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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**% *Date of Decision : 21.08.2026*# **CNR No. DLHC010392142026**+ **W.P.(C) 12189/2026 & CM APPL. 56503/2026****INDIAN PHARMACEUTICAL ALLIANCE** Petitioner

Through: Mr. Raj Shekhar Rao, Senior Advocate along with Mr. Shyam Kumar, Mr. Iqra Khan, Ms. Kumari Ruchi and Ms. Akanksha Sinha, Advocates.

Versus

CENTRAL DRUGS STANDARD CONTROL ORGANISATION

.....Respondent

Through:

CORAM:**HON'BLE MR. JUSTICE TEJAS KARIA****TEJAS KARIA, J. (ORAL)****CM APPL. 56504/2026 (Exemption)**

1. Exemption is allowed, subject to all just exceptions.
2. The Application stands disposed of.

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3. The present Writ Petition has been preferred by the Petitioner, Indian Pharmaceutical Alliance (“IPA”), under Article 226 of the Constitution of India, 1950 (“**Constitution**”), seeking to ensure the uniform, effective and proper enforcement of the provisions pertaining to spurious drugs, as defined under Section 17B of the Drugs and Cosmetics Act, 1940 (“**Act**”), *inter alia*, with the following prayers:

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Signed By: NEELAM SHARMA
Signing Date: 31.08.2026
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“A. Incorporate and expressly record violations of Section 17B (Spurious Drugs) of the Drugs and Cosmetics Act, 1940, including violations under Section 17B(e), in the Government Analyst's report in Form-13, in addition to chemical or pharmacopeial test results;

B. Mandatorily call for, obtain, and retain authentic reference samples and comparative verification reports from the original genuine licensed manufacturer whose product is alleged to have been counterfeited, for the purpose of determining identity, origin, and spuriousness of the seized or suspected drug;

C. Mandate comparative examination of the seized or suspected drug with the genuine product, including comparison of physical characteristics, packaging, labelling, batch details, trade dress, and other identifying features, in addition to chemical analysis;

D. Require that the findings of such comparative examination and the verification report of the original manufacturer be incorporated and reflected in Form-13, so as to conclusively determine whether the seized drug is "spurious" within the meaning of Section 17B of the Act;

E. Ensure time-bound and fast-track investigation and initiation of prosecution in complaints involving spurious drugs under Section 17B of the Drugs and Cosmetics Act, 1940, within prescribed timelines;

F. Direct the Respondent to integrate the reporting of Spurious Drugs under Section 17B into the SUGAM /National Single Window System (NSWS) portal to ensure real-time alerts across all State Drug Control Authorities immediately upon a manufacturer's verification of a counterfeit batch;”

4. The principal grievance urged by IPA in the present Petition is that, in the absence of a uniform and binding Standard Operating Procedure (“SOP”) governing the investigation of offences relating to spurious drugs, counterfeit drugs bearing the branding and trade dress of genuine manufacturers are being treated as non-actionable merely on the basis that the seized samples have passed limited or standard chemical analysis.



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5. Accordingly, it was submitted by learned Senior Counsel for the IPA that the Respondent, Central Drugs Standard Control Organisation, be directed to issue a uniform and binding Circular / SOP requiring all State Drug Control Authorities to:

- i. incorporate violation of Section 17B (Spurious Drugs) of the Act in Form 13 of the Act;
- ii. call for, obtain, and retain authentic reference samples from the original / genuine / licenced manufacturer whose product is alleged to have been counterfeited;
- iii. conduct a comparative examination of the seized or suspected drug with the genuine product, including comparison of physical characteristics, packaging, labelling, batch details, and trade dress, and to prepare and place on record comparative test reports in Form 13 based on both physical and chemical parameters of seized or suspected drugs versus the original product; and
- iv. complete timebound fast track investigation / initiate action in complaints *qua* violation of Section 178 of the Act.

6. Learned Senior Counsel for IPA submitted that, under Section 20 of the Act, Government Analysts, being scientific analysts, are appointed for the purpose of testing and analysing drugs and cosmetics to ascertain whether the same conform to the provisions of the Act. It was further submitted that Section 21 of the Act provides for the appointment of Drug Inspectors, who are entrusted with the functions of inspection, seizure, sampling and ensuring compliance with the provisions of the Act by



manufacturers, wholesalers, retailers and distributors of drugs and cosmetics. Section 22 of the Act confers powers upon Drug Inspectors to inspect premises, take samples and cause such samples to be tested by Government Analysts.

7. Learned Senior Counsel for IPA further submitted that Section 23 of the Act regulates the manner in which powers conferred upon Drug Inspectors are to be exercised and prescribes the mandatory procedure in that regard. It was also submitted that, in terms of Section 25 of the Act, the test report in Form 13, as prescribed under Rule 46 of the Drugs and Cosmetics Rules, 1945 (“**Rules**”), constitutes *prima facie* evidence for determining whether enforcement action under the Act is required to be initiated or curtailed at the threshold.

8. Learned Senior Counsel for IPA submitted that the existing Form 13 is confined solely to recording the results of laboratory analysis and testing, and does not record, examine or advert to violations relating to spuriousness, misbranding or allied contraventions prohibited under Section 17B of the Act.

9. Learned Senior Counsel for IPA further submitted that, in these circumstances, IPA seeks appropriate directions to remedy the regulatory lacuna, ensure comprehensive enforcement, and prevent the object and purpose of the Act from being defeated by an unduly restrictive evidentiary framework.

10. Having considered the submissions advanced, this Court is of the considered view that, while exercising jurisdiction under Article 226 of the Constitution, it would not be appropriate for this Court to issue directions



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mandating modification of Form 13 so as to include an examination of spuriousness under Section 17B of the Act, including verification of the true origin and manufacturer of the drug by the Drug Inspector. Such matters fall within the legislative or delegated rule-making domain, either by way of amendment to the Act by the Legislature or amendment to the Rules.

11. In view of the above, learned Senior Counsel for IPA submitted that IPA may be granted liberty to approach the Respondent and / or any other competent authority by submitting a detailed representation for redressal of its grievances and for consideration of the suggestions made in the present Writ Petition.

12. Accordingly, it is directed that, in the event that IPA submits such a representation, the same shall be considered by the Respondent or any other appropriate authority expeditiously, in accordance with law.

13. Accordingly, the present Writ Petition stands disposed of in the aforesaid terms. The pending Application also stands disposed of.

TEJAS KARIA, J

AUGUST 21, 2026/sms