

**MINISTRY OF HEALTH AND FAMILY WELFARE****(Department of Health and Family Welfare)****NOTIFICATION**

New Delhi, the 12th August, 2024

**S.O. 3284(E).**— Whereas, the Central Government in exercise of the powers conferred by section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of Etodolac + Paracetamol vide notification number S.O. 4706 (E), dated the 7<sup>th</sup> September, 2018, published in the Gazette of India, Extraordinary, Part II, Section 3, sub-section (ii), dated the 7<sup>th</sup> September, 2018;

And Whereas, the said notification was challenged by M/s. Emcure Pharmaceuticals Ltd. in W.P. (C) No. 10098/2018 before the High Court of Delhi, claiming that fixed dose combination of S(+) Etodolac + Paracetamol is not covered under the notification;

And Whereas, the Hon'ble High Court of Delhi has passed judgement dated 22<sup>nd</sup> January, 2020, the operative part of the which is reproduced below:-

“This court is of the view that the Impugned Notification, in so far as it is stated to be applicable to the FDC of S(+) Etodolac + Paracetamol cannot be sustained. The same is set aside. The matter is remanded back to DTAB/Sub-committee constituted by it to examine the issue regarding the said FDC in accordance with the directions issued by the Supreme Court in Pfizer Limited and others (Supra). The DTAB/Sub- Committee shall submit its report to the Central Government who may act thereon in accordance with law.”;

And Whereas, the Drugs Technical Advisory Board in its 88<sup>th</sup> meeting held on 26<sup>th</sup> September, 2022 deliberated the issue and recommended for constitution of a DTAB Sub- committee to examine the matter in light of the judgement passed by the Hon'ble Delhi High Court;

And where as, the DTAB Sub-Committee considered the said fixed dose combination as irrational and recommended for its prohibition in public interest under section 26A of Drugs and Cosmetics Act, 1940;

And Whereas, based on the recommendation of DTAB Sub- committee, matter was further deliberated in 90<sup>th</sup> meeting of Drugs Technical Advisory Board held on dated 25<sup>th</sup> January, 2024 and made recommendation for prohibiting the manufacture, sale and distribution for human use of fixed dose combination of S(+) Etodolac + Paracetamol;

Now, therefore, on the basis of the recommendations of the Drugs Technical Advisory Board and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale and distribution for human use of drug fixed dose combination of **S(+)** **Etodolac + Paracetamol** with immediate effect as the said drug is found to have no therapeutic justification and may involve risk to the human beings.

[F.No. X.11035/485/2017-DRS]

RAJIV WADHAWAN, Advisor (Cost)