

**No. 31015/74/2017-Pricing  
GOVERNMENT OF INDIA  
MINISTRY OF CHEMICALS & FERTILIZERS  
DEPARTMENT OF PHARMACEUTICALS**

A Wing, Shastri Bhawan,  
New Delhi 110 001

**Subject: Review application of M/s Roche Products (India) Private Limited against price fixation of “Herclon Injection containing Trastuzumab 440mg/50ml and Neorecormon Injection containing Erythropoietin 2000 IU/ml.” vide NPPA order No. S.O. 2058(E), dated 30.06.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).**

**Ref: 1) Review application dated 28.07.2017  
2) NPPA notification under review S.O. No.2058(E) dated 30.06.2017  
3) Record Note of discussions held in the personal hearing held in the matter on 17.10.2017.**

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Roche Products (India) Private Limited (hereinafter called the petitioner) against notification S.O. No.2058(E) dated 30.06.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Herclon Injection containing Trastuzumab 440mg/50ml and Neorecormon Injection containing Erythropoietin 2000 IU/ml.

2. The petitioner has contended as under:

**In respect of Herclon Injection containing Trastuzumab 440 mg/50 ml and Neorecormon Injection containing Erythropoietin 2000 iu/ml:-**

I. National Pharmaceutical Pricing Authority (NPPA) issued a notification no S.O. 2058 (E) dated 30<sup>th</sup> June 2017, fixing prices of 616 Scheduled formulations, inter-alia, including Price of Scheduled formulations **Trastuzumab 440MG/50ML** at Sr. No. 598 and **Erythropoietin 2000IU/ML** at Sr. No. 209 after giving effect of Goods and Services Tax (GST) implementation.

II. AND WHEREAS, the National Pharmaceutical Pricing Authority had issued Office Memorandum dated 19<sup>th</sup> June, 2017 requesting companies to “provide the list of such scheduled formulations, with excise duty exemption along with the relevant excise duty notifications as on 31<sup>st</sup> August, 2015”.

III. AND WHEREAS, NPPA further issued provisional ceiling prices of 761 formulations on account of GST Implementation on 27<sup>th</sup> June, 2017 vide F. No 19(1064)/2016/DP/Div.II/NPPA requesting companies to inform NPPA of any corrections that may be required by 29<sup>th</sup> June, 2017.

IV. AND WHEREAS, NPPA had issued the provisional multiplication factor of “1” for our formulation **Erythropoietin 2000IU/ML** in the list at Sr. No. 264.

V. AND WHEREAS, ROCHE was represented by the Organization of Pharmaceutical Producers of India (OPPI) vide dated 21<sup>st</sup> June, 2017 to NPPA

requesting NPPA to rectify the multiplication factor of its formulation **Trastuzumab 440MG/50ML** from “0.95905” to “1”.

VI. AND WHEREAS, NPPA has erred by considering the multiplication factor of “0.95905” for both the aforesaid formulations in its price notification vide **S.O 2058 (E)** dated 30<sup>th</sup> June, 2017.

VII. AND WHEREAS, ROCHE has clearly submitted all relevant Exise Notifications in support of its claim of excise exemption / excise duty @0% as on 31<sup>st</sup> August, 2015.

VIII. AND WHEREAS, ROCHE through OPPI, once again, requested the Chairman of NPPA vide letter dated 24<sup>th</sup> July, 2017, to correct the ceiling price for the aforesaid formulations, however, no revision in ceiling price was notified.

***Under the circumstances:***

a. Both the aforesaid formulations; Trastuzumab 440MG/50ML and Erythropoietin 2000IU/ML were excise exempted as on 31<sup>st</sup> August, 2015;

b. It need to be appreciated that ceiling prices as notified for Scheduled formulations Trastuzumab 440MG/50ML and Erythropoietin 2000IU/ML 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 OPPI letter dated 21<sup>st</sup> June, 2017;

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

IX. Under the circumstances, The Applicant prayed as under:

(i) To consider and conclude that the ceiling prices as notified vide S.O. 2058 (E) dated 30<sup>th</sup> June, 2017 is ultra vires and contravention of provisions of Drugs (Prices Control) Order, 2013 in respect of the captioned formulations Trastuzumab 440MG/50ML and Erythropoietin 2000IU/ML.

(ii) Pass a speaking order in respect hereof.

(iii) Any other order in interest of this manufacturer.

3. **Comments of NPPA:**

3.1 Ceiling price of **Trastuzumab Injection** was notified as Rs. 54,582.25/pack whereas ceiling price of **Erythropoietin 2000 IU/ml** was notified Rs. 559.11/pack vide S.O. 2058(E) dated 30.06.2017 as per para 4, 6, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.

