

No. 31015/6/2018-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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 Sun Pharmaceutical Industries Ltd. (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 Cefixime + Ofloxacin Tablet (Ranixime Plus).

2. The applicant has contended as under:-

2.1 In retail price notification of above formulations, market based data were not considered; rather previously notified prices were extended. As per para 9(4) of DPCO 2013 – “Market based data for fixing the retail price of new drugs available in the market, shall be the data available for the month ending immediately before six months of receipt of application for fixing the price of the new drug.” Therefore, the price notified for captioned formulations appear to be contrary to DPCO provisions.

2.2 Through OM F.No.19(78)/2014/DP/NPPA/Div.II dated 19.12.2017; NPPA clarified that retail price for such formulations were notified on 18.12.2017 where the price of the similar drug was already approved by NPPA, by extending the same price already notified by NPPA. Such extension of previously notified price to current date is arbitrary and unfair. Company highlighted the previously notified price vis-a vis recently notified price product-wise :-

Products	Composition	Price per unit notified on 18.12.2017 (Rs.)	Previous Price per unit (Rs.)	NPPA S.O. /Date
Ranixime Plus	Cefixime 200 mg + Ofloxacin 200 mg Tablet	9.46	9.86	S.O.2965 (E)/ 15.09.2016

2.3 Working sheet of these price notifications was not uploaded on the NPPA official website. It is pertinent to note that working sheet helps in understanding the price methodology & calculation and brings transparency in procedure.

2.4 Company also reproduced extract of “Examination” and “Government Decision” of Review Order No. 31015/73/2016-PI.I dated 10.01.2017:-

“Examination:
As per provision of para 5(1) read with para 9(4) of DPCO 2013 NPPA is required to consider the PTR of available drugs in the market, take simple average of all those who have more than 1% market share and consider the new drug price as per the simple

average formula contained in para 4(1) of DPCO 2013. NPPA has fixed the retail price of Rs. 14.30/ml based on the Form-I application submitted by M/s Nitin Lifesciences (Ltd.) (manufacturer) and M/s Galpha lab Ltd. (marketing company) for the same composition vide S.O. 1562(E) dated 27/04/2016, based on the decision taken in 14th meeting of Authority held on 23/04/2014 that the price for formulations having same composition and strength shall be valid for one year. This decision is not in accordance with the provisions of DPCO, 2013.

Government Decision:

Based on the above, the Government has decided as under:

“Review application of the company is accepted and NPPA is directed to re-fix the price as per the provisions of DPCO 2013 within one month of this Order, rather than deciding the prices on its own derived principles which are beyond the provisions of DPCO 2013. The calculation sheets should also be put up in the public domain.”

2.5 In view of above, company requested to issue necessary directive to NPPA to revise the retail price of captioned formulation.

3. Comments of NPPA:

3.1 Retail price of Ranixine Plus Tablet (Cefixime 200mg+Ofloxacin 200mg Tablet) notified as Rs 9.46, vide S.O. 3915 (E) dated 18.12.2017 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 .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
Company stated that In retail price calculation of above formulation, market based data were not considered; rather previously notified prices were extended. As per Para 9(4) of DPCO, 2013 the prices notified for captioned formulation appear to be contrary to DPCO, 2013 provisions. Through OM 19(78)/2014/DP/NPPA/Div II date 19.12.2017, NPPA clarified that retail price for such formulations were notified on 18.12.2017 where the price of the similar drug was already approved by NPPA, by extending the same price already notified by NPPA. Such extension of previously notified price to current data is arbitrary unfair. Company further stated that the earlier notified price was 9.86 per tablet vide SO 2965 (E) dated 15.09.2016 whereas, NPPA vide SO 2915 (E) dated 18.12.2017 fix the price as Rs 9.46 per	The Authority examined the Form I application submitted by the company and decided in 51 st Authority meeting that wherever the application has been received by NPPA for any new drug for which NPPA has already notified the price, the same would be extended to the subsequent applicants also. Accordingly NPPA fixed the retail price of Ranixine Plus Tablet (Cefixime 200mg+Ofloxacin 200mg Tablet) as Rs 9.46, vide S.O. 3915 (E) dated 18.12.2017 as per per decision of the Authority. This decision has been endorsed at a high level meeting which has been communicated to all concerned. Earlier price of the same formulation was fixed as Rs 9.86 per tablet vide SO 2965 (E) dated 15.09.2016 when the excise duty was applicable. While fixing the

tablet. Company also stated that working sheet of this price notification was not uploaded on NPPA,s official website. Company is of the opinion that working sheet helps in understanding the price methodology & calculation and bring transparency in procedure.	subject formulation vide SO 3915 (E) dated 18.12.2017 the excise component was removed by multiplication factor of 0.095905 on account of GST implementation.
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4. Examination:

4.1 NPPA cannot decide to adopt a different methodology for fixing of retail price of a new drug when the DPCO, 2013 clearly lays down the procedure for fixing such a price. The decision taken by NPPA in its 51st Authority Meeting held on 15.12.2017 was against the provisions of DPCO and hence it cannot be a basis for fixing the retail price of a new drug.

4.2 Review application of the applicant is accepted.

5. Government Decision:

“NPPA is hereby directed to refix the retail price of new drug Ranixime Plus Tablet (Cefixime 200 mg + Ofloxacin 200 mg Tablets) 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 29th day of May, 2018.

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

Copy to :-

1. M/s Sun Pharmaceutical Industries Ltd., 8-C, 8th Floor, Hansalaya Building, 15-Barakhamba Road, 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