

No. 31015/40/2015-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 applications of M/s. Sun Pharmaceuticals Industries Ltd. against fixation of ceiling price of “Ciprofloxacin 500 mg tablet” and “Ciprofloxacin 250 mg tablet” vide NPPA notification S.O. No. 1686(E) dated 09.05.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013).

Ref. 1) Two Review applications dated 04.06.2016
 2) NPPA notification under review S.O. No. 1686(E) dated 09.05.2016
 3) Record Note of discussions held in the personal hearing held in the matter on 15.07.2016

This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Sun Pharmaceuticals Industries Ltd. (hereinafter called the petitioner) against notification S.O. No.1686(E) dated 09.05.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of “Ciprofloxacin 500 mg tablet” and “Ciprofloxacin 250 mg tablet”.

2. The main grievances of the company are that –

For Ciprofloxacin 500 mg tablets :

1. The working sheet showing calculation of ceiling price displayed on the website of NPPA on 10.05.2016 is not correct. The ceiling price was revised as Rs. 3.30 per Tablet. As per calculation shown in working sheet, it is apparent that total 15 packs, having 1% Market Share or above were considered in calculating ceiling price. On careful observation, it was found that 6 packs out of 15 have been taken into consideration in ceiling price calculation, which ideally should not have been included, as either they are Innovative tablets like Once a Day Extended Release Tablets or they are discontinued/seem to be discontinued. Details of these 6 packs are described as follows:
 - I. 1 pack of CIPRACT 500 MG TABLET 10 (mentioned at Sr. no. 41 of working sheet) is discontinued, and 1 pack of ALCIFLOX 500 MG TABLET 10 (mentioned at Sr. no. 5 of working sheet) seems to be discontinued.
 - II. 3 packs viz. ALCIPRO OD 500 MG TABLET 10 (mentioned at Sr. no. 6 of working sheet), CIPLOX OD 500 MG TABLET 5 (mentioned at Sr. no. 14 of working sheet) and CIFRAN OD 500 MG TABLET 5 (mentioned at Sr. no. 39 of working sheet) are Once Daily Product, and, thus, are innovative products.

2. Department of Pharmaceuticals' Notification S.O. 701(E) dated 10.03.2016, which explains at explanation 2 (Page No. 50) - "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." Considering this explanation, innovative Ciprofloxacin 500 mg Tablets (sustained release, controlled release products, and other related) should not have been considered in calculating ceiling price, as the innovative category is not categorized for Ciprofloxacin 500 mg Tablet in the list of NLEM 2015. This is beyond the provision of notification.
3. 1 pack of CIFRAN OD 500 MG TABLET 10- this is innovative product, as well as discontinued from the market. Despite being an innovative product, that is now discontinued, has been considered in ceiling price calculation. The above mentioned 6 packs have been considered in calculation of ceiling price, and thus have led to fixation of incorrect ceiling price.
4. Working sheet (dated 10.05.2016) of ceiling price calculation suggest that price data reference period of MAT August 2015 was taken. Price data of six months prior to the date of notification, which in this case appears November 2015, should have been considered ideally. It would be fair treatment to industry for taking 6 months prior data in ceiling price calculation.

For Ciprofloxacin 250 mg tablets :

5. The working sheet showing calculation of ceiling price displayed on the website of NPPA on 10.05.2016 is not correct. The ceiling price was revised as Rs. 1.62 per Tablet. As per calculation shown in working sheet, it is apparent that total 13 packs, having 1% Market Share or above were considered in calculating ceiling price. On careful observation, it was found that 4 packs out of 13 packs have been taken into consideration in ceiling price calculation, which ideally should not have been included, as they are either discontinued or seem to be discontinued. Details of these 4 packs are described as follows:
 - I. 1 pack of CIPRACT 250 MG TABLET 10 (mentioned at Sr. no. 35 of working sheet) is discontinued.
 - II. 3 packs - CIPROFLOXACIN (BLUE CROSS) 250 MG TABLET 10 (mentioned at Sr. No. 12) , NEOCIP 250 MG TABLET 10 (mentioned at Sr. No. 16), GERCIP 250 MG TABLET 10(mentioned at Sr. No. 41)seems to be discontinued.
 - III. Despite having discontinued, these 4 packs were considered in calculation, and that have led to fixation of incorrect ceiling price.
 - IV. Working sheet (dated 10.05.2016) of ceiling price calculation suggest that price data reference period of MAT August 2015 was taken. Price data of six months prior to the date of notification, which in this case appears November 2015, should have been considered ideally. It would be fair treatment to industry for taking 6 months prior data in ceiling price calculation.
 - V. The details in the calculation / working sheet in terms of Price to Retailer (PTR), as on August 2015 of our product CIFRAN TABLETS 250 mg 10's

pack, is not given correctly. While actual Price to Retailer (PTR) was Rs. 18.63, in the work sheet it was considered as Rs. 16.76.

6. They requested this Department to kindly issue necessary directives to NPPA to recalculate the ceiling price.

Comments of NPPA:

- i) NPPA has fixed the ceiling price of Rs. 1.62 & 3.30 per tablet for Ciprofloxacin 250 mg & 500 mg tablet respectively vide S.O. 1686(E) dated 09.5.2016.
- ii) NLEM, 2011 and NLEM, 2015 of DPCO, 2013 does not distinguish common and innovative category for these formulation.
- iii) Company's representations are also under examination.
- iv) Para 21(2) of DPCO, 2013 was not followed for discontinuation of the above mentioned formulations by the respective companies.
- v) Formulations under reference are scheduled formulations under DPCO, 1995, NLEM 2011 and NLEM 2015.

