

No. 31015/8/2018-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 16.01.2018 filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Pfizer 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 Ferrous Ascorbate + Folic Acid + Cyanocobalamin + Zinc Sulphate Monohydrate tablet (Autrin - XT).

2. The applicant has contended as under:-

2.1 NPPA has erred in fixing the retail price of company's product Autrin XT by not following the procedure laid down in Para 5 of the DPCO 2013 and also not considering the facts submitted by the company to the NPPA. The retail price per tablet has been fixed and notified by NPPA at Rs.3.63 whereas the same formulation Solfe AZ Tablets marketed by Abbott which have the same composition and strength as that of company's product Autrin XT, is available in the market at a price of Rs 95 for 10 tablets.

2.2 Autrin XT tablets containing Ferrous Ascorbate 100 mg+ Folic Acid 1.5mg+ Cyanocobalamine 15mcg+ Zinc Sulphate Monohydrate 22.5mg is not a Scheduled - formulation under DPCO 2013. Since the Company is the existing manufacturer of Folvite Tablet which contains Folic Acid 5 mg, Autrin XT Tablets has been considered by company as a 'New drug' under Para 2(u) of the said DPCO and hence applied to NPPA for price approval by submitting Form I of Schedule II to the DPCO 2013 on May 30, 2016 in compliance with Para 15 of the said DPCO for a price of Rs 100 for strip of 10's tablets in line with the competitors' price.

2.3 Necessary DCGI approval and State FDA licence for manufacturing the product were also intimated to NPPA. In terms of Para 5 of DPCO, 2013, if the retail price of the new drug is available in the domestic market, the price for new drug shall be calculated as per provisions of Para 4. NPPA has not considered the price of a similar product Solfe AZ available in market while fixing the price of company's product.

2.4 In view of the position stated above, company submitted that the retail price of company's product Autrin XT tablets has not been fixed in the manner as provided for in the DPCO 2013 and thus may be withdrawn immediately and re-fixed in true spirits of the DPCO considering the inputs provided by the company.

2.5 The price approval application in Form I was submitted by company in May 2016 for the product Autrin XT with the intention to commence the manufacturing by the last

quarter of 2016. Since there has been huge delay in the price fixation, company has not been able to bring this drug to the market, causing significant business losses to the Company and inability of patients to benefit from this product.

2.6 Without prejudice to the above submissions, company has now decided to bring the product in the market at the notified price and the first batch of the Autrin XT is expected by early April 2018. Accordingly company is not in a position to upload the relevant Form V in this regards in IPDMS of NPPA as required under para 31 of the said DPCO before filing the Review Application but company assures that this will be filed soon.

3. **Comments of NPPA:**

NPPA fixed the retail price of Autrin XT tablet manufactured by M/s Tirupati Medicare Limited & marketed by M/s Pfizer Limited at Rs 3.63 per tablet, vide S.O. 3915(E) dated 18.12.2107 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. The price of the similar formulation was fixed earlier for “Ferrous Ascorbate +Adenosylcobalamine+Zinc sulphate+Folic Acid Tablet” manufactured by M/s Theon Pharmaceuticals Ltd and marketed by MS Intas Pharmaceutical Ltd at Rs 3.79 per tablet vide SO 853 (E) dated 25.03.2015. This decision has been endorsed at a high level meeting which has been communicated to all concerned.

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 Autrin XT tablets containing Ferrous Ascorbate+Folic Acid IP+Cyanocobalamin IP+Zinc Sulphate Monohydrate IP 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 22nd day of June, 2018.

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

Copy to:-

1. M/s Pfizer Limited, The Capital, 1802/1901, Plot No.C-70, G Block, Bandra Kurla Complex, Bandra (East), Mumbai-400 051.
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