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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

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Date of Decision : 18.09.2026# **CNR No. DLHC010445822026**+ **W.P.(C) 13762/2026, CM APPL. 64183/2026****GLENMARK PHARMACEUTICALS LIMITED
& ANR.**

.....Petitioners

Through: Mr. Amit Sibal, Senior Advocate with
Mr. Ajay Bhargava, Ms. Vanita
Bhargava, Ms. Archana Sahadeva,
Mr. Nilind Jain, Ms. Phalguni Nigam
and Ms. Smriti Nair, Advocates.

versus

UNION OF INDIA & ORS.

.....Respondents

Through: Ms. Radhika Bishwajit Dubey, CGSC
for UOI with Ms. Gurleen Kaur
Waraich, Mr. Kritarth Upadhyay, Mr.
Vivek Sharma and Ms. Shreya
Rakheja, Advocates for R-1 & 2.

CORAM:**HON'BLE THE CHIEF JUSTICE****HON'BLE MR. JUSTICE TEJAS KARIA****TEJAS KARIA, J. (ORAL)****CM APPL. 64184/2026 (Exemption)**

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

W.P.(C) 13762/2026 and CM APPL. 64183/2026

3. The present Writ Petition challenges Notification dated 18.08.2026
("Impugned Notification"), issued by Respondent No. 1, Union of India



under Section 26A of the Drugs and Cosmetics Act, 1940 (“Act”). The Impugned Notification restricts the manufacture, sale or distribution of all formulations of fixed dose combinations containing Chlorpheniramine Maleate and Phenylephrine Hydrochloride unless manufacturers state the warning “*fixed dose combination shall not be used in children below four years of age*” on the drug label, package insert or promotional literature.

4. Learned Senior Counsel for the Petitioners submitted that Petitioner No. 1 has, for several years, lawfully manufactured and/or marketed fixed dose combinations containing Chlorpheniramine Maleate and Phenylephrine Hydrochloride under valid approvals granted by the drug authorities and without restriction. One such formulation, also containing Paracetamol IP, Sodium Citrate IP and Menthol IP, was approved by Respondent No. 3-State Drugs Controller, Himachal Pradesh as recently as 06.04.2026.

5. Learned Senior Counsel for the Petitioners further submitted that the Impugned Notification records the Central Government’s satisfaction that other fixed dose combinations containing Chlorpheniramine Maleate and Phenylephrine Hydrochloride may pose a risk to children below four years of age and that safer alternatives are available. The Petitioners were not afforded an opportunity to justify the use or demonstrate the safety of Petitioner No. 1’s formulations and, accordingly, the Impugned Notification was issued without consultation, show cause notice or prior intimation.

6. Learned Senior Counsel for the Petitioners submitted that Petitioner No. 1 complied with the Impugned Notification immediately upon its issuance. Every formulation manufactured after 18.08.2026 bears the prescribed warning on its label, package insert or promotional literature.



7. It was submitted on behalf of the Petitioners that although the Impugned Notification expressly took effect upon publication in the Official Gazette on 18.08.2026, Respondent No. 3-State Drugs Controller, Himachal Pradesh issued an Advisory dated 27.08.2026 (“**Advisory**”) requiring compliance for existing stocks, while Respondent No. 4-Additional Drugs Controller, Bangalore issued a letter dated 01.09.2026 (“**Letter**”) directing the stoppage/recall of batches manufactured before 18.08.2026.

8. Learned Senior Counsel for the Petitioners contended that applying the Advisory and the Letter to stocks manufactured before 18.08.2026 would give retrospective effect to the Impugned Notification.

9. It was submitted by learned Senior Counsel for the Petitioner that the principal grievance of the Petitioners was confined to the retrospective application to stocks manufactured prior to 18.08.2026.

10. In support of the above submissions, learned Senior Counsel for the Petitioners relied on this Court’s order dated 24.04.2025 in ***Glenmark Pharmaceuticals Limited & Anr. v. Union of India & Anr.*** W.P.(C) 5037/2025 (“**Order**”), concerning an earlier Notification dated 15.04.2025 (“**2025 Notification**”) relating to the fixed dose combination of Chlorpheniramine Maleate and Phenylephrine Hydrochloride. It was submitted that the 2025 Notification and the Impugned Notification are materially similar regarding the mandatory warning and commencement upon publication in the Official Gazette.

11. Learned Senior Counsel submitted that the Order permitted the sale/distribution of stocks manufactured up to 15.04.2025, subject to the stipulated conditions, and protected compliant parties from coercive action



under Section 28B of the Act and a similar order may be passed for stocks manufactured before 18.08.2026.

