

**No. 31015/73/2017-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 Biocon Limited against price fixation of “Trastuzumab Injection - 400mg/50ml - 400mg/50ml” 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 24.01.2018.**

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Biocon 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 Trastuzumab Injection - 400mg/50ml - 400mg/50ml

2. The petitioner has contended as under:

(i) Company has referred to NPPA's S.O. 2058(E), dated 30.06.2017 wherein at Sl. No. 598 Trastuzumab injection 440 mg/ 50 ml ceiling price (CP) has been revised to Rs. 54, 582.25 based on the multiplication factor 0.95905.

(ii) The use of **multiplication factor 0.95905 was in correct and untenable since the said product was exempted from excise duty** applicable as on 31.08.2015. Further, as per NPPA Office memorandum (OM) even no. dated 09.06.2017 in point b) state that *“In case of schedule formulations, which are exempted from excise duty, no multiplication factor would be applicable. The existing ceiling price would be the ceiling price exclusive of GST rates as applicable”*. Furthermore, as per NPPA Office memorandum (OM) even no. dated 19.06.2017, NPPA has requested to apex pharmaceutical associations to provide the list of such schedule formulations with excise duty exemption along with the relevant excise duty notification applicable as on 31.08.2015.

(iii) WHEREAS it is mentioned in note (n) of S.O. 2058 (E) dated 30.06.2017, the inputs received from pharmaceutical companies, associations federations etc. have been taken into consideration while revision of CP for the said formulation in question.

(iv) Having been aggrieved by the fact that the ceiling price of the captioned formulation Trastuzumab injection 440 mg/ 50 ml was not correctly notified under S.O. 2058 (E) dated 30.06.2017 due to inadvertently consideration of multiplication factor as mentioned hereinabove; company enclosed the excise duty exemption notifications and believed that the supporting documents provided by them would convince Department that multiplication factor has been wrongly considered for revision of CP for said formulation by NPPA. So the same may be deleted and subsequently needs to be re-

worked.

(v) In view of the above facts, company requested this Department to pass a speaking order in the matter rectify the Ceiling Price of "Trastuzumab injection 440 mg/ 50 ml" as notified vide S.O. 2058 (E) dated 30.06.2017 by applying a multiplication factor of 1, which would mean the ceiling price should be rectified to Rs. 56, 912.83 (exclusive of GST).

3. **Comments of NPPA:**

I. Ceiling price of **Trastuzumab Injection-440mg/50ml** was notified as Rs. 54,582.25/pack vide S.O. 2058(E) dated 30.06.2017 as per para 4, 6, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.

II. The company has stated that correct methodology was not followed in arriving at the ceiling price of **Trastuzumab Injection-440mg/50ml**. 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
Company has stated that NPPA has revised the price of Trastuzumab Injection-440mg/50ml to Rs. 54,582.25 by applying the factor of 0.95905. The use of multiplication factor is incorrect and un-tenable since the said product was exempted from excise duty applicable as on 31.08.2015. NPPA vide OM dated 09.06.2017 stated that "In case of scheduled formulations, which are exempted from excise duty, no multiplication factor would be applicable. The existing ceiling price would be the ceiling price exclusive of GST rates as applicable." NPPA also requested to apex pharmaceuticals associations to provide the list of such schedule formulations with excise duty exemption along with the relevant excise duty notification applicable as on 31.08.2015. Company submitted copy of notification no. 12/2012-Custom dated 17.03.2012 in support of their claim and requested to apply the multiplication factor of 1 instead of 0.95905.	Custom vide its notification no. 6/2016-Customs dated 28.01.2016 removed the excise exemption of Trastuzumab Injection-440mg/50ml based formulation. To give the effect of GST with effect from 01.07.2017, NPPA revised the ceiling price of Trastuzumab Injection-440mg/50ml 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 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.

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

4.1 The Company has filed the instant review application being aggrieved by the ceiling price for the formulation Trastuzumab Injection 440mg/50ml which has

been notified by National Pharmaceutical Pricing Authority (NPPA) vide its office letter No.F.19 (1064)/2016/DP/Div.II/NPPA dated 27.06.2016. Upon a perusal of the said notification, it has been noted that the price for the formulation in question has been fixed by using a multiplication factor of 0.95905 as against the multiplication factor of 1 which in the respectful submission of the company should have been used.

