

No.31015/49/2023-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

A Wing, Shastri Bhawan,
New Delhi-110001.

Subject: Review application of M/s Lupin Limited against NPPA's notification S.O. No. 878(E) dated 24.02.2023 in respect of Fixed Dose Combination of Dapagliflozin 10 mg + Vildagliptin 100 mg (SR) +Metformin Hydrochloride IP 500 mg (SR) and Dapagliflozin 10 mg + Vildagliptin 100 mg (SR) +Metformin Hydrochloride IP 1000 mg (SR) - regarding.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Lupin Limited (hereinafter called the petitioner) against notification S.O. No. 878(E) dated 24.02.2023 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Fixed Dose Combination of Dapagliflozin 10 mg + Vildagliptin 100 mg (SR) +Metformin Hydrochloride IP 500 mg (SR) and Dapagliflozin 10 mg + Vildagliptin 100 mg (SR) +Metformin Hydrochloride IP 1000 mg (SR).

2. Any review petition under paragraph 31 of the DPCO has to be submitted within 30 days of the publication of the notification in the gazette or the receipt of the order. The same is being reproduced as below:

31. Power to review.— Any person aggrieved by any notification issued or order made under paragraphs 4, 5 and 6 of this Order, may apply to the Government for a review of the notification or order within a period of thirty days of the date of publication of the notification in the Official Gazette or the receipt of the order by him, as the case may be, and the Government may make such order on the application as it may deem proper:

Provided that pending a decision by the Government on the application submitted under the above paragraph, no manufacturer shall sell a scheduled formulation or a new drug, as the case may be, at a price exceeding the ceiling price or retail price, as the case may be, fixed by the Government of which a review has been applied for.

3. The petitioner has filed the review petition on 28.03.2023, that is, more than 30 days after the notification of the NPPA. As the petition has not been submitted within the time limit prescribed in paragraph 31 of the DPCO, the same is rejected.

Issued on this, the 19th day of May, 2023.


19/05/2023
(Awadhesh Kumar Choudhary)

Sr. Economic Adviser to the Government of India
[For and on behalf of the President of India]

To

M/s Lupin Limited, 4th Floor, World Trade Tower, Barakhamba Avenue, Connaught Place,
New Delhi-110 001.

Copy to:

1. The Chairman, National Pharmaceutical Pricing Authority, YMCA Cultural Centre Building, New Delhi-110001.
2. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi.
3. PSO to Secretary(Pharma), Shastri Bhawan, New Delhi.
4. Technical Director, NIC for uploading the order on Department's Website.
5. Guard File