

No. 31015/105/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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A- Wing, Shastri Bhawan,
New Delhi 110 001

Order

1. This is an order on an application dated 20.12.2017 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.3722(E) and 3723(E), dated 23.11.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling prices of Oxaliplatin 100mg Injection and Oxaliplatin 50mg Injection. M/s Sun Pharmaceutical Industries Limited also filed review application dated 20.12.2017 on the similar issue. Since the substantial issue and arguments raised by both the companies are same, the review applications of both the companies are disposed of by this order.

2. The companies have contended as under:-

2.1 The Schedule-I of DPCO, 2013 and NLEM-2015 covers the formulations as Oxaliplatin 5 mg/ml injection, however the price notified vide SO 3722(E) and 3723(E) were for each pack of Oxaliplatin 100 mg Injection (as licensed) and Oxaliplatin 50 mg Injection (as licensed) separately, and not for injection Oxaliplatin 5 mg/ml. This appears to be contrary to DPCO provisions.

2.2 M/s Sun Pharma Laboratories Limited, in its review application stated that in working sheet of Oxaliplatin injection (as licensed) 50 mg uploaded on NPPA website on 28.11.2017, MAT August 2015 value of company's one product is captured incorrectly. MAT August 2015 of OXIPLAT 50 MG INJECTION is Rs.52,31,598.12 as per Pharmatrac data available with the company, however same is erroneously captured as Rs.52,31,480.00 in ceiling price calculation. Similarly, MAT August 2015 value of company's one product OXIPLAT 100 MG INJECTION is Rs.84,66,880.00 as per Pharmatrac data available with the company, however, same is erroneously captured as Rs.84,66,177.00 in ceiling price calculation.

2.3 M/s Sun Pharmaceutical Industries Limited, in its review application stated that in working sheet of Oxaliplatin injection (as licensed) 50 mg uploaded on NPPA website on 28.11.2017, company's pack OXIDACH 50 MG INJECTION pack was not included in the ceiling price calculation. Company enclosed the invoice copy of the captioned product for the month of July 2015. Similarly, PTR of their product pack OXIDACH 100 MG INJECTION was erroneously captured as Rs. 1900.00/- per pack in the ceiling price calculation, however the actual PTR in August 2015 was Rs 4728.09/-per pack. Company enclosed the invoice copy of the captioned product for the month of July 2015.

2.4 In view of above submission, companies requested this Department to issue necessary directive to NPPA to revise the ceiling price of Oxaliplatin 5 mg/ml injection.

3. Comments of NPPA:

3.1 Ceiling price of Oxaliplatin 100MG Injection per pack and Oxaliplatin 50MG Injection per pack was notified as Rs. 4055.10 and Rs 2303.01 per Pack, vide S.O. 3722(E) and 3723 (E) dated 23.11.2017 as per Para 4, 6, 10, 11, 14, 15, 16, 17 and 18 of DPCO, 2013.

3.2 Oxaliplatin 50MG Injection was a scheduled formulation under NLEM 2011. The attempt was made to trace the subject formulation of 5mg/ml. However, the Pharmatrac did not contain any such data. In order to check the discrepancy, NPPA considered the data of available brands in the Pharmatrac and upload the draft-ceiling price on the website for two pack and fixed the ceiling price for 100mg/pack and 50mg/pack as Rs.4055.10 and Rs 2303.01 per Pack respectively.

3.3 NPPA uploaded draft-working sheet of proposed ceiling price of this formulation also on its website. The draft-working sheet placed on the website of NPPA on 25.10.2017. Both the companies did not make any representation/request against the proposed ceiling price uploaded on NPPA website.

3.4 The products OXIPLAT 50MG injection and OXIPLAT 100MG injection of M/s Sun Pharma Laboratories Limited were included in ceiling price calculation on the basis of data provided by Pharmatrac for the period of August 2015. Therefore, the contention of the companies is not tenable.

3.5 Regarding non-consideration of OXIDACH 50MG INJECTION of M/s Sun Pharmaceutical Industries Limited, it is stated that the same did not appear in the data provided by Pharmatrac. Their product OXIPLAT 50MG injection was included in ceiling price calculation as the same was reflected in the data provided by Pharmatrac for the period of August 2015. However company did not submit the requisite data (including MAT and PTR) related to OXIDACH 50MG INJECTION and OXIDACH 100MG INJECTION in response to the worksheet uploaded on the website. Hence the same could not be considered.