3.2 The company has stated that correct methodology was not followed in arriving at the ceiling price of **Trastuzumab Injection-440mg/50ml and Erythropoietin 2000**

**IU/ml.** 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:-

Sl. No.	Company's Grievances	NPPA's comments
1.	<p>Company has stated that NPPA issued a notification no. 2058(E) dated 30.06.2017 fixing prices of 616 scheduled formulations, including price of scheduled formulation including <b>Trastuzumab Injection</b> and <b>Erythropoietin 2000 IU/ml</b> after giving effect of Goods and Services Tax (GST) implementation. An OM dated 19.06.2017 was issued by NPPA requesting companies to "provide the list of such scheduled formulations, with excise duty exemptions along with the relevant excise duty notifications as on 31<sup>st</sup> August, 2015". Vide file no. 19(1064)/2016/DP/Div.II/NPPA dated 27.06.2017, NPPA further issued provisional ceiling price of 761 formulations on account of GST implementation and requested companies to inform NPPA of any correction that may be required by 29.06.2017. NPPA issued provisional multiplication factor of "1" for their formulation <b>Erythropoietin 2000 IU/ml</b>. On 21<sup>st</sup> June, OPPI represented to NPPA to rectify the multiplication factor for their formulation <b>Trastuzumab Injection-440mg/50ml</b> from 0.95905 to 1.</p>	<p>Custom vide its notification no. 6/2016-Customs dated 28.01.2016 removed the excise exemption of <b>Trastuzumab Injection</b> and <b>Erythropoietin 2000 IU/ml</b> based formulation. To give the effect of GST with effect from 01.07.2017, NPPA revised the ceiling price of <b>Trastuzumab Injection</b> and <b>Erythropoietin 2000 IU/ml</b> base formulations by removing the excise components vide S.O. 2058(E) dated 30.06.2017. This revision of ceiling price was based on the earlier notification no. 1039(E) dated 01.04.2017 and notification no. 1271(E) dated 21.04.2017 during which period also the excise exemption was not applicable (since the exemption has been withdrawn from 28.01.2016). Thus, the contention of company is not tenable.</p>
2.	<p>NPPA has erred by considering the multiplication factor of 0.95905 for both the above said formulations in its price notification vide SO 2058(E) dated 30.06.2017. Company submitted relevant documents in support of their claim and requested Chairman NPPA vide letter dated 24.07.2017 through OPPI but NPPA did not consider their request.</p>	<p>NPPA has applied multiplication factor of 0.95905 after consideration of notification no. 6/2016-Customs dated 28.01.2016.</p>

3.3 Company has not challenged S.O. No. 2058(E) dated 30.06.2017 in any Court.

4. During the personal hearing, company representatives, in addition to the review petition, further stated the following:

- 1) The last ceiling price calculation for the aforesaid formulations was based on August, 2015 when the formulations were excise exempted.
- 2) In January 2017, when excise duty was first made applicable on the aforesaid formulations, NPPA did not permit an increase in the ceiling price citing a lack of provision enabling the same under the Drugs (Prices Control) Order 2013.
- 3) However, during implementation of GST in June 2017, NPPA reduced the ceiling price to provide an effect for removal of excise duty without citing any provision under DPCO 2013 which allowed for such a reduction in the Ceiling Price of Scheduled formulations due to a reduction in Excise Duty.

Thus, NPPA has not maintained a parity in implementation of the provisions of DPCO 2013 with respect to ceiling price. **If there was no provision for increase in ceiling price at the time of excise implementation in January 2017, which provision enabled NPPA to decrease the ceiling price due to removal of excise duty in June 2017?**

4.2 Further, the company representatives referred to NPPA's Office Memorandum dated 19<sup>th</sup> June 2017 and stated that **NPPA has not followed its own directive despite OPPI and company representations, and providing all excise notifications as applicable in August 2015.** The OM read as under:

"The Authority in its 46<sup>th</sup> Meeting held on 08.06.2017 has decided to notify ceiling prices of scheduled formulations, exclusive of applicable GST rates, after the GST rates are notified by the government.

**0.2 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, you are requested to provide a list of such scheduled formulations, with excise duty exemption along with the relevant excise duty notifications applicable as on 31-Aug-2015."**

Based on the above-mentioned OM, the company filed its representation providing data for the aforesaid formulations in OPPI letter dated 21<sup>st</sup> June 2017 and company letter dated 28<sup>th</sup> June 2017. While, most formulations with excise duty exemption were given a multiplier factor of 1, our formulations were given a multiplier factor of 0.95905 despite repeated representations.