12. In view of the same, learned Senior Counsel for the Petitioners, on instructions, stated that the Petitioners do not press Prayers (b) and (c), which challenge the Advisory and the Letter, respectively, subject to liberty to pursue any remedy available in law, if required, with regard to the said prayers. Learned Senior Counsel of the Petitioners also sought deletion of Respondent Nos. 3 to 5 from the array of parties.

13. Learned CGSC appearing for Respondent Nos. 1 and 2 submitted, upon instructions, that Respondent Nos. 1 and 2 have no objection to the disposal of the present Petition by issuing directions analogous to those contained in the Order, subject to such terms and conditions as this Court may deem appropriate in the facts and circumstances of the case.

14. We have considered the submissions of learned Senior Counsel for the Petitioners and learned CGSC for Respondent Nos. 1 and 2.

15. At the outset, in view of the statement made on behalf of the Petitioners, Prayers (b) and (c) of the Writ Petition are dismissed as withdrawn, with the liberty as prayed for. Further, upon the oral request of the Petitioners, Respondent Nos. 3 to 5 are deleted from the array of parties. The Petitioners shall file an amended Memo of Parties within two weeks.

16. A perusal of the Impugned Notification reveals that it came into force upon its publication in the Official Gazette on 18.08.2026 and restricts the manufacture, sale or distribution of all fixed dose combinations containing Chlorpheniramine Maleate and Phenylephrine Hydrochloride unless manufacturers state the warning, "*fixed dose combination shall not be used*



in children below four years of age”, on the drug label, package insert or promotional literature.

17. The Petitioners state that Petitioner No. 1 has complied with the Impugned Notification for formulations manufactured after 18.08.2026, which bear the prescribed warning and the grievance of the Petitioners is confined to stocks manufactured before 18.08.2026.

18. The Coordinate Bench of this Court, *vide* the Order, while considering the 2025 Notification containing a warning requirement identical to that prescribed by the Impugned Notification, held that in the absence of an express provision conferring retrospective effect, the 2025 Notification could not operate retrospectively. The Order further observed that the 2025 Notification employed the word ‘*shall*’ in relation to the warning requirement and came into force upon its publication in the Official Gazette.

19. Likewise, the Impugned Notification employs the word ‘*shall*’ in relation to the warning requirement and expressly provides that it shall come into force upon publication in the Official Gazette and, therefore, operates prospectively with effect from 18.08.2026.

20. Having regard to the submissions of the Parties for passing directions analogous to those contained in the Order in respect to 2025 Notification, while considering the object of the Impugned Notification and the concern regarding the use of such formulations in children below four years of age, we dispose of the present Petition in the following terms:

A. The Petitioners, as undertaken by them, shall compulsorily comply with the requirement of the terms of the Impugned Notification by



mentioning the prescribed warning on all stocks manufactured and circulated after 18.08.2026.

- B. The Petitioners shall put an unambiguously worded notice in two national newspapers, one in English and the other in Hindi, having nationwide circulation in all their editions. The size and space of the notice to be published by the Petitioners under this order shall be such which may instantly attract the attention of the readers.
 - C. The Petitioners shall also issue advisory to the doctors, retailers and also to the chemists clearly indicating therein that the fixed dose combination of the drugs as per the Impugned Notification shall not, in any circumstance, be prescribed for administration to the children below the age of four years.
 - D. The notice and the advisory as aforesaid shall be published/ issued within two weeks from today.
 - E. The Petitioners shall file an affidavit before this Court giving details of their stocks, which were manufactured up to 18.08.2026 along with copies of the notice and the advisory as aforesaid, within four weeks.
21. In case the Petitioners abide by the conditions aforesaid of publishing and issuing the notice and advisory and also filing the affidavit containing the details in respect of sale / distribution of the drug in question manufactured up to 18.08.2026, no coercive measures in terms of Section 28B of the Act shall be taken against the Petitioners.
22. Publishing of the notice in the newspaper as aforesaid shall not be construed to be an advertisement so as to entail any action against the



Petitioners for breach of the terms and conditions of the license for manufacture of the drug.

23. With the aforesaid observations and directions, the present Petition along with pending applications, if any, stands disposed of.

24. We, however, may observe that all the pleas on behalf of the Parties are left open to be considered in some appropriate matter in future.

25. List on 05.11.2026 for compliance.

TEJAS KARIA, J

DEVENDRA KUMAR UPADHYAYA, CJ

SEPTEMBER 18, 2026

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