

**No. 31015/86/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

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A- Wing, Shastri Bhawan,
New Delhi 110 001

Subject: Two Review applications of M/s Sun Pharmaceutical Industries Limited against price fixation of "Ciprofloxacin 250mg and Ciprofloxacin 500mg tablets" vide NPPA order No. S.O. 2401(E), dated 28.07.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Two Review applications, both dated 25.08.2017
2) NPPA notification under review S.O. 2401(E), dated 28.07.2017
3) Record Note of discussions held in the personal hearing held in the matter on 07.11.2017.

1. These are two petitions under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Sun Pharmaceutical Industries Limited (hereinafter called the petitioner) against notification S.O. No.2401(E), dated 28.07.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Ciprofloxacin 250mg and Ciprofloxacin 500mg tablets.

2. The petitioner has contended as under:-

In respect of Ciprofloxacin 250 mg Tablets:

(i) The price notification S.O. No. 2401(E) dated 28/07/2017 came in effect of Review Order No. 31015/40/2015-PI.I dated 29.11.2016 and 31015/45/2016-PI.I dated 18.04.2017, and the working sheet was displayed on NPPA website on 02.08.2017.

(ii) In the working sheet, PTR of company's product CIFRAN 250 MG TABLET 10 was captured as Rs.16.76 per pack of 10 Tablets, however the correct PTR applicable in the month of August 2015 was Rs.18.63 per pack of 10 tablets. Company had already submitted the required details through their letter dated 16.01.2017 in response to NPPA letter dated 10.01.2017 based on Review Order. Despite providing all the required details, correct PTR of CIFRAN 250 MG TABLET 10 applicable in the month of August 2015 was not considered in ceiling price calculation.

(iii) Company has submitted the price list in Form V of DPCO 2013 of the captioned ceiling price of Ciprofloxacin 250 mg Tablets.

In respect of Ciprofloxacin 500 mg Tablets:-

(i) The price notification S.O. No. 2401(E) dated 28/07/2017 came in effect of Review Order No. 31015/40/2015-PI.I dated 29.11.2016 and 31015/45/2016-PI.I dated 18.04.2017, and the working sheet was displayed on NPPA website on 02.08.2017.

(ii) The referred review order No. 31015/40/2015-PI.I reads as “NPPA is directed to adopt the correct methodology in all such cases of calculating the ceiling price of scheduled formulations as per para 4(i) of DPCO, 2013 and provisions of existing schedule-I by including market shares of only generic/brands and not company wise MAT percentage and to re-fix the ceiling price of the Ciprofloxacin 500 mg and Ciprofloxacin 250 mg tablets, on merit, after due verification of all data within a period of one month from the date of issue of this order.”

(iii) Company submitted that despite having explicitly mentioned in Review Order product CIPLOX OD 500 MG Tablet 5 of M/S CIPLA LTD. having market share less than 1% was captured in the ceiling price calculation. Moreover this seems to be an incremental innovated formulation which should not have been captured in the ceiling price calculation.

(iv) Furthermore, company's product CIFRAN OD 500 MG TABLET 5 is an incrementally innovated formulation, thus should not have been captured in ceiling price calculation as per explanation (2) of Department of Pharmaceuticals' notification S.O. 701 (E) dated 10.03.2016. Generally, the dose frequency of CIFRAN conventional formulation is twice a day, while that of CIFRAN OD is once a day in effecting the same level of treatment. Patient would need lesser doses of OD formulation compared to conventional formulation in completing the therapy. Thereby, pricing of OD formulation should be exclusive and excluded from conventional formulation. The respective Review Order (Ref. No. 31015/40/2015-PI.I dated 29.11.2016) have considered separate treatment of incrementally innovated formulations from immediate release formulations – it read as:

“The existing Schedule- I of DPCO, 2013 is very clear that “the formulations developed through incremental innovation or novel drug delivery systems like lipid/liposomal formulations, sustained release/controlled release etc. should be considered as included only if specified in the list against any medicine. NPPA may also be directed to comply with these provisions of Schedule – I.....”

(v) Further, company also take cognizant that review order issued in respect of Propranolol 40mg capsules (DoP Ref No. 31015/102/2016-PI.I dated 24.08.2017), is also in same tone.

(vi) Company has submitted the price list in Form V of DPCO 2013 of the captioned ceiling price of Ciprofloxacin 500 mg Tablets.

3. In view of above, company requested this Department to issue necessary directive to NPPA to revise the ceiling price calculation of CIFRAN 250 MG TABLET 10 and Ciprofloxacin 500 mg Tablets.

Comments of NPPA:

1. Ceiling price of **Ciprofloxacin 250mg and 500mg tablets** was notified as Rs.1.89/tab and Rs.3.31/tab vide S.O. 2401(E) dated 28.07.2017 as per para 4, 6, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.

