

No. 31015/10/2018-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 11.01.2018 filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Dr. Reddy's Laboratories Limited (hereinafter called the applicant) against notification S.O. No.02(E), dated 01/01/2018 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling prices of Atocor CV 20 mg Capsule.

2. The applicant has contended as under:-

2.1 NPPA issued notification no S.O. 02(E), dated 1st January, 2018 fixing retail price of ATOCOR CV 20MG CAPSULE under the provisions of Para 5, 11 and 15 of DPCO, 2013.

2.2 AND WHEREAS, NPPA issue the same retail price as provided to M/S. Orbit Lifescience Pvt. Ltd. and M/s Genx Pharma Ltd. vide notification no S.O. 3141(E) dated 10th December, 2014.

2.3 AND WHEREAS, Para 5(1) of DPCO, 2013 clearly state that "The retail price of the new drug available in domestic market shall be calculated as provided in sub-paragraph (1) of paragraph 4."

2.4 AND WHEREAS, The aforesaid formulation has been available in domestic market available through multiple suppliers based on AWACS – AIOCD data relating to aforesaid formulation.

2.5 AND WHEREAS, This decision of the NPPA basing upon the decision of the Authority Committee to provide the same retail price to a company as issued three years prior to the date of application is ultra vires Para 5(1) of DPCO, 2013. Para 5(1) of the DPCO, 2013 provides for the calculation of the retail price of the new drug as per Para 4(1). The method of Issuing of same retail price to DRL as issued to M/S. Orbit Lifescience Pvt. Ltd. and M/s Genx Pharma Ltd. vide notification no S.O. 3141(E) dated 10th December, 2014 after a period of three years without taking into consideration the changes in the market that would have taken place during this period is not contemplated under the provisions of the DPCO, 2013.

2.6 DRL files this Review Petition under Para 31 of the Drugs (Prices Control) Order, 2013 against the S.O. 02(E), dated 01st January, 2018 and as also provisions under Para 4 of Drugs (Prices Control) Order, 2013 and request to pass a speaking order in the matter. Price Notification S.O. 02(E), dated 01st January, 2018 was notified and being aggrieved by this Price Notification, this Review Petition is being filed within 30 days from the date of notification. Consequently, the Review Petition under Para 31 of Drug (Prices Control) Order, 2013 is filed within prescribed time limit.

Under the circumstances:

- a. NPPA must calculate the retail price of company's "New Drug" ATOCOR CV 20MGCAPSULE containing ATORVASTATIN 20MG AND CLOPIDOGREL 75MG under the provisions of Para 5(1) of DPCO, 2013.
- b. NPPA has wrongly notified retail price for company's formulation ATOCOR CV 20MG CAPSULE containing ATORVASTATIN 20MG AND CLOPIDOGREL 75MG.
- c. The Authority Committee decision to notify retail price is not backed by any provision of DPCO, 2013 and must be corrected.

2.7 In view of above, company prayed as under:

- a. To consider and conclude that NPPA had erred in notifying the retail price for their formulation ATOCOR CV 20MG CAPSULE containing ATORVASTATIN 20MG AND CLOPIDOGREL 75MG.
- b. NPPA must recalculate the retail price based on simple average market price existing Six month prior to the date of application as per Para 5(1) and 4(1) of DPCO, 2013.
- c. Pass a speaking order in respect hereof.
- d. Any other order in interest of this manufacturer.

3. **Comments of NPPA:**

NPPA fixed the retail price of ATOCOR CV 20MG Capsule manufactured/ marketed by Dr. Reddy's Laboratories Ltd as Rs 10.596 per capsule, vide S.O. 02(E) dated 01.01.2018 under the provision of Para 5, 11 and 15 of DPCO, 2013, 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. This decision has been endorsed at a high level meeting which has been communicated to all concerned. Accordingly, the price was fixed as per the above decision.

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. Decision:

“NPPA is hereby directed to refix the retail price of new drug Atocor CV 20 mg Capsule strictly as per provision of para 5(1) read with para 9(4) of DPCO, 2013.”

Issued on this date, the 29th day of May, 2018.

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

Copy to:-

1. M/s Dr. Reddy's Laboratories Limited, Global Generics – India, 7-1-27, Ameerpet, Hyderabad-500 016. Telangana.
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