5. Examination:

5.1 The NLEM is revised on the recommendation of Ministry of Health and Family Welfare. Technically the standard Oxaliplatin injections marketed, contain either 50mg or 100mg Oxaliplatin in appropriate aqueous solution. The standard strength of the injections, however, is 5mg/ml. The description of the product is normally labeled in terms of total quantity of API in the standard vial of ml or 20ml volume.

5.2 NLEM 2011 described only Oxaliplatin 50mg injection vial. However, the NLEM, 2015 substituted this formulation with a more generic description to read as Oxaliplatin injection 5mg/ml. The coverage of the revised description is broader than the earlier

description which covered only 50mg injection vial without including the other strength of 100 mg injection vial based upon Oxaliplatin.

5.3 The present description, in essence covers both of the conventional formulations containing 50mg and 100mg injection vials that are currently licensed to be manufactured. The new description of Oxaliplatin Injection in NLEM, 2015 will enable the NPPA to cover any other strength of Oxaliplatin Injections, that might be approved to be manufactured at any later date also.

5.4 In view of the fact that technically the standard strength of Oxaliplatin injection is 5mg/ml, however, the product is normally labeled in terms of total quantity of the API in the standard vial of 10ml or 20ml volume. Therefore, the ceiling price fixation by NPPA for Oxaliplatin 50mg Injection and Oxaliplatin 100mg Injection is in order. Hence, the request of the companies has got no merit and cannot be accepted.

5.5 M/s Sun Pharma Laboratories Limited has stated that the MAT value of their products OXIPLAT 50MG injection and OXIPLAT 100MG injection is different from the MAT value considered by NPPA. It is seen from the data provided by the company that there is very meager difference in MAT value claimed by the Company and what has been considered by NPPA. It does not make any impact on the market share %age of the company. Moreover, NPPA considered the data provided by Pharmatrac. Therefore, the request of the company has got no relevance and cannot be accepted.

5.6 M/s Sun Pharmaceutical Industries Limited stated that their pack OXIDACH 50MG INJECTION pack was not included in the ceiling price calculation. Company also claimed that PTR of their product pack OXIDACH 100MG INJECTION was erroneously captured as Rs.1900.00 per pack in the ceiling price calculation, whereas the actual PTR in August 2015 was Rs.4728.09 per pack. In support of its claim, the company furnished invoice copies of both the products for the month of July, 2015.

5.7 In regards to the claim of company about availability of Oxidach 50mg Injection pack, NPPA needs to examine the relevant documents furnished by company, and after verification, refix the ceiling price of Oxaliplatin 50mg and Oxaliplatin 100mg injection, on merit. Regarding the wrong PTR of Oxidach 100mg Injection, on going through the calculation sheet of Oxaliplatin 100mg Injection, it is seen that the PTR shown for the product pack Oxidach 100mg Injection of the company is shown as Rs.1900 per pack. However, it is also observed that the market share of the company's MAT value is only 0.07% and NPPA has not considered their PTR of the subject product for averaging purposes under para 4 of DPCO, 2013. Even capturing the correct PTR of the product of the company, as claimed by the company, would not have made any impact on the price fixation of the formulation.

6. Decision:

“Technically the standard strength of Oxaliplatin injection is 5mg/ml. However, the product is normally marketed and labeled in terms of total quantity of the API in the standard vial of 10ml or 20ml volume. Therefore, the ceiling price fixation by NPPA for Oxaliplatin 50mg Injection and Oxaliplatin 100mg Injection is in order. Hence, the request of the companies has got no merit and cannot be accepted.”

“However, NPPA is directed to examine the documents furnished by M/s Sun Pharmaceutical Industries Limited in support of its claim about availability of Oxidach 50mg Injection pack, i.e. copies of sample invoices July, 2015, and after verification, to refix the ceiling price of Oxaliplatin 50mg injection, on merit, within a period of thirty days from the date of issue of the Order.”

Issued on this date, the 22nd day of June, 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-110001.
2. M/s Sun Pharmaceutical Industries Limited, Sun House, Plot No.201 B/1, Western Express Highway, Goregaon (E), Mumbai-400 063.
3. Member Secretary, National Pharmaceutical Pricing Authority, YMCA Cultural Centre Building, 1, Jai Singh Road, New Delhi-110001
4. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.
5. PS to MoS(C&F), Shastri Bhawan, New Delhi for information.
6. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
7. T.D., NIC for uploading the order on Department's Website