2. The company has stated that correct methodology was not followed in arriving at the ceiling price of **Ciprofloxacin 250mg and 500mg tablets**. 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:-

Sl. No.	Company's Grievances	NPPA's comments
1	<p><u>Ciprofloxacin 500mg tablet:-</u> Company has stated that the said price notification came in effect of review order no. 31015/40/2015-PI-I dated 29.11.2016 and 31015/45/2015-PI-I dated 18.04.2017 and the working sheet was displayed on NPPA website on 02.08.2017. Referred review order no. 31015/40/2015-PI-I reads as:- "NPPA is directed to adopt the correct methodology in all such cases of calculating the ceiling price of scheduled formulation as per para 4(1) of DPCO, 2013 and provisions of existing schedule-I by including market shares of only generic/brands and not company wise MAT percentage and to re-fix the ceiling price of the Ciprofloxacin 500mg and Ciprofloxacin 250mg tablets on merit, after due verification of all data within a period of one month from the date of issue of this order". Company has pointed out that Ciplox OD 500mg tablet 5 of M/s Cipla Ltd. having market share less than 1% even then the same was included by NPPA in the calculation sheet. In the opinion of company, Ciplox OD 500mg tablet of M/s Cipla Ltd. and their product Cifran OD 500mg tablet are incremental innovated formulation, thus, should not have been included in calculation sheet as per explanation 2 of DOP notification S.O. 701(E) dated 10.03.2016. Company has also stated that they have submitted price list in Form-V of DPCO, 2013 of Ciprofloxacin 500mg tablet.</p>	<p>NPPA fixed ceiling price of Ciprofloxacin 500mg tablets as Rs. 3.31/tab vide S.O. 2401(E) dated 28.07.2017 as per the directions given by DOP vide review order no. 31015/40/2015-PI-I dated 29.11.2016 against the review application of M/s Sun Pharmaceuticals Industries Ltd. in respect of Ciprofloxacin 500mg tablets and review order no. 31015/45/2016-PI-I dated 18.04.2017 against the review application of M/s Cipla Ltd. in respect of Ciprofloxacin 500mg tablet.</p> <p>The Authority in its 47th Meeting held on decided that the ceiling/retail price would be fixed by considering the brands having 1% or more market share. In respect of the product Ciplox OD 500 of M/s Cipla, the brand Ciplox have more than 1% market share and hence, considered in the calculation of ceiling price. NPPA has included Ciplox OD 500 mg of M/s Cipla Ltd. and Cifran OD 500mg of M/s Sun Pharmaceuticals Industries Ltd. in price calculation sheet as per the decision of 27th Authority Meeting held on 29.03.2016 which states all variants of the product is to be taken while calculating the price fixation of the formulation unless different variants of the formulations are specially mentioned against any formulation in NLEM, 2015.</p>
2	<p><u>Ciprofloxacin 250mg tablets:-</u> Company has stated that the said price notification came in effect of</p>	<p>NPPA fixed ceiling price of Ciprofloxacin 250mg tablets as Rs.</p>

<p>review order no. 31015/40/2015-PI-I dated 29.11.2016 and 31015/45/2015-PI-I dated 18.04.2017 and the working sheet was displayed on NPPA website on 02.08.2017.</p> <p>In the working sheet, PTR of their product Cifran 250mg tablet 10 was considered as Rs. 16.76/pack of 10 tablet against the actual PTR Rs. 18.63 applicable in the month of August 2015. Company has claimed that they had submitted the required details vide their letter dated 16.01.2017 in response to NPPA letter dated 10.01.2017 based on review order. Company reiterated that despite providing all the required details correct PTR of Cifran 250mg tablet 10 applicable in the month of August 2015 was not considered by NPPA in price calculation sheet for fixation of ceiling price of subject formulation. Company has also stated that they have submitted price list in Form-V of DPCO, 2013 of Ciprofloxacin 250mg tablet.</p>	<p>1.89/tab vide S.O. 2401(E) dated 28.07.2017 as per the directions given by DOP vide review order no. 31015/40/2015-PI-I dated 29.11.2016 against the review application of M/s Sun Pharmaceuticals Industries Ltd. in respect of Ciprofloxacin 250mg tablets and review order no. 31015/45/2016-PI-I dated 18.04.2017 against the review application of M/s Cipla Ltd. in respect of Ciprofloxacin 250mg tablet. The details relating to PTR was send to Pharmatrac for verification. Pharmatrac in its reply stated that PTR of Rs. 18.63 for Ciprofloxacin 250mg tablet as claimed by company was not having maximum count, therefore, the same was not considered by the Authority.</p>
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3. Company has not challenged S.O. No. 2401(E) dated 28.07.2017 in any Court.

4. Examination:

Ciprofloxacin 250mg tablet:

The company claimed that the actual PTR of one of their products, i.e. CIFRAN 250mg tablet 10's pack, is Rs.18.63 whereas NPPA has captured Rs.16.76 per pack. In support of its claim, the company has submitted necessary documents, i.e. MAT and PTR data along with sample packs, invoices to retailer and summary of all invoices issued for the month of August, 2015. NPPA stated that Pharmatrac has not considered the PTR of Cifran 250mg of the company on the ground that the product is not having maximum count. Since the company has submitted necessary documents in support of the actual PTR of their product, company should not be deprived of their claim by not considering the actual PTR. In view of this, NPPA may be directed to examine the documents submitted by the petitioner company, and after verification, re-fix /revise the ceiling price of Ciprofloxacin 250mg tablet, on merit.