Another noteworthy factor is that the draft multiplier as released by NPPA on 27<sup>th</sup> June 2017 and shared vide Annexure 4 has Erythropoetin at a multiplier factor of "1".

4.3 The Company representatives also humbly submitted that there is no question of application of the Anti-Profiteering clause of GST as the company has seen consistent reductions in net realisable value since August 2015 and a multiplier factor of "1" will only reduce the monetary hardship suffered by the company on excise implementation, and not lead to unjust enrichment or profiteering. The net realisable value of the formulation will continue to be remain lower than January 2017 at the time of excise implementation. Further, profits and cost are no longer a consideration under DPCO 2013.

4.4 NPPA in addition to the reply mentioned above, further stated that the ceiling price notification no. 2058(E) dated 30.6.2017 was issued just to give the effect of excise duty factor with the implementation of GST from 01.7.2017. The notification no. 2058(E) dated 30.6.2017 for ceiling price fixation of **Trastuzumab 440 mg/50 ml**

injection and **Erythropoietin 2000 IU/ml injection** has superseded the earlier notification no. 1039(E) dated 01.4.2017 during which also the excise duty was applicable for the subject formulations.

#### 5. **Examination:**

NPPA, vide its S.O. 2058(E), dated 30.06.2017, fixed prices of specified pharma 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 when the original ceiling price was notified on 21.4.2017 vide SO 1271(E) for Erythropoietin Injection 2000IU/ml and Trastuzumab Injection 440mg/50ml on 9.5.2016 vide SO 1687(E), the PTR as prevalent in August 2015 was considered in the working. As both the formulations were exempted from Excise duty and CVD in August 2015, the PTR did not include Excise duty element and as such there was no need to apply factor 0.95905 to fix the ceiling price post GST. The company, therefore, requested to work out the post-GST ceiling price by multiplying pre-GST ceiling price by a factor of 1 and not 0.95905.

5.2 Department of Revenue, Ministry of Finance vide its Gazette Notifications No.12/2012-Customs and 12/2012-Central Excise has exempted the formulations Erythropoietin Injection 2000IU/ml and Trastuzumab Injection 440mg/50ml from Central Excise and Counter Vailing Duty (CVD). NPPA fixed the ceiling prices of the subject formulations by considering the data of August, 2015. At that time, the drugs/formulations were exempted from Central Excise and CVD. However, Department of Revenue, Ministry of Finance vide its notification No.6/2016-Customs, dated 28.01.2016 has removed the exemption of subject formulations.

5.3 The company contended that when the original ceiling price was notified, the calculation was based on August, 2015 data when the formulations were excise exempted. In January 2017, when excise duty was first made applicable on the aforesaid formulations, NPPA did not permit an increase in the ceiling price citing a lack of provision enabling the same under the Drugs (Prices Control) Order 2013. However, during implementation of GST in June 2017, NPPA reduced the ceiling price to provide an effect for removal of excise duty without citing any provision under DPCO 2013 which allowed for such a reduction in the Ceiling Price of Scheduled formulations due to a reduction in Excise Duty.

5.4 The above contention of the petitioner company has got no relevance as levy of or exemption from any duties (excise/custom) has no bearing on fixation or revision of ceiling prices under the provisions of DPCO, 2013. The ceiling prices are fixed on market based data and not on cost based data. As such any plea for revision/refixation of ceiling prices on account of any modification in the applicable duty rates is not tenable under the provisions of DPCO, 2013. Applying factor of 0.95905 by NPPA while revising the ceiling price of post-GST regime is in order. Therefore, the request of the company cannot be considered and the review application may be rejected.

#### 6. **Government Order:**

**“Levy of or exemption from any duties (excise/custom) has no bearing on fixation or revision of ceiling prices under the provisions of DPCO, 2013. The ceiling prices are fixed on market based data and not on cost based data. Any**

plea for revision/refixation of ceiling prices on account of any modification in the applicable duty rates is not tenable under the provisions of DPCO, 2013. Applying factor of 0.95905 by NPPA while revising the ceiling price of post-GST regime is in order. Hence, the request of the company cannot be considered and the review application stands rejected.”

Issued on this date of 31<sup>st</sup> day of January, 2018.

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

**To**

- 1. M/s. Roche Products (India) Private Limited,  
1503, 15<sup>th</sup> Floor, “The Capital”,  
Bandra Kurla Complex, Bandra (East),  
Mumbai-400 051,**
- 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**