

No. 31015/59/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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**A- Wing, Shastri Bhawan,
New Delhi 110 001**

Subject: Review application of M/s Cipla Ltd. against price fixation of “Ondansetron 4mg tablet & Ondansetron 2mg/ml injection” vide NPPA order No. S.O. 1351(E) [corrected 1951(E)], dated 02.06.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref: 1) Two Review applications dated 29.06.2016
2) NPPA notification under review S.O. 1351(E) [corrected 1951(E)], dated 02.06.2016
3) Record Note of discussions held in the personal hearing held in the matter on 03.01.2017 and 28.02.2017.**

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Cipla Ltd. (hereinafter called the petitioner) against notification S.O. No.1351(E) [corrected 1951(E)], dated 02.06.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Ondansetron 4mg tablet & Ondansetron 2mg/ml injection

2. The petitioner has contended as under:-

- I. Their products Ondansetron 4 mg tablet and Ondansetron 2 mg/ml Injection were included under NLEM 2011 and continued to be included under the revised NLEM 2015. Ceiling prices of Ondansetron 4 mg tablet and Ondansetron 2 mg/ml Injection were already in force prior to the issuance of this SO no. 1351(E) **{corrected S.O. 1951(E)}** dated 02/06/2016. Please refer to S.O. No. 644 (E) dated 2nd March 2016, S.O. No. 2244 (E) dated 22/07/2013 and S.O. No. 1803(E) dated 21/06/2013 respectively for the earlier prices. While Para 17(1) clearly provides for fixation of ceiling prices in respect of products newly added in the scheduled category, Para 18 of the DPCO provides for a revision to the said Ceiling Price only if the MAT value changes of the concerned product and under certain conditions.

Para 18: Revision of ceiling price on the basis of moving annual turnover (MAT):

The revision of ceiling prices on the basis of moving annual turnover value shall be carried out:

- (i) *as and when the National List of Essential Medicines is revised by the Ministry of Health and Family Welfare or five years from the date of fixing the ceiling price under this Order, whichever is earlier;*

(ii) when the number of manufacturers of a scheduled formulation, having price of a scheduled formulation more than or equal to seventy-five percent of the ceiling price fixed and notified by the Government, has decreased by twenty-five percent or more than the number of manufacturers as existing on the reference date;

(iii) when the number of manufacturers of a scheduled formulation, having prices of their scheduled formulation equal to or lower than twenty five percent of the ceiling price fixed by the Government, has increased by twenty-five percent or more than the number of manufacturers as existing on the reference date.

Explanation: For the purpose of item (ii) and (iii) the "reference date" shall be for first revision of ceiling price May, 2012 and for second or subsequent revision the date of previous revision of the ceiling price.

- II. In this regard, they further submitted that annual revision in ceiling prices of these products were already carried out, effective from 01/04/2016, under para 16 of DPCO, 2013. Further revision in ceiling prices under para 18 without any exercise carried out on changes in MAT value and changes in the market structure of the respective product is inconsistent with the para 4(xi) of NPPP-2012 and scheme of pricing of DPCO, 2013.
- III. They further submitted that as per Para 4 of DPCO 2013 with regard to calculation of ceiling price of a scheduled formulation, only those brands that have more than 1% market share have to be considered for the purpose of calculation of the Ceiling Price. Whereas, the work sheet shows calculations on the basis of clubbing all the brands of a company irrespective of whether they hold 1% share or not. This is against the provisions of DPCO and against the spirit of Drug Policy (Para 4(xi)).
- IV. In view of the above, they requested this Department to consider their submissions made above to review ceiling prices fixed for Ondansetron 4 mg tablet and Ondansetron 2 mg/ml Injection and withdraw the notification S.O. No. 1351(E) **{corrected S.O. 1951(E)}** dated 02/06/2016 issued by the NPPA.

Comments of NPPA:

- (i) NPPA has fixed the ceiling price of Rs. 4.76/ tablet for **Ondansetron 4mg tablet** vide S.O. 2244(E) dated 22.7.2013 and the same was revised to Rs. 5.06, Rs. 5.25, & Rs. 5.11 vide S.O. 1156(E), 619(E), & 644(E) dated 28.4.2014, 26.02.2015, & 02.3.2016 respectively under NLEM 2011. Ceiling Price for Ondansetron 4mg tablet was again fixed to Rs. 4.35/tablet vide S.O. No. 1951(E) dated 02.6.2016 under NLEM- 2015.
- (ii) Ceiling Price for **Ondansetron 2mg/ml injection** was fixed at Rs. 7.37/ml vide S.O. No. 1803(E) dated 21.6.2013 for the first time and the same was revised to Rs. 7.84, Rs. 8.14 & Rs. 7.92/ml vide S.O. 1156(E), 619(E), & 644(E) dated 28.4.2014, 26.02.2015, & 02.3.2016 respectively under NLEM 2011 and ceiling price for Ondansetron 2mg/ml injection was again fixed to Rs. 5.43/ml vide S.O. 1951(E) dated 02.6.2016 under NLEM- 2015 considering para 18(1) of DPCO 2013.

