

No. 31015/107/2017-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 19.12.2017, filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Dr. Reddy's Laboratories Ltd. (hereinafter called the applicant) against notifications 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 formulations Oxaliplatin 100mg and Dacotin 50mg Injection containing Oxaliplatin 50mg.

2. The company has contended as under:

2.1 National Pharmaceutical Pricing Authority had issued Office Memorandum dated 19th June, 2017 on the subject - "Revision of ceiling price on account of the GST", mentioning that "...Some representations have been received stating that ceiling price of few formulations which are exempt from excise duty need not be revised. In this respect, it is requested to provide the list of such scheduled formulations with excise duty exemption along with the relevant excise duty notifications as on 31st August, 2015...."

2.2 NPPA further issued provisional ceiling prices of the aforesaid formulations on account of GST Implementation on 25th October, 2017 vide F.No.8(35)/2016/DP/Div.II/NPPA requesting companies to inform NPPA of any corrections that may be required within 10 working days and NPPA had issued the provisional multiplication factor of "0.95905" for the formulations **Oxaliplatin 100 mg and Oxaliplatin 50mg injections** in the list.

2.3 DRL clearly stated that formulations were exempted from excise and did not attract any excise either on 31st August, 2015 or 30th June, 2017. DRL along with its letter has clearly submitted all relevant Excise Notifications in support of its claim in respect of excise exemption / excise duty @ 0% as on 31st August, 2015.

Under the circumstances:

- a. Both the aforesaid formulations; Oxaliplatin 100 mg and Oxaliplatin 50mg injections were excise exempted;
- b. It need to be appreciated that ceiling prices as notified for Scheduled formulations Oxaliplatin 100 mg and Oxaliplatin 50mg injections was never inclusive of excise duty;
- c. NPPA has reduced ceiling price for the aforesaid formulations to the extent of

excise duty @ 5% despite receiving information for both the formulations vide DRL letter dated 2nd November 2017;

- d. NPPA has failed to correct the errors in multiplication factor of ceiling prices of scheduled formulation on GST implementation.

2.4 Having been aggrieved by the fact that the ceiling price of captioned Oxaliplatin 100 mg and Oxaliplatin 50mg injections were reduced by a multiplication factor of “0.95905” despite multiple representations that the said formulations were excise exempted, and the application of the multiplication factor of 0.95905 is factually erroneous and must be corrected.

2.5 DRL filed this Review Petition under Para 31 of the Drugs (Prices Control) Order, 2013 against the S.O. No. 3722(E) and S.O. No. 3723 (E) dated 23rd November 2017 and **requested to pass a speaking order in the matter.**

2.6 In view of the above, company requested this Department as under:-

- (i) To consider and conclude that the ceiling prices as notified vide S.O. No. 3722(E) and S.O. No. 3723 (E) dated 23rd November 2017 is ultra vires and contravention of provisions of Drugs (Prices Control) Order, 2013 in respect of the captioned formulations Oxaliplatin 100 Mg and Oxaliplatin 50 Mg.
- (ii) Apply the multiplication factor of 1 instead of 0.95905 and revise the price of captioned formulations Oxaliplatin 100 Mg and Oxaliplatin 50 Mg
- (iii) Pass a speaking order in respect hereof.
- (iv) Any other order in interest of this manufacturer.

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 The company has stated that correct methodology was not followed in arriving at the ceiling price of Oxaliplatin Injection. The points raised by the company are not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013. Details are as follows:-

Company's Grievances	NPPA's comments
Petitioner Company stated that NPPA fixed the price of Oxaliplatin 100MG and Oxaliplatin 50MG Injection vide S.O No 3722 (E) and 3723 (E) dated 23.11.2017 by reducing the excise duty @ of 5% application of multiplication factor of 0.95905 . Company also pointed out that NPPA	NPPA fixed the price of Oxaliplatin 100MG and Oxaliplatin 50MG Injection after GST implementation vide S.O No 3722 (E) and 3723 (E) dated 23.11.2017 as Rs 4055.10 and Rs 2303.01 respectively considering the data provided by Pharmatrac for the period of August 2015.

uploaded the draft working sheet vide F.No.8(35)/2016/DP/Div.II/NPPA dated 25.10.2017. Accordingly the company vide its letter dated 02.11.2017 stated that formulation were exempted from excise and did not attract any excise either on 31.08.2015 or 30.06.2017.

Petitioner Company reiterated that the ceiling price of captioned Oxaliplatin 100MG and Oxaliplatin 50MG Injection were reduced by a multiplication factor of "0.95905" despite multiple representations that the said formulations were excise exempted and the application of multiplication factor of "0.95905" is factually erroneous and must be corrected. Company filed the review petition under Para 31 of DPCO, 2013 against the SO No 3722(E) and S.O. No 3723 (E) dated 23/11/2017 within prescribed time limit and requested to apply the multiplication factor of 1 instead of 0.95905 and revise the price of captioned formulation Oxaliplatin 100MG and Oxaliplatin 50MG Injection.

