

No. 31015/2/2018-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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A - Wing, Shastri Bhawan,
New Delhi 110 001

Order

1. This is an order on an application dated 29.12.2017 filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Lupin Limited (hereinafter called the applicant) against notification S.O. No. 3915(E), dated 18.12.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling prices of Ramipril IP 5mg + Amlodipine 5mg.

2. The applicant has contended as under:-

2.1 Company referred to minutes of the Authority meeting of NPPA held on 15/12/2017. Para 4.1 mentions about the methodology adopted to fix the prices for Form I applications received. Based on such methodology, NPPA has allowed the same price which was notified in 2015. By adopting the methodology discussed in the authority meeting, NPPA has ignored the laid down methodology detailed in Para 4, 5 & 15 of DPCO, 2013 to dispose of Form I application.

2.2 NPPA fixed the price in 2015 erroneously applying the principles of monopolistic criteria (Para 6) against the price applied for under Para 15 by submitting Form I. Monopolistic pricing formula under Para 6 is applicable only to Scheduled formulation and the same is not applicable to New drugs, which are Non-scheduled.

2.3 Subsequent to the fixation of Retail price, NPPA in its Authority Meeting held on 15th July 2015, had taken a decision that monopolistic conditions will not be made applicable to retail price fixation under Form I prospectively.

2.4 Looking at the facts referred to above, NPPA has erred in fixing the same old price, which was notified in 2015 erroneously considering monopoly, even after NPPA has decided to rectify the same prospectively in their Authority Meeting on 15th July 2015. Thus company requested this Department to quash the order under reference and direct NPPA to refix the price as per the provisions of DPCO, 2013.

3. Comments of NPPA:

3.1 Retail price of Ramipril IP 5mg + Amlodipine 5mg tablet notified as Rs 4.11 vide S.O. 3915 (E) dated 18.12.2017 as per Para 5, 11 and 15 of DPCO, 2013.

3.2 The company has stated that correct methodology was not followed in arriving at the retail price of Ramipril IP 5mg + Amlodipine 5mg tablet. The points raised by the company are not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013. Details are as follows:-

Company's Grievances	NPPA's comments
<p>Company referred to minutes of Authority meeting of NPPA held on 15/12/2017. Para 4.1 mentioned about the methodology adopted to fix the price for form I application received. Based on such methodology, NPPA has allowed the same price which was notified in 2015. By adopting the methodology discussed in the Authority meeting, NPPA has ignored the laid down methodology detailed in Para 4, 5 & 15 of DPCO to dispose of Form I application. NPPA fixed the price in 2015 erroneously applying the principles of monopolistic criteria (Para 6) against the applied for under Para 15 by submitting Form I. Monopolistic price formula under Para 6 is not applicable to new drug. Subsequently to fixation of retail Price, NPPA in its Authority meeting held on 15/07/2015, had taken decision that monopolistic conditions will not be made applicable to retail price fixation under Form I prospectively.</p> <p>Thus company requested to quash the order under reference re fix the price as per the provisions of DPCO, 2013.</p>	<p>NPPA fixed the retail price of Ramipril IP 5mg + Amlodipine 5mg tablet manufactured/ marketed by M/s Lupin Limited as Rs 4.11 per tablet, vide S.O. 3915 (E) dated 18.12.2017 as per the decision taken in 51st Authority meeting, wherein it was decided that wherever the application has been received by NPPA for any drug for which NPPA has already notified the price, the same would be extended to the subsequent applicants also, accordingly the price was fixed as per the above decision. This decision has been endorsed in a high level meeting. As regards Company's contention of erroneously applying the principles of monopolistic criteria is concerned, it is stated that firstly, the retail price of this formulation was fixed in 2015 and currently valid also.</p> <p>Therefore, no further action is required and review order in this case may be treated as closed.</p>

4. **Examination:**

4.1 The decision taken in 51st Authority meeting of NPPA, held on 15.12.2017 was erroneous as it was beyond the powers of NPPA to take such a decision which was contrary to the clear provisions provided in DPCO, 2013 for fixing retail price of a new drug. In the result that the ground on which NPPA fixed the price of subject formulation is wrong and against provisions provided in DPCO, 2013.

4.2 In view of the position explained above, the NPPA needs to be directed to fix the retail price of new drug strictly as per provision of para 5(1) read with para 9(4) of DPCO, 2013.

5. Government Decision:

“NPPA is hereby directed to refix the retail price of new drug Ramipril IP 5mg+ Amlodipine 5mg Tablet strictly as per provision of para 5(1) read with para 9(4) of DPCO, 2013.”

“NPPA is further directed to take similar action in all similar cases within a period of one month from the date of issue of the order.”

Issued on this date, the 8th day of June, 2018.

(M.K. Bhardwaj)
Deputy Secretary
For and on behalf of the President of India

Copy to:-

1. M/s Lupin Limited, 4th Floor, World Trade Tower, Barakhamba Avenue, Connaught Place, New Delhi-110 001.
2. The Member Secretary, National Pharmaceutical Pricing Authority, YMCA Cultural Centre Building, New Delhi-110001
3. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.
4. PS to MoS(C&F), Shastri Bhawan, New Delhi for information.
5. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
6. T.D., NIC for uploading the order on Department's Website