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\* **IN THE HIGH COURT OF DELHI AT NEW DELHI**  
+ **W.P.(C) 8466/2023 & CM APPL. 32255/2023**  
**GLENMARK PHARMACEUTICALS LIMITED & ANR.**

..... Petitioner

Through: Mr. Darpan Wadhwa, Sr. Adv. with  
Mr. Ajay Bhargava, Mr. Aseem Chaturvedi, Ms.  
Ananmika Trehan, Mr. Karan Gupta, Mr. Milind  
Jain, Advs.

versus

**UNION OF INDIA & ANR.**

..... Respondent

Through: Mr. Rakesh Kumar, CGSC with Mr.  
Sunil, Advs.  
Mr. Avshreya Pratap Singh, Adv.  
Mr. Kirtiman Singh, CGSC  
Mr. Rishikant Singh, Waize Ali Noor, Mr. Yash  
Upadhyay, Advs. for R-2

**CORAM:**

**HON'BLE MR. JUSTICE JASMEET SINGH**

**HON'BLE MR. JUSTICE VIKAS MAHAJAN**

**ORDER**

% **14.06.2023**

**CM APPL. 32256/2023-EX.**

Allowed subject to all just exceptions.

The application stands disposed.

**W.P.(C) 8466/2023 & CM APPL. 32255/2023**

1. This is a petition seeking writ, order or direction to set aside the impugned notification S.O. 2399 (E) dated 02.06.2023 issued by the respondent No.1 which prohibits manufacture for sale and distribution for human use, the Fixed Dose Combination (FDC) of Ammonium

Chloride + Bromhexine + Dextromethorphan (“Subject FDC”) with immediate effect. The Petitioner No. 1 has been manufacturing the Subject FDC under the brand name Ascodex Dx Syrup.

2. The petitioner manufactures the said syrup for over last 30 years containing the above mentioned FDCs.
3. The impugned notification based on the recommendations of the Expert Committee and Drugs Technical Advisory Board has prohibited the manufacture for sale or distribution for human use or drug FDC of Ammonium Chloride + Bromhexine + Dextromethorphan (“Subject FDC”) with immediate effect. The Petitioner No. 1 has been manufacturing the Subject FDC under the brand name Ascodex Dx Syrup.
4. In the present case, it is stated that the impugned notification only states that the FDC may involve risk in human beings without specifying the reasons / extent and the nature. In addition, the FDC has been in the market for more than 30 years.
5. Issue notice. Mr. Kirtiman Singh, learned CGSC accepts notice, seeks and is granted 2 weeks to file a reply.
6. In somewhat similar circumstances, this Court in WP(C) 9739/2018 dated 14.09.2018 granted interim protection for the drugs already in the distribution network. Hence, it is directed that the drugs which are already in the distribution channel shall not be withdrawn. However, no fresh manufacture of the drug will take place till the next date of hearing. In addition, no coercive steps will be taken against the petitioner for the drugs which are already in the distribution channel.
7. The parties will complete the pleadings and list the matter before the

Roster Bench on 03.07.2023.

8. The petitioner will file the details of their stock before the next date of hearing and will give the affidavit of stock in circulation.

**JASMEET SINGH, J  
(VACATION JUDGE)**

**VIKAS MAHAJAN, J  
(VACATION JUDGE)**

**JUNE 14, 2023 / (MS)**

*Click here to check corrigendum, if any*