

No. 31015/69/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

.....

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 Pharmaceutical Industries Ltd. against fixation of ceiling price of “Ondansetron 8 mg tablet” vide NPPA notification S.O. No. 2193(E)[corrected SO No.2195(E)] dated 23.06.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013).

- Ref.
- 1) Review application dated 21.07.2016
 - 2) NPPA notification under review S.O. No. 2193(E)[corrected SO No.2195(E)] dated 23.06.2016
 - 3) Record Note of discussions held in the personal hearing held in the matter on 06.09.2016

This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Sun Pharmaceutical Industries Ltd. (hereinafter called the petitioner) against notification S.O. No. 2193(E)[corrected SO No.2195(E)] dated 23.06.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of “Ondansetron 8 mg tablet”.

2. The main grievances of the company are that –

- I. This has reference to the ceiling price notification No. 2193(E) **{Corrected S.O. No. 2195(E)}** dated 23.06.2016 issued by NPPA. The notification was displayed on the official website of NPPA on 26.06.2016, and the working sheet on 28.06.2016. The said notification has revised the ceiling price of Ondansetron 8mg Tablets at Sr. No. 28. The price calculation shown in working sheet captures our 3 formulations – 2 plain Tablets (ZOFER 8 MG TABLET 4, ZOFER 8 MG TABLET 10) and 1 Mouth Dissolving (MD) Tablet(ZOFER MD 8 MG TABLET MD 10). As mouth dissolving tablets have added benefits over plain tablets like rapid onset of action, improved bioavailability, lesser side effects, these should not have been clubbed with plain formulation of Ondansetron Tablets while calculating the revised ceiling price. Hereby, we submit that we are aggrieved with this notification and, we therefore seek a review of the same under paragraph 31 of DPCO 2013.
- II. The working sheet showing calculation of ceiling price displayed on the website of NPPA on 28.06.2016 incorrectly captures Mouth Dissolving Tablets, and Sustained Release Tablets. As per calculation shown in working sheet, it is apparent that total 12 packs, having 1% Market Share or above were considered in calculating ceiling price. On careful observation, it was found that 4 packs out of 12 are either SR (Sustained Release) formulation, or MD formulation (Mouth Dissolving)- including one of Sun Pharma, and hence should not have been considered in ceiling price calculation, as per explanation (2) of **Department of Pharmaceuticals**' notification S.O. 701 (E) dated 10.03.2016.

- III. Thus the ceiling price notified as Rs. 9.06 per Tablet should not be applicable to Zofer MD 8 mg Tablet (Ondansetron 8 mg Tablet).

Comments of NPPA:

- (i) NPPA has fixed the ceiling price of Rs. 11.07/tablet vide S. O. 1618(E) dated 14.6.2013 and same was revised to Rs. 11.77, Rs. 12.22 & Rs. 11.89 per tablet vide S.O. 1156(E), 619(E) & 644(E) dated 28.4.2014, 26.02.2015 & 02.3.2016 respectably under NLEM 2011. Ceiling price for this formulation was again fixed to Rs. 9.06 /tablet as per para 4, 10, 11, 14, 16, 17, & 18 of DPCO, 2013 under NLEM 2015 as per data provided by pharmatrac for August 2015.
- (ii) There is no provision of separate pricing for **Ondansetron 8mg Tablet** (Conventional & Mouth Releasing / Sustained Releasing tablet) in NLEM, 2015. Therefore, the request of company to review the ceiling price for the subject formulation is not tenable.
- (iii) Review Authority (i.e. DOP) vide review order no 31015/12/2014/PI.I dated 30.8.2016 also noted that "...there is no therapeutic value for the patients and also there is no provision in the DPCO to consider gelatin coating differently...".
- (iv) As per information available with M&E division (through IPDMS report), company has not submitted Form-V for subject formulation notified vide S.O. 2195(E) dated 23.6.2016. DOP is also requested to verify the same from the company before hearing.

3. During the personal hearing, the representatives of the company confirmed that they have complied with the price notification of the formulation under review before filing the Review Application and filed Form V on 20.7.2016 and also submitted hard copy of the same during the hearing.

The company representative further submitted that inclusion of incremental formulation in ceiling price calculation led to a ceiling price which is higher than that of its conventional formulation. Due to this, consumers end up paying higher price for conventional formulation also.

In response to NPPA's comments referred DoP dated 30th August, 2016, stating "...there is no therapeutic value for the patients and also there is no provision in the DPCO to consider gelatin coating differently...", company representative mentioned that the captioned formulation is not related to example given by NPPA. Company has already submitted the advantages of captioned formulation over conventional formulation.

NPPA representative submitted that conventional and mouth dissolving tablet in respect of the formulation Ondansetron 8 mg Tablet has been taken together while calculating the ceiling price since no differentiation has been mentioned in NLEM 2015. Further, the mouth dissolving tablet does not increase the therapeutic value for the patients. Hence, DoP may be requested to refer the Review Order No.31015/12/2014-PI.I, dated 30.8.2016.

Regarding increase in ceiling price of conventional tablet due to taking into consideration of other variants of the tablet (mouth dissolving tablet), it may be stated that the ceiling price has been fixed based on the applicable provisions and orders.

4. **Examination:**

In the instant case, the only contention of the company is that NPPA has considered the data of 4 packs out of 12, which are either SR (Sustained Release) formulation, or MD formulation (Mouth Dissolving) - including one of Sun Pharma, while fixing the ceiling price of the formulation Ondansetron Tablet, which is a plain tablet. According to the petitioner company, the PTR of SR formulation or MD formulation should not have been considered, while fixing the ceiling price of plain tablet.

The description of formulations in NLEM 2015 do not provide any differential treatment about pricing of formulations having different delivery system or with extra added features. Through the amendment in the DPCO vide SO No.701(E), dated 10th June, 2016, an explanation (2) as footnote is provided, whereby “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.”

This explanation, however, do not categorically state that such different dosage forms are to be treated as non-scheduled for the purposes of price fixation. Furthermore, the DPCO has no separate methodology that may be adopted to arrive at a separate ceiling price of such formulations. As such, until requisite methodology is notified for the purpose to decide about the incremental innovation involved or the formula for deciding the ceiling prices, such request may not be feasible to be entertained.

In view of the above, hearing authority is of the opinion that the request of company to review the ceiling price for the subject formulation is not tenable, and the review petition may be rejected.

5. **Government Decision:**

“The point raised by the petitioner company in their review petition, dated 21.7.2016 against fixing of ceiling price for the formulation “Ondansetron 8mg Tablet” has got no merit and stands rejected.”

Issued on this date, the 22nd day of December, 2016.

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

To

- 1. M/s. Sun Pharmaceutical Industries Ltd.,
Acme Plaza, Andheri-Kurla Road,
Andheri (East), Mumbai-400 059.**
- 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**