

No. 31015/31/2015-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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B Wing, Janpath Bhawan, New Delhi

O R D E R BY REVIEWING AUTHORITY UNDER PARA 31 OF DPCO, 2013

Subject: Review application of M/s. Lupin Ltd. against S.O. No. 1213(E) dated 06.05.2015 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013) for price fixation of “Ramipril + Amlodipine Tablets”.

Ref. 1) The Review application dated 13.05.2015
2) NPPA notification under review S.O. No. 1213(E) dated 06.05.2015
3) Record Note of discussions held in the personal hearing held in the matter on 08.06.2016

This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Lupin Ltd. (hereinafter called the petitioner) against notification S.O. No.1213(E) dated 06.05.2015 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the retail price of their new drug, i.e. “**Ramipril + Amlodipine Tablets**”.

2. After considering the submissions of the petitioner on which comments given by NPPA representative during the hearing and Government’s comments on the issue, is recorded against each point:

Petitioner: The petitioner representative referred to NPPA Notification SO 1213(E), dated 6.5.2015 regarding fixation of retail price of their formulation Ramipril + Amlodipine Tablets. The petitioner representative mentioned that the monopoly condition under para 6 should not have been applied in their case as para 5 does not deal with scheduled formulations while para 6 deals with scheduled formulations. Further, Form I, i.e. form for fixation of retail price of new drug, does not specify para 6.

NPPA Comments: NPPA representative stated that DPCO provides only 2 formulae for price fixation, i.e. average basis under para 4(1) and monopoly basis under para 6(1). Since, only one manufacturer exists, price has been fixed by applying monopoly condition as per para 6(1) of DPCO 2013. Para 6 refers to those cases where price fixation has been carried out by using para 4 and the formula prescribed in para 4 is applicable for both scheduled and new drug. This has been done uniformly in all other similar cases.

NPPA representative mentioned that paras quoted in Form I are not for fixation of prices, it is only for submission of information to NPPA. For price fixation in DPCO, 2013, average formula of para 4 for more than one manufacturer and monopoly formula of para 6(1) for single manufacturer is application.

3. Department's comments:

The company representative stated that the price should have been fixed under para 5 and that para 6 applies to only scheduled drugs and does not apply to new drugs. The NPPA representative stated that as per available data, there was only one manufacturer and hence monopoly formula has been applied by NPPA.

In case of new drug price fixation, para 5(1) of DPCO 2013 refers to para 4(1). Para 4(1) provides methodology for fixing ceiling prices of scheduled formulations. Therefore, intention of framers of DPCO is to fix new drug prices with same methodology as for scheduled formulations. Para 6(1) stipulates that if there is no reduction in case of application of para 4(1), the monopoly method contained in para 6 will apply. The company has no merit in arguing that their formulation is not scheduled and, therefore, monopoly condition does not apply.

4. Decision of the Government:

The points raised by the petitioner company have no merit. Therefore, the review application of the petitioner may be rejected.

Issued on this date, the 6th day of October, 2016.

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

To

- 1. M/s. Lupin Ltd.,
C/4, Laxmi Tower, Bandra Kurla Complex (East),
Mumbai-400 051.**
- 2. The Member Secretary,
National Pharmaceutical Pricing Authority,
YMCA Cultural Centre Building, New Delhi-110001**

Copy to :

- 1. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.**
- 2. Sr. PPS to Secretary (Pharma), Shastri Bhawan, New Delhi for information.**
- 3. Technical Director, NIC with the request to upload the review order on the Department's website**