



2025:DHC:2910-DB



\$~69 & 70.

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

+

Date of Decision: 24.04.2025

% W.P.(C) 5037/2025 & CM APPL. 23137/2025, CM APPL.
23138/2025

GLENMARK PHARMACEUTICALS LIMITED & ANR.

.....Petitioner

Through: Mr. Amit Sibal, Sr. Adv. with Mr.
Ajay Bhargava, Ms. Vanita Bhargava,
Mr. Aseem Chaturvedi, Mr. Milind
Jain, Mr. Ankit Handa, Mr. Ankur
Vyas and Mr. Saksham Dhingra,
Advts.

versus

UNION OF INDIA & ANR.

.....Respondent

Through: Mr. Nishant Gautam, CGSC with Mr.
Vardhman Kaushik, Mr. Vipul Verma
and Mr. Prithviraj Dey, Advts.
Mr. Rishikant Singh, Mr. Dinesh
Kumar, Advts., Mr. Arvind Kukrety,
DDC(I), Mr. Vijay Chandankar,
DDC(I), Mr. Deepak Kumar, ADC(I),
Mr. Pratyush Kumar, ADC(I)

+ W.P.(C) 5038/2025 & CM APPL. 23139/2025, CM APPL.
23140/2025, CM APPL. 23141/2025

ZUVENTUS HEALTHCARE LIMITED & ANR.....Petitioner

Through: Mr. Dayan Krishnan, Sr. Adv. with
Ms. Archana Sahadeva, Mr. Sreedhar
Kale and Mr. Surkit Seth, Advts.



2025:DHC:2910-DB



versus
UNION OF INDIA & ANR.

Through:

.....Respondent

Mr. Nishant Gautam, CGSC with Mr. Vardhman Kaushik, Mr. Vipul Verma and Mr. Prithviraj Dey, Advs.

Mr. Rishikant Singh, Mr. Dinesh Kumar, Advs., Mr. Arvind Kukrety, DDC(I), Mr. Vijay Chandankar, DDC(I), Mr. Deepak Kumar, ADC(I), Mr. Pratyush Kumar, ADC(I)

CORAM:

HON'BLE THE CHIEF JUSTICE

HON'BLE MR. JUSTICE TUSHAR RAO GEDELA

DEVENDRA KUMAR UPADHYAYA, C.J. (ORAL)

1. Heard the learned counsel for the parties.
2. These petitions instituted under Article 226 of the Constitution of India assail the validity of notification dated 15.04.2025 (hereinafter referred to as the Impugned Notification) issued by the Ministry of Health and Family Welfare (Department of Health and Family Welfare), Government of India whereby the Government has restricted the manufacture, sale or distribution of all formulations of fixed dose combination of Chlorpheniramine Maleate + Phenylephrine Hydrochloride subject to the condition that the manufacturers shall mention the warning "fixed dose combination shall not be used in children below four years of age" on the label and package insert or the promotional literature of the drug.
3. Various grounds have been urged to impeach the Impugned Notification, including that before issuing the Impugned Notification,



2025:DHC:2910-DB



opportunity of hearing was not provided to the manufacturers and other stakeholders which is mandatory in terms of the law laid down by the Hon'ble Supreme Court in *Union of India and Anr. v. Pfizer Limited And Others, (2018) 2 SCC 39*.

4. One of the arguments raised is that irrespective of the validity or otherwise of the Impugned Notification, it cannot be made applicable retrospectively in the sense that the respondents cannot insist to put such a label to the stock already manufactured on or before 15.04.2025.

5. Learned senior counsel for the petitioners have also stated that so far as the prospective application of the Impugned Notification is concerned, the petitioners do not have any objection and, accordingly, they undertake that all the stock which may be manufactured after 15.04.2025 shall necessarily contain the label as per the requirement of the Impugned Notification. However, a concern has been expressed on behalf of the petitioners that since the Impugned Notification is to operate, in its terms itself, prospectively, the drugs and formulations which are the subject matter of the notification, which have already been manufactured and are already in circulation in the market, cannot bear the label as required. The submission thus is that circulation and sale of such formulations cannot be checked taking aid of the Impugned Notification.