Ciprofloxacin 500mg tablets:

On perusal of the calculation sheet, it is seen that NPPA has considered the PTR of Ciplox OD 500MG Tablet 5 of M/s Cipla Ltd., MAT value of which is only 0.1%. NPPA stated that ceiling/retail price has been fixed by considering the brands of M/s Cipla Ltd. having 1% or more market share. The principle adopted by NPPA is not as per the provisions of DPCO, 2013. It may be mentioned here that DPCO, 2013 does not allow averaging of all brands of a company but provides for averaging only of brands with more than 1% market share. Therefore, the PTR of Ciplox OD 500MG Tablet 5 of M/s Cipla Ltd. having MAT value of less than 1% market share should not be considered while fixing the ceiling price of the subject formulation. In view this, NPPA may be directed to re-fix and renotify the ceiling price of Ciprofloxacin 500mg tablets by considering PTR of those formulations having MAT value of more than 1% market share, as per para 4 of DPCO, 2013.

The petitioner company requested for considering separate pricing for their product CIFRAN OD 500 MG tablet 5's pack being an incrementally innovated formulation. Company stated that generally the dose frequency of conventional formulation is twice a day while that of CIFRAN OD is once a day effecting the same level of treatment and patient would need lesser doses of OD formulation compared to conventional formulation in completing the therapy. NPPA stated that all variants of the product are taken while calculating the price fixation of the formulation unless different variants of the formulations are specially mentioned against any formulation in NLEM, 2015.

As per para 11(3&4), in case of injections or inhalation or any other medicine for which dosage form or strength or both are not specified in the Schedule I of Drugs (Prices Control) Order, 2013, the Government may fix and notify separate ceiling price or retail price for such formulations, with specified therapeutic rationale, considering the type of packaging or pack size or in the unit dosage as the case may be, conforming to Indian Pharmacopeia or other stands as specified in the Drugs and Cosmetics Act, 1940 (23 or 1940) and the rules made thereunder for the same formulation. The existing Schedule-I of DPCO, 2013 [Explanation(2) of SO 701(E), dt.10.3.2016] also states that innovation in medicine must be encouraged. The formulations developed through incremental innovation or novel drug delivery systems like lipid/liposomal formulations, sustained release/controlled release etc. should be considered as included only if specified in the list against any medicine. Such different formulations should be considered differently for purposes such as procurement policy, pricing, etc.

The company claimed that generally the dose frequency of conventional formulation is twice a day while that of CIFRAN OD is once a day effecting the same level of treatment and patient would need lesser doses of OD formulation compared to conventional formulation in completing the therapy. In view of this, the request of the company for separate pricing of their product being incrementally innovated on the ground of lesser dose for the same level of treatment deserve to be considered by Expert Committee under the provision in para 11(3&4) of DPCO, 2013. Therefore, it is proposed that NPPA may be directed to refer the matter to the Expert Committee to examine and recommend whether separate ceiling price can be considered based on lesser doses of OD formulation compared to conventional formulation in completing the therapy. Thereafter, the recommendation of the Expert Committee may be examined by

NPPA to take a decision about refixation of separate ceiling price of Cifran OD 500 MG tablet, containing Ciprofloxacin 500mg, on merit.

Government Order:

“NPPA is hereby directed to examine the information/documentary proof, i.e. MAT and PTR data of CIFRAN 250mg tablets 10’s pack along with sample packs, invoices to retailer and summary of all invoices issued for the month of August, 2015, submitted by the petitioner company, and after verification, re-fix/revise the ceiling price of Ciprofloxacin 250mg, on merit.”

“NPPA is further directed to revise the ceiling price of Ciprofloxacin 500mg tablets, considering only the brands and generic versions of the medicine having market share more than or equal to 1% of the total market turnover on the basis of MAT of that medicine.”

“NPPA is also directed to refer the matter to the Expert Committee to examine and recommend whether separate ceiling price can be considered for Cifran OD 500mg tablet, based on lesser doses of OD formulation compared to conventional formulation in completing the therapy. Thereafter, the recommendation of the Expert Committee may be examined by NPPA to take a decision about refixation of separate ceiling price of Cifran OD 500 MG tablet, containing Ciprofloxacin 500mg, on merit.”

“The above directions be implemented within a period of thirty days from the date of issue of this order and compliance report be submitted.”

Issued on this date, the 26th day of February, 2018.

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

To

1. M/s. Sun Pharmaceutical Industries Limited,
Sun House, Plot No.201 B/1,
Western Express Highway, Goregaon (E),
Mumbai-400063.
2. Member Secretary,
National Pharmaceutical Pricing Authority,
YMCA Cultural Centre Building,
1, Jai Singh Road, New Delhi-110001

Copy to :

1. PS to Hon’ble Minister (C&F), Shastri Bhawan, New Delhi for information.
2. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
3. T.D., NIC for uploading the order on Department’s Website