

No. 31015/23/2018-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

A- Wing, Shastri Bhawan,
New Delhi 110 001

Order

1. This is an order on an application dated 14.03.2018 filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Sun Pharma Laboratories Limited (hereinafter called the applicant) against notification S.O. No. 650(E), dated 13.02.2018 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling prices of Methylprednisolone 40mg/ml Injection; Isosorbide-5-Mononitrate 20mg Tablet; Adenosine 3mg/ml Injection; Sodium Valproate Cr 300mg Tablets and Sodium Valproate Cr 500mg Tablets.

2. The applicant has contended as under:-

2.1 As per minutes of the 182nd and 50th Meeting of Authority under DPCO, 2013 held on 22.11.2017, our review order no 31015/13/2017-Pricing dated 27.08.2017 of Methylprednisolone Injection 40 mg/ml have been closed/not implemented without assigning any reason.

2.2 As per minutes of the 186th and 54th Meeting of Authority under DPCO, 2013 held on 05.02.2018, our review order no 31015/39/2017- Pricing dated 24.08.2017 of Isosorbide-5-mononitrate 20 mg tablet have been closed/not implemented, stating that *"Pharmatrac confirmed that PTR claimed by the company was not the highest count and PTR reported by Pharmatrac is as per the highest count. The Authority approved no change in the price."* We refer to DoP order no 31015/89/2017-Pricing dated 10.01.2018 as per which DoP have stated that *"Since the company has submitted all necessary documents in support of its claim of actual PTR of the company's product for the month of August, 2015, the stand of Pharmatrac for not considering actual PTR of the company, having less count, is not justified."*

2.3 The working sheet showing calculation of revised ceiling price of captioned formulations have not been displayed on NPPA website. In absence of working sheet, it is not possible to ascertain whether correct data were captured in arriving revised ceiling price.

2.4 In view of above, company requested to issue necessary directive to NPPA to re-notify the retail price of captioned formulations.

3. Comments of NPPA:

3.1 The ceiling price of formulation fixed by NPPA, vide S.O. No. 650 (E) dated 13.02.2018 is detailed below:-

Sl. No.	Name of the Formulation	Notified Price (Rs.)
1.	Methyl Prednisolone 40mg/ml Injection	48.97/ml
2.	Isosorbide -5- mononitrate 20mg Tablet	2.98/tablet

3.2 With respect to Methyl Prednisolone 40mg/ml Injection, M/s Sun Pharma Laboratories Ltd. had earlier also filed review petition against which DoP gave its review order no. 31015/13/2017-Pricing dated 27.8.2017. The Authority considered all the issues stated in the review order on merit and approved no change in ceiling price in its 50th Meeting of the Authority held on 22.11.2017. Accordingly the review order no. 31015/13/2017-Pricing dated 27.8.2017 was treated as closed by the Authority.

3.3 With respect to Methyl Prednisolone 40mg/ml Injection M/s Pfizer Limited had also filed review petition. Accordingly NPPA has revised the ceiling price of Methyl Prednisolone 40mg/ml Injection at Rs. 48.97/ml vide S.O. 650(E) dated 13.02.2018 based on the review order no. 31015/26/2017-Pricing dated 30.10.2017 of M/s Pfizer Limited.

3.4 The matter of Isosorbide -5- mononitrate 20mg Tablet was considered by the Authority. The Authority observed that the PTR claimed by the company was not the highest count, accordingly, the Authority approved no change in the ceiling price of subject formulation.

4. Examination:

4.1 Based on the review application filed by M/s Sun Pharma Laboratories Ltd. against SO 248(E), dated 24.1.2017, fixing the ceiling price of Methylprednisolone 40mg/ml Injection, DoP issued review order No.31015/13/2017-Pricing, dated 24.8.2017. Similarly, based on review application M/s Pfizer Products India Private Limited for the same formulation, DoP issued order No.31015/26/2017-Pricing, dated 30.10.2017 for that company. In both the review orders, NPPA was directed to verify the documents/information submitted by the company(s), and revise the ceiling price of the formulation, on merit.

4.2 Both the review orders were considered in NPPA's Authority meetings and all the issues stated in the orders were considered on merit. In the case of M/s Sun Pharma Laboratories Ltd., the 50th Authority meeting approved no change in ceiling price. However, NPPA's 54th Authority Meeting, considering the merits in the issues raised by M/s Pfizer Limited in its review application, has upwardly revised the ceiling price of Methylprednisolone 40mg/ml Injection (from Rs.43.55/ml to Rs.48.97/ml) and accordingly SO 650(E), dated 13.2.2018 was notified. All the review orders are being considered on merits by NPPA, based on the issues raised by the companies.

4.3 Company further stated that review order No. 31015/39/2017-Pricing dated 24.8.2017 of Isosorbide -5- mononitrate 20mg Tablet has been closed /not implemented, stating that "Pharmatrac confirmed that PTR claimed by the company was not the highest count and PTR reported by the Pharmatrac is as per the highest count, the Authority approved no change in the price". In this connection, company referred DoP order no. 31015/89/2017-Pricing dated 10.01.2018 which stated that "since the company has submitted all necessary document in support of its claim of actual PTR of the company's products for the month of August, 2015, the stand of Pharmatrac for not considering actual PTR of the company, having less count is not justified".

4.4 In this connection, it is stated DoP, in its order No.31015/89/2017-Pricing, dated 10.1.2018, directed NPPA to consider the actual PTRs of company's product Suminat

25mg and Suminat 50mg., which were in less count. NPPA had considered the PTR of these formulations which were in high count. This order was deliberated in NPPA's 54th Authority meeting and it was decided not to change the ceiling price as the PTR claimed by the company (to be considered for calculation under para 4 of DPCO) was not the highest count.

4.5 The representation of M/s Sun Pharma Laboratories Ltd. against Review Order No. 31015/39/2017-Pricing, dated 24.8.2017, on considering high count by NPPA, was deliberated in DoP. On reconsideration, it was decided that considering the PTR of the formulations of the company, which is in high count, is a logical and right decision. Therefore, the NPPA's 54th Authority Meeting decision of not considering the actual PTR of Isosorbide -5- mononitrate 20mg Tablet as on August, 2015, as claimed by the company, is a right decision, as the said PTR, as per Pharmatrac data, was not in high count. The same principle will be applicable in all future cases.

4.6 In view of the above, the request of the company about considering the actual PTR of their product Isosorbide -5- mononitrate 20mg Tablet as on August, 2015, cannot be accepted being on less count.

5. **Decision:**

“Considering the PTR of the formulations of the company, which is in highest count, is a logical and right decision. Therefore, the request of the company about considering the actual PTR of their product Isosorbide -5- mononitrate 20mg Tablet as on August, 2015, cannot be accepted being on less count.”

Issued on this date, the 2nd day of July, 2018.

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

Copy to:-

1. M/s Sun Pharma Laboratories Limited, 8-C, 8th Floor, Hansalaya Building, 15- Barakhamba Road, Connaught Place, New Delhi-110 001.
2. The Member Secretary, National Pharmaceutical Pricing Authority, YMCA Cultural Centre Building, New Delhi-110001
3. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.
4. PS to MoS(C&F), Shastri Bhawan, New Delhi for information.
5. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
6. T.D., NIC for uploading the order on Department's Website.