6. Our attention has also been drawn to the fact that the drug in question with the formulation as given in the Impugned Notification has been manufactured by the petitioners under a valid license and terms of the said license do not require the petitioners to put any such label and, therefore, for



2025:DHC:2910-DB



the stocks already manufactured till 15.04.2025 cannot be subjected to the Impugned Notification and sale of such formulation cannot be the basis of any coercive action in terms of Section 28B of the Drugs and Cosmetics Act, 1940 (hereinafter referred to as the Act).

7. Learned counsel representing the respondents has, however, opposed the prayers so far as quashing of the Impugned Notification dated 15.04.2025 is concerned. He has submitted that the Impugned Notification has been issued by the Central Government in exercise of its statutory power vested in it under Section 26A of the Act and due consultation with the Subject Expert Committee and Drugs Technical Advisory Board was done before taking the impugned decision in the matter. He has further stated that the administration of such drug would likely involve risk to children below four years of age and, accordingly, keeping in view the safety and health concerns of the children, the Impugned Notification has been issued, that too in consultation with and on recommendation of the expert bodies.

8. He has also stated that the ratio laid down by the Hon'ble Supreme Court in *Pfizer Limited* (supra) will have no application in the facts of the present case. However, learned counsel for the respondents could not dispute that the Impugned Notification shall operate prospectively and, accordingly, he has stated that the condition of putting a label as per the requirement of the Impugned Notification may not be insisted upon so far as the stocks manufactured upto 15.04.2025 are concerned, yet, it is the duty of the petitioners and other such manufacturers to ensure that appropriate caution is taken by the doctors prescribing the drugs and also by the retailers



2025:DHC:2910-DB



and chemists in the market.

9. Having considered the submissions made by learned counsel for the respective parties, we are of the opinion that the Impugned Notification cannot apply retrospectively for the simple reason that the Impugned Notification does not provide for its retrospective application. It is also to be noticed that the Impugned Notification requires that manufacturers “shall” mention the warning as given in the Impugned Notification and further that it shall come into force on the date of its publication in the Official Gazette.

10. It is trite in law that any statutory provision or a piece of subordinate legislation or even a statutory notification under some statute will operate prospectively unless the statute or the notification itself provides for its retrospective application. A perusal of the Impugned Notification does not indicate that it provides for its application retrospectively.

11. Learned senior counsel for the petitioners have extended undertaking on behalf of the petitioners that so far as the stocks to be manufactured after 15.04.2025 are concerned, the petitioners shall necessarily and compulsorily comply with the requirement of the Impugned Notification. Their concern is confined only to the stocks which were manufactured upto 15.04.2025.

12. As noticed above, learned counsel representing the respondents, on instructions, from the officer present in the Court, Mr. Vijay Vitthalrao Chandankar, has unambiguously stated that the Impugned Notification will have no retrospective application.

13. In view of the aforesaid and also taking into account the concern of learned counsel for the respondents and further considering the fact that the



2025:DHC:2910-DB



Impugned Notification has been issued to safeguard the health concerns of the children below four years of age, we dispose of the writ petitions 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 wording “fixed dose combination shall not be used in children below four years of age” on the label and package insert and the promotional literature of the drug, on all stocks manufactured and circulated after 15.04.2025.
- B. The petitioners shall put an unambiguously worded notice in two national newspapers, one in English and the other in Hindi, having nation-wide 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 a week from today.
- E. The petitioners shall file an affidavit before this Court giving details of their stocks which were manufactured upto 15.04.2025 along with copies of the advertisement and the advisory as aforesaid, within two weeks.



2025:DHC:2910-DB



14. In case the petitioners abide by the conditions aforesaid of publishing and issuing the notice and advisory and also filing the affidavit containing the said details, in respect of sale/ distribution of the drug in question manufactured upto 15.04.2025, no coercive measures in terms of Section 28B of the Act shall be taken.
15. 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.
16. With the aforesaid observations and directions, the writ petitions along with pending applications, if any, stands disposed of.
17. 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.
18. List on 19.05.2025 for compliance.

DEVENDRA KUMAR UPADHYAYA, CJ

TUSHAR RAO GEDELA , J

APRIL 24, 2025

N.Khanna