

**No. 31015/34/2015-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 application of M/s. Sun Pharmaceuticals Industries Ltd. against fixation of ceiling price of “Ciprofloxacin HCL Tablet 250 mg” vide NPPA notification S.O. No. 1882(E) dated 13/7/2015 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013).**

Ref. 1) The Review application dated 12.08.2015  
2) NPPA notification under review S.O. No. 1882(E) dated 13/7/2015  
3) Record Note of discussions held in the personal hearing held in the matter on 07.06.2016

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.1882(E) dated 13.07.2015 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of “**Ciprofloxacin HCL Tablet 250 mg**”.

2. The main grievance of the company is that the data considered by NPPA was pertaining to September, 2013 while the notification was issued by them in September, 2014, which is one year later while the period is six months as per DPCO, 2013. Further, the company stated that they did not avail any WPI. However, WPI was due to for the year 2012 as well as 2013. Company representative further referred the Hon'ble Bombay High Court Order dated 14.1.2005 in WP No.6135/03 vacated the interim orders, if any. The company further referred to the Hon'ble Bombay High Court Order dated 15.3.2005 vide which the ad interim order dated 20.3.2003 stood revived. The company referred to the Hon'ble Bombay High Court Order dated 22.6.2006 by which the petition of the company was dismissed. Civil application of the company was also disposed off. The company mentioned that there is no order stating that interim orders of 20.10.2003 stand vacated. The company also referred to the Order dated 27.6.2006 vide which civil application of the company was restored and there is no order to the vacation of interim order. The company mentioned that as per Order dated 20.10.2003 granting an interim stay to the company, the company is not required to follow the ceiling price notified by NPPA.

3. NPPA clarified that at the outset price fixation of essential medicines of Ciprofloxacin 250 mg has been carried out by NPPA in accordance with the provisions of DPCO, 2013. There is no bar neither in 2013 nor it was in DPCO 1995 to carry out price fixation of Ciprofloxacin. NPPA denied the contention of the review applicant as NPPA has carried out price fixation in 1995 in accordance with the provisions of DPCO, 1995 which were continuing till the promulgation of DPCO, 2013. In accordance with

the provisions of para 10 of DPCO, 2013, NPPA has carried out the price fixation of Ciprofloxacin as per policy listed in 1995. Ceiling prices fixed by the company for Ciprofloxacin were carried out in 2013 as per para 10 of DPCO 2013. As regards the contention of petitioner company about continuing the stay in respect of Writ Petition 6135 of 2003 in Hon'ble Bombay High Court, NPPA stated that no stay was continuing as per available information, and requested the company to give the copies of that, which was not given to them. However, petitioner company forwarded certain copies of the judgements, which were not relevant and cannot be extended in this case.

4. The petitioner company further mentioned that the prices under para 10 to be fixed as per the formula given in para 4 by taking PTR of all the existing formulations having market share of 1%. The company mentioned that NPPA in their response to letter dated 10.11.2015 has mentioned that WPI is to be taken by the companies themselves on completion of one year. PTR of Rs.2.86 per tablet does not take into account WPI of 7.54% which should have been added by NPPA while fixing the ceiling prices as the said prices applicable for the company's products was decided by NPPA.

5. NPPA representative mentioned that they have notified the price as per procedure followed in such cases under the provisions of DPCO, 2013.

6. During the personal hearing on 7.6.2016, the company representatives sought amicable and fair solution of this unresolved issue of price fixation of ciprofloxacin HCL tablets 250 mg. pending since 2014 and also proposed following three possible options:-

- (a) Revision of ceiling price from Rs.2.33 per tablet to Rs.2.57 per tablet;
- (b) In case proposal (a) is not acceptable, the price should be revised from Rs.2.33/tablet to Rs.2.36/tablet;
- (c) Here, under proposal (b), petitioner company asked only WPI of calendar year 2012, i.e. 7.54%. The authority has revised ceiling price dated 21.8.2014 wherein the authority has considered WPI of previous calendar year in revising ceiling price of 36 formulations.

7. NPPA representative stated that submission and proposals submitted by the company will be examined by the Competent Authority and will be put up in their internal meeting, in case, it is found worth considering.

8. **Examination:**

The points raised by the company regarding the data, it is mentioned that as per provisions of para 10(1) of DPCO 2013, the price of common formulations under DPCO, 1995 and 2013 fixed and notified upto 31<sup>st</sup> May, 2012 have to remain effective for one year i.e. upto 31<sup>st</sup> May, 2013 and the manufacturers may revise the prices of such formulations as per WPI for the previous calendar year i.e. January 1, 2012 to 31.12.2012. In this paragraph, the WPI increase has been left to the manufacturers and if for commercial reasons, some companies choose not to avail WPI increase, it cannot be provided while fixing the prices. After taking the data of September, 2013, the prices are required to be fixed as per para 4(1). In the instant case, company did not avail WPI. Therefore, they have no merit in claiming WPI increase for 2012.

9. As regards the petitioner company's point of WPI for 2013, it may be seen from calculation sheet that NPPA has already provided WPI for 2013 in 2014. Hence, the point raised by the company has no merit.

10. Regarding the claim of petitioner company that as per Order of Hon'ble Bombay High Court, dated 20.10.2003 granting an interim stay to the company, the company is not required to follow the ceiling price notified by NPPA. It may be seen from the Orders of Hon'ble Bombay High Court dated 20.10.2003 that the company was required to furnish bank guarantee for full sum covering the difference between the control price and ceiling price during pendency of hearing and final decision of the petition, Hon'ble Court stayed the operation and implementation of the impugned notice dated 14.8.2003 vide which NPPA have directed to manufacturer to company with the Govt./NPPA fixed/notified prices. Hon'ble Court had stayed the compliance of price notification and not quashed the price notification already issued by NPPA. The Hon'ble Court had also restrained NPPA from taking any steps in furtherance of the impugned notice dated 14.8.2003. The order was restraining NPPA to call upon the company to comply with the NPPA fixed/notified prices for its drug "Ciprofloxacin HCL tablet 250 mg". Thus, it is clear that the prices notified by NPPA have not been quashed rather their implementation till final decision of the petition has been restrained so far as the company is concerned. Neither the prices fixed under DPCO 1995 have been quashed by Hon'ble Court nor NPPA has been restrained to fix prices under the subsequent DPCO, i.e. DPCO 2013. Thus the company has no merit in this point.

11. Another point raised by the company that prices under para 10 read with para 4 of DPCO 2013 have to be fixed by taking PTR of all formulations having market share of 1% is not maintainable as the price notified by NPPA under DPCO 1995 have not been quashed by the Hon'ble Court. Only a direction to NPPA has been given against any coercive action that too against a bank guarantee of difference in the notification and selling prices. Therefore, any price which is subject to review by the Hon'ble Court cannot be considered for price fixation until it reaches finality.

12. Further, the three options suggested by the petitioner during the personal hearing given on 7.6.2016 have no merit.

**13. Government Decision:**

**In view of the examination above, the review application of the company has no merit and is dismissed.**

Issued on this date, the 29<sup>th</sup> 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**