NPPA applied the multiplication factor of "0.95905" for working out ceiling price calculation due to GST impact since, the nomenclature mentioned by the company in the excise duty notification as on 17.03.2012 and 30.06.2017 is sterile Lyophilized oxaliplatin whereas name mentioned in the list of custom notification is Trans 1- diamine cyclohexane oxalatoplatinium.

Hence, the excise exemption was not considered by NPPA while fixing the ceiling price.

4. During the personal, the company made the following further submissions:-

- 1) Bill of Entry both under Excise and GST acts: The documents clearly state that Oxaliplatin is the same as 'Trans1 Diamino Cyclohexane Oxalato platinum'. The rate of Excise was at 0% as per Customs notification dated 17th march 2012 and 5% under GST notification dated 30th June 2017.
- 2) Draft Monograph from the Indian Pharmacopeia Commission and various other web sources clearly stating that 'Oxaliplatin' and 'Trans1 Diamino Cyclohexane Oxalato platinum' are synonyms of CAS no. 61825-94-3.
- 3) Finally, the company representatives also submitted proof of compliance with the ceiling price as notified vide S.O 3722(E) and S.O 3722(E) Dated 23.11.2017 and 100% compliance with IPDMS.

Thus, as the aforesaid formulation was taxed at a rate of 0% customs Duty as at 30th June 2017, NPPA must not apply the factor of 0.95905.

5. **Examination:**

5.1 NPPA, vide its S.O. 3722(E) and 3723(E), dated 23.11.2017 fixed prices of Oxaliplatin 50mg and Oxaliplatin 100mg formulations after excluding the excise duty levied prior to GST regime by applying a factor of 0.95905 on prevailing earlier prices, wherever applicable. Company contended that Oxaliplatin is the same as 'Trans1 Diamino Cyclohexane Oxalato platinum' as stated in Custom Notification.

The rate of Excise was at 0% as per Customs notification dated 17th March 2012 and 5% under GST notification dated 30th June 2017. The company further stated that as the aforesaid formulation was taxed at a rate of 0% customs Duty as at 30th June 2017, NPPA must not apply the factor of 0.95905.

5.2 From the material furnished by the applicant to prove that the Oxaliplatin is also termed as Trans1 Diamino Cyclohexane Oxalato Platinum, as stated in Custom Notifications, cannot be relied upon. The ingredient Trans1 Diamino Cyclohexane Oxalato Platinum is only a chemical, which is used in the formulation Oxaliplatin Injection, which is a pharmaceutical product. Company, in its representation dated 2nd November, 2017 to NPPA, itself stated that the molecule used in the formulation Dacotin 50mg Injection and Dacotin 100mg Injection (containing Oxaliplatin) is Sterile Lyophilized Oxaliplatin. NPPA applied the multiplication factor of "0.95905" for working out ceiling price calculation due to GST impact since, the nomenclature mentioned by the company in the excise duty notification as on 17.03.2012 and 30.06.2017 is sterile Lyophilized oxaliplatin whereas name mentioned in the list of custom notification is Trans 1- diamine cyclohexane oxalatoplatinium.

5.3 Excise/custom duties are levied or exempted based on the product under Harmonised System (HS) classification.. From the Custom Notification No.12-2012- Customs, dated 17th March, 2012, which is relied upon by Dr. Reddy's Laboratories, it is observed that the exemption is available to Trans1 Diamino Cyclohexane Oxalato Platinum. It is a fact that Trans1 Diamino Cyclohexane Oxalato Platinum is a synonym of Oxaliplatin, as can be seen from the copy of Chemical book relied upon by the company. However, the fact is that Trans1 Diamino Cyclohexane Oxalato Platinum, which is synonym of Oxaliplatin, is only a chemical, classifiable under Chapter 29 of HS Classification. This chemical is used as API in preparing Oxaliplatin Injection, classifiable under Chapter 30 of HS classification. The exemption is granted to a chemical and not to a pharmaceutical product, i.e. Oxaliplatin Injection. On the other hand, the product Lyophilized oxaliplatin Injection is entirely different from API, since it contains relevant excipients along with therapeutic dosage of the relevant API. Thus, the action taken by NPPA is in order.

5.4 In view of the above, the contention of the company has got no relevance as exemption was available only to a chemical Trans1 Diamino Cyclohexane Oxalato Platinum and not to Lyophilized oxaliplatin Injection, which is a pharmaceutical product. Hence, applying factor of 0.95905 by NPPA while revising the ceiling price of post-GST regime is in order. Accordingly, the request of the company cannot be considered and the review application needs to be rejected.

6. **Government Order:**

"The contention of the company is not tenable as exemption was available only to a chemical Trans1 Diamino Cyclohexane Oxalato Platinum and not to Lyophilized oxaliplatin Injection, which is a pharmaceutical product. Hence, applying factor of 0.95905 by NPPA while revising the ceiling price of post-GST regime is in order. Accordingly, the request of the company cannot be considered and the review application stands rejected."

Issued on this date of 29th day of May, 2018.

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

Copy to :-

1. M/s. Dr Reddy's Laboratories Ltd., Global Generics – India, 7-1-27, Ameerpet, Hyderabad-500 016. Telangana.
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