3. During the personal hearing on 03.01.2017, the representatives of the company stated that they **have got only one issue** that as per Para 4 of DPCO 2013 with regard to calculation of ceiling price of a scheduled formulation, only those brands that have more than 1% market share have to be considered for the purpose of calculation of the Ceiling Price. Whereas, the work sheet shows calculations on the basis of clubbing all the brands of a company irrespective of whether they hold 1% share or not. This is against the provisions of DPCO and against the spirit of Drug Policy [Para 4(xi)].

However, in the review application, the company raised one more grievance that while revising the NLEM 2015 under DPCO 2013, the ceiling prices of only those products should be fixed which are newly added in the scheduled category in the revised NLEM. The representatives of the company were not clear about the issues raised in the review petition and being taken up during the personal hearing and requested the Hearing Authority for another date so that all the issues raised in the review petitions are taken up in the next hearing.

Accordingly another hearing was given on 28.02.2017, wherein the representatives of the company further submitted that in accordance with para 4(xi) of NPPP 2012 and the provisions of para 17 and 18(i) of DPCO 2013, NPPA can only revise ceiling price of formulations which have been newly added in the schedule I of DPCO 2013. Since, all the aforesaid formulations were covered and continue to be included in the Schedule I, the question of revision of ceiling price does not arise.

4. **Examination:**

The petitioner company has challenged the NPPA S.O. 1351(E) [corrected SO 1951(E)] dated 02.06.2016 for price fixation of their formulations **Ondansetron 4mg tablet & Ondansetron 2mg/ml injection** and the main contentions of the company are that the ceiling prices of the aforesaid formulations should not be revised as the formulations were in NLEM 2011 and continue to be included under the revised NLEM 2015. Ceiling prices of the above mentioned formulations were already in force prior to issuance of SO No. 1351(E) [corrected SO 1951(E)] dated 02.06.2016. Further, only those brands having more than 1% market share should be considered for the purpose of calculation of the ceiling prices.

As regards the contention of the petitioner company that ceiling prices for the medicines “added” in the NLEM 2015 have to be fixed and not for the products which are already in NLEM 2011, it is stated that **Para 18(i) of DPCO 2013** clearly states that the revision of ceiling prices on the basis of moving annual turnover value shall be carried out “**as and when the National List of Essential Medicines is revised by the Ministry of Health and Family Welfare or five years from the date of fixing the ceiling price under this Order whichever is earlier.**” In view of this, **NPPA has revised the ceiling prices of the formulations**, mentioned in amended list of scheduled formulations, **strictly as per the provision of DPCO 2013.** Therefore, the petitioner company has no merit in this contention.

Regarding the contention of the petitioner company about the criteria for fixing ceiling price of the subject formulations, on examination, it is found that NPPA has erred in calculating ceiling price as per para 4 of DPCO, 2013, which reads as under :-

“4. Calculation of ceiling price of a scheduled formulation

(1) The ceiling price of a scheduled formulation of specified strengths and dosages as specified under the First Schedule shall be calculated as under:-

Step 1: *First the Average price to Retailer of the scheduled formulation i.e. P(s) shall be calculated as below:-*

Average Price to Retail P(s) = *(Sum of prices to retailer of all the brands and generic versions of the medicine having market share more than or equal to one percent of the total market turnover on the basis of moving annual turnover of that medicine)/(Total number of such brands and generic versions of the medicine having market share more than or equal to one percent of total market turnover on the basis of moving annual turnover for that medicine).”*

It clearly mentions that the medicines are to be taken for calculation. In the instant case, the principles applied by NPPA go beyond what is mentioned in DPCO. Hence, NPPA may be directed to refix the ceiling price in accordance with the provisions of DPCO. The DPCO does not recognise a company for average PTR but only medicines/ formulations. Thus, only those formulations are to be considered, which are having MAT value of more than 1% market share. On going through the calculation sheet of each of the formulations, it is observed that the number of formulations which are to be considered having more than 1% market share and number of formulations to be excluded, as per table given below:-

<u>Formulation name</u>	<u>Number of brands to be considered having more than 1% market share</u>	<u>Number of brands to be excluded</u>
Ondansetron 4mg tablet	11	18
Ondansetron 2mg/ml injection	13	17

In view of the above, the contention of the petitioner company, that ceiling prices for the medicines “added” in the NLEM 2015 have to be fixed and not for the products which are already in NLEM 2011, has got no merit as NPPA has revised the ceiling prices in accordance with the provisions of para 18(i) of DPCO, 2013. However, NPPA may be directed to refix the ceiling prices of the formulations by considering only those medicines / formulations having MAT value of more than 1%

market share, as DPCO does not recognise a company for average PTR but only medicines / formulations.

5. Government Decision:

“NPPA is hereby directed to refix the ceiling prices of the formulations Ondansetron 4mg tablet & Ondansetron 2mg/ml injection by considering only those medicines / formulations having MAT value of more than 1% market share, as DPCO does not recognise a company for average PTR but only medicines / formulations.”

Issued on this date, the 18th day of April, 2017.

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

To

1. M/s. Cipla Ltd.,
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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. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
3. T.D., NIC for uploading the order on Department's Website