

August 23, 2024

To,

All Trade Partners, Stockists & Retailers,

Subject: Interim Relief granted by Hon'ble Delhi High Court against the Ban notification of **Tab Proxym-XT** i.e. FDC of S(+) Etodolac + Paracetamol issued by Ministry of Health & Family Welfare vide S.O. 3284 dated 12.08.2024.

Dear Trade Partners,

We, Emcure Pharmaceuticals Ltd, had received an interim relief vide order dated 22.08.2024 against the Ban notification of **Tab Proxym-XT** i.e. FDC of S(+) Etodolac + Paracetamol (S.O. 3284 dated 12.08.2024) by Honorable Delhi High Court in W.P.(C) 11566/2024

Hon'ble Delhi High Court is pleased to grant the Interim protection for the drugs already in the distribution network. Hence, court has directed that the drugs which are already in the distribution channel shall not be withdrawn. In addition, no coercive steps will be taken against the petitioner for the drugs which are already in the distribution channel. The distribution channel would cover all persons including stockists, wholesalers, retailers, Hospitals, etc.

The copy of the said order is attached herewith for your reference.

Therefore, we request all our Trade Partners to continue selling the stock of **Tab Proxym-XT** available with you.

Yours Sincerely,

For Emcure Pharmaceuticals Ltd.

Authorized Signatory

Emcure Pharmaceuticals Limited

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

+ W.P.(C) 11566/2024, CM APPL. 48078/2024, CM APPL. 48079/2024 & CM APPL. 48080/2024

EMCURE PHARMACEUTICALS LIMITED & ORS.....Petitioners

Through: Mr. Raj Sekhar Rao, Senior Advocate
with Ms. Archana Sahadeva and Mr.
Ajay Sabharwal, Advocates

versus

UNION OF INDIA & ANR

.....Respondents

Through: Mr. Kirtiman Singh, CGSC with Mr.
Waize Ali Noor, Mr. Maulik
Khurana, Mr. Ranjeev Khatana and
Mr. Varun Pratap Singh, Advocates
for UOI

CORAM:

HON'BLE THE ACTING CHIEF JUSTICE

HON'BLE MR. JUSTICE TUSHAR RAO GEDELA

ORDER

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22.08.2024

1. Present writ petition has been filed seeking quashing of the notification dated 12th August, 2024, whereby the manufacture for sale and distribution for human use of the fixed dose combination of S(+) Etodolac + Paracetamol ("subject matter FDC") was prohibited with immediate effect.
2. Learned senior counsel for the petitioners states that the report of the sub-committee, on the basis of which the ban has been notified by the respondents, has not been made public till date. He states that it remains unclear why complete prohibition of the subject matter FDC has been



recommended. He contends that the impugned notification is non-speaking and not in compliance of the judgment of the Supreme Court in ***Union of India And Anr. v. Pfizer Limited and Ors.*** [Civil Appeal No. 23472 of 2017].

3. Learned senior counsel for the petitioners has drawn the attention of this Court to the order dated 3rd July, 2023 passed in W.P.(C) No. 8593/2023 titled ***Lupin Limited and Anr. v. Union of India and Anr.*** The said order passed by the Coordinate Bench reads as under:

“1. Learned counsel for the Parties, at the outset, have drawn the attention of this Court towards an order dated 28.06.2023 passed in W.P.(No. 8593/2023. The said order passed by the Coordinate Bench reads as under:

“CM APPL. 32649/2023 (Exemption)

- 1. Exemption allowed, subject to all just exceptions.*
- 2. The application stands disposed of.*

W.P.(C) 8593/2023 & CM APPL 32648/2023

3. This is a petition seeking writ, order or direction to set aside the impugned notification S.O. 2405 (E) dated 2 June 2023 issued by Respondent 1 which prohibits manufacture for sale and distribution for human use, the Fixed Dose Combination (FDC) of Phenytoin + Phenobarbitone Sodium (“Subject FDC”) with immediate effect. The Petitioner No. 1 has been manufacturing the Subject FDC under the brand name, EPILAN.

4. The petitioner manufactures the said tablet since 2022 containing the above mentioned FDCs.

5. 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 Phenytoin + Phenobarbitone Sodium (“Subject FDC”) with immediate effect. The Petitioner No. 1 has been manufacturing the Subject FDC under the brand name, EPILAN.

6. 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 marked since 1988.

7. Issue notice. Mr. Rakesh Kumar, learned CGSC accepts notice, seeks and is granted two weeks to file a reply.

8. In somewhat similar circumstances, this Court in WP(C) 8465/2023 vide order dated 14 June 2023 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.

9. It is clarified that the direction against taking of coercive action would apply with respect to stocks manufactured on or before 2 June 2023 and that the distribution channel would cover all persons including stockists, wholesalers, retailers etc., with whom the stocks or the drug in question may be present after they have left the premises of the petitioner.

10. The parties will complete the pleadings and list the matter before the Roster Bench on 3 July 2023.

11. The petitioner will file the details of their stock as on 2 June 2023 before the next date of hearing and will give the affidavit of stock in circulation.”

*2. In the light of the aforesaid order passed by the Coordinate Bench, in order to maintain parity, it is directed that the interim-order – which has been extracted hereinabove, passed in **Lupin Limited & Anr. Vs. Union of India and Anr.** shall apply mutatis mutandis in respect of the drugs which are subject matter of the present writ petitions.*

3. The Petitioners shall file details of the stock of their respective drugs as on today, before the next date of hearing. They will also give an affidavit of stock in circulation, within one week from today.

4. As prayed for, the respondent/ Union of India is granted ten days' time to file a counter affidavit. Rejoinder, if any, be filed on or before the next date of hearing.

5. List all the above matters on 17.07.2023.”



4. In light of the aforesaid order passed by the Co-ordinate Bench and in order to maintain parity, it is directed that the interim-order, extracted above, shall apply in respect of the drug, which is subject matter of the present writ petition.
5. The petitioners shall file details of the stock of their drug as on today within a week. The petitioners will also give an affidavit of stock in circulation, within one week.
6. As prayed for, the respondent is granted four weeks' time to file the counter-affidavit. Rejoinder affidavit, if any, be filed before the next date of hearing.
7. List on 15th January 2025.

ACTING CHIEF JUSTICE

TUSHAR RAO GEDELA, J

AUGUST 22, 2024

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