- 4.2 Company pointed out that the formulation in question was exempt from excise duty vide notification bearing No. 12/2012-Central Excise dated 17.03.2012. Pursuant to imposition of GST, company was informed vide Memorandum dated 19.06.2017 that the revision of the ceiling price of the formulation would be done so as to take into account the impact of the imposition of GST. In terms of the said memorandum the companies were directed to provide a list of scheduled formulations with excise duty exemption applicable as on 31.08.2015. A perusal of the said office memorandum makes it evident that the date for consideration of the status of excise exemption was 31.08.2015 and for the formulations which were exempt on the said date, no revision of their prices would be required.
- 4.3 As afore stated the formulations in question had been granted excise exemption vide notification bearing No. 12/2012-Central Excise dated 17.03.2012. The said exemption was invoked as on 31.08.2015 i.e. the relevant date as per the office memorandum dated 19.06.2017. That the notification exempting the formulation from the excise duty has been placed along with the review application as Annexure 5 and the same was valid till 28.01.2016, i.e. the date when the excise exemptions were withdrawn. However, as on 31.08.2015, i.e. the date considered by the NPPA for considering the products in the excise duty exemption, there was no excise duty on the said product.
- 4.4 Accordingly, the price for the said formulation did not require any revision as a multiplier factor of 1 was to be used in terms of the office memorandum dated 09.06.2017 bearing F. No. 19(1064)/2016/DP/Div.II/NPPA. It is respectfully submitted that the contention of NPPA that it has correctly used a multiplier of 0.95905 as the price for formulation in question as fixed in SO No.2058 (E) dated 30.06.2017 has been fixed by revising the price fixed vide notification bearing No.1039 (E) dated 01.04.2017 is incorrect and untenable.
- 4.5 It is submitted that if as per office memorandum dated 19.06.2017 price status of excise exemption as on 31.08.2015 was to be taken into consideration, NPPA's reference and reliance upon the ceiling price as fixed vide notification No.1039(E) dated 01.04.2017 is incorrect and untenable. It is further pertinent to mention that at no point of time pursuant to the withdrawal of excise exemption as on 28.01.2016, the price of the formulation was revised by NPPA to take into account the effect of withdrawal of the excise exemption. The revision of the price post 28.01.2016 have primarily been on account of the change in the WPI and not on account of the withdrawal of the excise exemption. The amount of excise which is payable on a formulation being in the nature of tax which is to the Government's own benefit, the Company should be permitted and granted an increase in the rate on account of its applicability. Thus accordingly in the instant case the existing ceiling price should have been revised using a multiplier factor of 1 as against a multiplier factor of 0.95905 as has been done in the instant case.

4.6 The aforesaid actions of NPPA are also contrary to the principles of equality and are liable to be set aside on the said account. As per the office memorandum dated 19.06.2017 it is evident that the relevant date for the prospective of consideration of a valid excise exemption was 31.08.2015. The said date whilst has been taken into consideration in respect of other drugs, the same has been ignored in the case of the formulation in question. The ceiling price of the formulation in question has been revised by taking into account the status as were applicable on 01.04.2017. The said actions of NPPA are thus evidently contrary to the principles of equality as the same yardstick for all formulations has not been adopted.

5. In addition to the comments already stated above, NPPA representative further stated that the Authority vide SO 2058(E), dated 30.6.2017 just removed the impact of excise duty in respect of the formulation where excise duty was applicable as on 30.6.2017. In respect of Trastuzumab Injection-440mg/50ml, the excise duty was applicable as on 30.6.2017. Further, the SO 2058(E) dated 30.6.2017 substituted the SO 1039(E), dated 1.4.2017 at which period also the excise duty was applicable on Trastuzumab Injection-440mg/50ml.

6. **Examination:**

NPPA, vide its S.O. 2058(E), dated 30.06.2017 (pages 15-32/c), 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 Trastuzumab Injection 440mg/50ml, the PTR as prevalent in August 2015 was considered in the working. As the formulation was 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.

6.2 Department of Revenue, Ministry of Finance vide its Gazette Notification No.12/2012-Customs and No.12/2012-Central Excise has exempted the formulation Trastuzumab Injection 440mg/50ml from Custom Duty, Central Excise and Counter Vailing Duty (CVD) (Notification at pages 5-8/c and Flag A). 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 Custom Duty, Central Excise and CVD. However, Department of Revenue, Ministry of Finance vide its notification No.6/2016-Customs, dated 28.01.2016 (page 4/c) has removed the exemption of subject formulations.

6.3 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, excise duty was first made applicable on the aforesaid formulations. 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.

6.4 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.

7. **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 26th day of February, 2018.

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

To

1. **M/s. Biocon Limited,
20th KM Hosur Road,
Electronics City,
Bangalore-560100.**
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**