

**No. 31015/85/2017-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 “Xeloda tablets containing Capecitabine 500mg, Ristova Injection and Ikgdar Injection containing Rituximub 10mg/ml.” vide NPPA order No. S.O. 2400(E), dated 28.7.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref: 1) Review application dated 24.08.2017
2) NPPA notification under review S.O. No.2400(E) dated 28.07.2017
3) Record Note of discussions held in the personal hearing held in the matter on 07.11.2017.**

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.2400(E) dated 28.07.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Xeloda tablets containing Capecitabine 500mg, Ristova Injection and Ikgdar Injection containing Rituximub 10mg/ml.

2. The petitioner has contended as under:

I. National Pharmaceutical Pricing Authority (NPPA) issued a notification no S.O. 2400(E) dated 28th July 2017, fixing prices of 28 Scheduled formulations, inter-alia, including Price of Scheduled formulations **Capecitabine 500 mg** at Sr. No. 15 and **Rituximab** at Sr. No. 26 after giving effect of Goods and Services Tax (GST) implementation.

II. AND WHEREAS, the National Pharmaceutical Pricing Authority had issued Office Memorandum dated 19th 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 31st August, 2015”.

III. AND WHEREAS, NPPA further issued provisional ceiling prices of 761 formulations on account of GST Implementation on 27th 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 29th June, 2017.

IV. AND WHEREAS, NPPA had issued the provisional multiplication factor of “0.95905” for their formulations *Capecitabine 500 mg* at Sr. No. 107 and *Rituximab* at Sr. No. 652.

V. AND WHEREAS, ROCHE was represented by the Organization of Pharmaceutical Producers of India (OPPI) vide dated 21st June, 2017 to NPPA requesting NPPA to rectify the multiplication factor of its formulations *Capecitabine 500 mg* and *Rituximab* from “0.95905” to “1”.

VI. AND WHEREAS, NPPA had earlier correctly considered the multiplication factor of "1" for both the aforesaid formulations in its price notification vide S.O 2059(E) dated 30th June, 2017. However, NPPA has, vide notification no S.O. 2400(E) dated 28th July 2017, later reduced the prices of formulation Capecitabine 500 Mg and Rituximab 10mg/ml by erroneously applying the multiplication factor of 0.95905.

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

Under the circumstances:

a. Both the aforesaid formulations; Capecitabine 500 Mg and Rituximab 10mg/ml were excise exempted as on 31st August, 2015;

b. It need to be appreciated that ceiling prices as notified for Scheduled formulations Capecitabine 500 Mg and Rituximab 10mg/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 21st June, 2017;

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

VIII. Under the circumstances, the Applicant prayed as under:

(i) To consider and conclude that the ceiling prices as notified vide S.O. 2400(E) dated 28th July, 2017 is ultra vires and contravention of provisions of Drugs (Prices Control) Order, 2013 in respect of the captioned formulations Capecitabine 500 Mg and Rituximab 10mg/ml.

(ii) Pass a speaking order in respect hereof.

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

3. Comments of NPPA:

I. Ceiling price of Xeloda tablets containing Capecitabine 500mg was notified as Rs.114.68/tab whereas ceiling price of Ristova Injection & Ikgdar injection containing Ritoximub 10mg/ml was notified as Rs.688.24/ml vide S.O. 2400(E) dated 28.07.2017 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 Xeloda tablets containing Capecitabine 500mg, Ristova Injection and Ikgdar injection containing Ritoximub injection 10mg/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. 2400(E) dated 28.07.2017, fixing prices of 28 scheduled formulations, inter-alia, including price of scheduled formulation Capecitabine 500mg tab and Ritoximub injection 10mg/ml 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 31st 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 on 27.06.2017 and requested companies to inform NPPA of any correction that may be required by 29.06.2017. NPPA issued provisional multiplication factor of "0.95905" for their formulation Capecitabine 500mg tab and Ritoximub injection 10mg/ml. On 21st June, OPPI represented to NPPA to rectify the multiplication factor for their formulation Capecitabine 500mg tab and Ritoximub injection 10mg/ml from 0.95905 to 1.</p>	<p>Custom vide its notification no. 6/2016-Customs dated 28.01.2016 removed the excise exemption of Capecitabine 500mg tab and Ritoximub injection 10mg/ml based formulation. To give the effect of GST with effect from 01.07.2017, NPPA revised the ceiling price of Capecitabine 500mg tab and Ritoximub injection 10mg/ml base formulations by removing the excise components vide S.O. 2400(E) dated 28.07.2017. 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.</p>
2.	<p>Company is of the opinion that NPPA had earlier correctly considered the multiplication factor of "1" for both the aforesaid formulation in its price notification vide S.O. 2059(E) dated 30.06.2017. However, NPPA has, vide notification no. 2400(E) dated 28.07.2017, later reduced the price of formulation Capecitabine 500mg tab and Ritoximub injection 10mg/ml by erroneously applying the multiplication factor of "0.95905".</p>	<p>NPPA has applied multiplication factor of 0.95905 after consideration of notification no. 6/2016-Customs dated 28.01.2016.</p>
	<p>Company reiterated that OPPI has clearly submitted all relevant excise notification in support of its claim in respect of excise exemption/excise duty @ 0% as on August, 2015. Even</p>	

	then, NPPA has failed to correct the errors in multiplication factor of ceiling prices of scheduled formulations on GST implementation.	
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III. Company has not challenged S.O. No. 2400(E) dated 28.07.2017 in any Court.

4. During the personal hearing, the company representatives further submitted that:-

A) In addition to the submission vide review petition, the company representatives 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) The last ceiling price calculation was based on August, 2015 data and it did considered Excise Duty @ 0%. Thus, the ceiling price did not include any taxes as levied by the government. Yet, on 28th July 2017, the rationale presented by NPPA for reduction in ceiling price was inclusion of excise duty in calculation of ceiling price which is not true in the instance case.

B) Further, the company representatives referred to NPPA's Office Memorandum dated 19th 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 46th 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 21st June 2017 and company letter dated 28th 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 price notification as released by NPPA vide SO 2059 (E) dated 30th June, 2017 has mentioned both CAPECITABINE 500 MG and RITUXIMAB 10MG/ML at a multiplier factor of "1".

C) 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.

D) Finally, the company representatives argued that 'Local Taxes' as defined under para 2(m) of DPCO 2013 as

““local taxes” means any tax or levy (except excise or import duty included in retail price) paid or payable to the Government or the State Government or any local body under any law for the time being in force by the manufacturer or his agent or dealer;”.

While excise duty does not form a part of 'local taxes' due to specific exemption, the Goods and Services Tax in its entirety is included as 'local taxes'. A change in local taxes due to implementation of GST does not warrant a change in ceiling price for formulation wherein excise duty was calculated at 0% under para 4.

NPPA representative did not submit any further comments in addition to what have been submitted earlier.

5. **Examination:**

NPPA, vide its S.O. 2400(E), dated 28.07.2017, 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 prices of Xeloda tablets containing Capecitabine 500mg, Ristova Injection and Ikgdar Injection containing Rituximub 10mg/ml. were notified, the PTR as prevalent in August 2015 was considered in the working. As the aforesaid 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 31st 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, 15th 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**