a sustainable reasoning.
7. The aromatic tincture of cardamom at issue is governed by the D&C Act, 1940 and the rules framed thereunder. Under this statutory framework, the manufacture, sale, and distribution of drugs are subject to a carefully calibrated regulatory regime. The D&C Act, 1940 classifies drugs, prescribes licensing requirements, mandates compliance with quality standards, and delineates the respective powers of Central and State authorities. Crucially, the power to impose a prohibition or to declare a drug as banned or restricted for reasons of public interest lies exclusively with the Central Government, as provided in Section 26A of the D&C Act, 1940, which has been reproduced hereunder:

“Section 26A: Powers 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

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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.”

8. Section 26A of the D&C 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 quantity 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 stems 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.
9. In the present case, there is no notification issued under Section 26A of the D&C Act, 1940 prohibiting or restricting the aromatic tincture of cardamom. The absence of such a notification is decisive. Without it, the tincture remains a licensed medicinal preparation that can be manufactured and sold in accordance with the general rules and the conditions of the license held by the Appellants. The Respondent authorities cannot, on their own accord, treat this lawful product as a “prohibited article.” Any such classification by subordinate authorities would undermine the statutory scheme, which deliberately centralizes the ultimate decision-making power over prohibition with the Central Government. To hold otherwise would effectively allow local officials to unilaterally bypass the checks and balances embedded in the Act, and to create, in practice, an ad hoc ban outside the statutory process.
10. It must be noted that the “aromatic tincture of cardamom” is not “prohibited” as can be seen from the list of prohibited drugs as issued by the Ministry of Health and Family Welfare through their gazette notifications which has been attached as Annexure P17 before us. The said tincture is prepared by licensed manufacturers who are duly approved by the Indian Government and the appellant procures

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the same from one such supplied, i.e. British Pharmacopoeia which is approved by the Indian Government. The Tincture list in British Pharmacopoeia 2022 has the following approved tinctures and serial number 11 contains Cardamom Tincture Compound:

1. Capsicum Tincture
2. Camphorated Opium Tincture
3. Concentrated Camphorated Opium Tincture
4. Bitter Orange Epicarp and Mesocarp Tincture
5. Orange Tincture
6. Arnica Tincture
7. Aromatic Cardamom Tincture
8. Belladonna Tincture
9. Belladonna Tincture Compound
10. Capsicum Tincture Standardized
11. Cardamom Tincture Compound
12. Compound Benzoin Tincture
13. Compound Cardamom Tincture
14. Compound Rhubarb Tincture
15. Concentrated Camphorated Opium Tincture
16. Gentian Tincture
17. Ginger Tincture
18. Ipecacuanha Tincture Standardized
19. Myrrh Tincture
20. Opium Tincture
21. Opium Tincture Camphorated
22. Opium Tincture Concentrated Camphorated
23. Opium Tincture Standardized
24. Quillaia Tincture

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25. Rhatany Tincture
26. Sage Tincture
27. Siam Benzoin Tincture
28. Standardized Belladonna Leaf Tincture
29. Standardized Ipecacuanha Tincture
30. Strong Ginger Tincture
31. Sumatra Benzoin Tincture
32. Tormentil Tincture
33. Valerian Tincture
11. The Respondent authorities have attempted to justify their actions by relying on Section 22(1)(d) of the D&C Act, 1940. This provision empowers Inspectors, within the local limits of their jurisdiction, to exercise such powers as may be necessary for carrying out the purposes of the Chapter or any rules made thereunder. The scope of this provision is essentially procedural, intended to facilitate inspection, sampling, seizure of non-compliant drugs, and enforcement of existing statutory and regulatory requirements. It does not, however, confer authority to impose new prohibitions or to classify a duly licensed drug as contraband. Section 22(1)(d) is not a substitute for Section 26A of the D&C Act, 1940. While an Inspector may inspect premises, verify licenses, ensure proper record-keeping, and take action against specific offenses under the Act, the Inspector cannot supplant the Central Government's prerogative by effectively banning a drug simply because of alleged misuse in certain quarters.
12. Similarly, even if the Respondent authorities are concerned about the high alcohol content of the tincture or its potential misuse by certain consumers, the D&C Act, 1940 and the rules framed thereunder provide mechanisms for addressing such issues without resorting to extra-statutory prohibitions. For instance, the authorities may ensure that licensees maintain proper records as mandated by the relevant rules; they may verify that a qualified pharmacist is present at the time of sale; they may inspect the premises regularly and take penal action if any license conditions are breached. If, upon gathering evidence and seeking expert advice, the authorities believe that the

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drug poses health risks serious enough to warrant prohibition, their proper recourse is to move the Central Government to consider exercising its powers under Section 26A of the D&C Act, 1940. Until such a notification is issued, the drug cannot be unilaterally banned at the local level.

13. By endorsing the characterization of the aromatic tincture of cardamom as a “prohibited article” without any notification from the Central Government, the impugned orders of the High Court have effectively circumvented the legislative design. The High Court’s reasoning overlooks the clear distinction drawn by the D&C Act, 1940 between general regulatory authority and the special, centralized power to prohibit drugs. This approach also disregards the rights of a duly licensed trader who is entitled to carry on business in a product that remains lawful unless and until lawfully prohibited. Fundamental principles of administrative law, as well as the very structure of the D&C Act, 1940, demand that any restriction on a licensed medicinal preparation must rest on a firm statutory footing.
14. It follows that the impugned orders dated 12.07.2022 and 22.09.2022 must be set aside. The Appellants, holding a valid license and acting within the boundaries of existing regulations, are entitled to resume their business of selling the aromatic tincture of cardamom and any other duly permitted medicines. The Respondent authorities, if genuinely concerned about 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.
15. The civil appeals are allowed.
16. The impugned orders dated 12.07.2022 and 22.09.2022 passed by the High Court of Judicature at Allahabad in Writ C No.13134 of 2022 and Civil Misc. Review Application No.355 of 2022, respectively, are hereby set aside.
17. Consequently, the orders dated 28.02.2022 and 11.04.2022 issued by the Respondent No.5 and Respondent No.8 are also quashed.

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It is further directed that the Respondent authorities shall not, in the absence of any valid prohibition or restriction notified by the Central Government under the D&C Act, 1940 or the rules made thereunder, impose any limitations, conditions, or curbs on the Appellants' lawful business activities relating to the sale, distribution, and wholesaling of the aromatic tincture of cardamom or any other duly licensed medicine. The Appellants shall be entitled to carry on their trade in accordance with their valid license and all applicable statutory provisions, free from unwarranted interference.

18. Pending applications, if any, shall stand disposed of.

Result of the case: Appeals allowed.

[†]*Headnotes prepared by:* Niti Richhariya, Hon. Associate Editor
(Verified by: Abhinav Mukerji, Sr. Adv.)