The company was given a personal hearing on 15.7.2016, where the petitioner company representative, in addition to their written submissions, further stated that -

Ciprofloxacin 250 mg tablets :

- i. Company had already instructed the manufacturer to stop manufacturing of Cipract tablet 250 mg. before notification of DPCO 2013, i.e. 15.5.2013. However, manufacturer had supplied last batch in September, 2013. The company agreed to file Form IV for discontinuation of the captioned formulation.
- ii. Market data of six month prior should have been considered while fixing the ceiling price for the captioned product, which would be a fair treatment for the industry.
- iii. Worksheet uploaded on the NPPA's website showing ceiling price has not captured data of Cifran 250 correctly. Necessary submission has already been made to NPPA for this.

As regards points no.(i), NPPA representative submitted that since it is reflecting in the Pharma Trac data, it is being taken while fixing the ceiling price. However, NPPA would examine the matter on receipt of information from the petitioner company regarding discontinuation of subject formulation.

Regarding point no.(ii), NPPA representative stated that August 2015 data has been taken since it is six months prior to the date of notification of the amended DPCO 2013 based on NLEM 2015 and thus it is as per the provisions of DPCO 2013.

As regards point No.(iii), NPPA representative submitted that matter is under examination.

Ciprofloxacin 500 mg tablets :

- i. Company had already instructed the manufacturer to stop manufacturing of Cipract tablet 500 mg. before notification of DPCO 2013, i.e. 15.5.2013.

- However, manufacturer had supplied last batch in September, 2013. The company agreed to file Form IV for discontinuation of the captioned formulation.
- ii. Market data of six month prior should have been considered while fixing the ceiling price for the captioned product, which would be a fair treatment for the industry.
 - iii. Worksheet uploaded on the NPPA's website showing of ceiling price has wrongly captured data of Cifran OD 500 mg., which is once a day extended release formulation and should not have been clubbed with plain ciprofloxacin 500 mg tablets. Necessary submission has already been made to NPPA for this. Company has submitted justification for excluding OD formulation referring to Explanation of No.2 of amended DPCO 2013, notified vide SO 701(E), dated 10th March, 2016.

As regards points no.(i), NPPA representative submitted that since it is reflecting in the Pharma Trac data, it is being taken while fixing the ceiling price. However, NPPA would examine the matter on receipt of information from the petitioner company regarding discontinuation of subject formulation.

Regarding point no.(ii), NPPA representative stated that August 2015 data has been taken since it is six months prior to the date of notification of the amended DPCO 2013 based on NLEM 2015 and thus it is as per the provisions of DPCO 2013.

As regards point no.(iii), NPPA representative stated that ciprofloxacin 500 OD tablet was developed long ago and NLEM 2015 does not mention different variants of ciprofloxacin 500 mg tablet. Hence, while fixing the ceiling price of ciprofloxacin tablet 500 mg, all variants of the tablet have been taken into account.

The company representative confirmed that before filing the review applications, the company has already submitted Form V to NPPA for implementing the notified ceiling price for both the above mentioned products.

7. Examination:

In the personal hearing on 15.7.2016, the company representative agreed to submit Form IV for discontinuation of the captioned formulations. However, after repeated reminders, NPPA confirmed on 23.9.2016, that the **petitioner company has not submitted Form IV.**

Therefore, the contention of the petitioner company that NPPA has taken the data of prices of drugs discontinued/seems to be discontinued while calculating the ceiling prices of the subject formulations, has got not merit.

The other point of taking price data of six months prior to the date of notification, which in this case appears November, 2015, but NPPA has taken MAT of August, 2015, NPPA has taken August 2015 data since it is six months prior to the date of notification of the amended DPCO 2013 based on NLEM 2015 and thus it is as per the provisions of DPCO 2013.

Regarding the contentions of the petitioner company regarding wrongly capturing data of Cifran 250 and Cifran 500, there is a basic flaw in calculating the

ceiling prices in the case of both Ciprofloxacin 250 mg and Ciprofloxacin 500 mg. In the computation sheet, NPPA has erred in taking the company-wise percentage of MAT instead of SKU-wise MAT. This is in gross violation of para 4(i) of the DPCO, 2013, which gives the methodology of calculating the ceiling prices of Scheduled formulations. It does not provide for calculating the ceiling prices of company-wise MAT percentages, but on individual brand and generic versions having market share of more than 1%. If the revised computation is done, only 8 versions would be used for computation of ceiling prices of Ciprofloxacin 250 mg and 8 versions also for Ciprofloxacin 500 mg., instead of 13 and 15 versions respectively considered by NPPA in their computation. Also, the existing data used for computation needs to be verified. 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 and to use the correct methodology for computation of ceiling by including market shares of only generic/brands and not company-wise MAT percentage.

9. Government Decision:

"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 prices 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".

Issued on this date, the 29th day of November, 2016.

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

To

- 1. M/s. Sun Pharmaceuticals Industries Ltd.,
SUN HOUSE, CTS No.201 B/1, Western Express Highway,
Garegaon (E), Mumbai-400063.**
- 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**