

**No. 31015/71/2017-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 Sanofi-Synthelabo (India) Pvt. Ltd. against price fixation of “Amiodarone Injection - 50mg/ml, Amiodarone Tablets 200mg and Amiodarone Tablets 100mg” 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 05.07.2017
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 10.10.2017.**

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Sanofi-Synthelabo (India) Pvt. Ltd. (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 Amiodarone Injection - 50mg/ml, Amiodarone Tablets 200mg and Amiodarone Tablets 100mg.

2. The petitioner has contended as under:

(i) The ceiling prices of Scheduled Formulations Amiodarone Tablets 200mg, Amiodarone Tablets 100 mg and Amiodarone Injection-50mg/ml are covered under this notification and are mentioned below:

Sl No	Medicines	Dosage Form and Strength	Unit	Existing SO	Existing Date	Ceiling Price wef 1.7.2017
22	Amiodarone	Tablet 200 mg	1 Tablet	1039 (E)	1.4.2017	10.28
23	Amiodarone	Tablet 100 mg	1 Tablet	1039 (E)	1.4.2017	5.18
24	Amiodarone	Injection 50 mg/ml 1	1 ml	1039 (E)	1.4.2017	17.79

The above ceiling prices (after excluding Excise Duty levied prior to the GST Regime) have been worked out for implementation after GST by applying a factor of 0.95905 on the ceiling prices notified earlier, which included element of Excise Duty but excluded VAT. Actual GST as applicable is to be added to the above ceiling price to arrive at MRP post implementation of GST.

(ii) The existing ceiling prices notified vide Notification SO 1039 dated 01-04-2017 were as follows:-

Sl No	Medicines	Dosage Form and Strength	Unit	Ceiling Price wef 1.4.2017 after considering	Then Existing SO Number and Date
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				WPI increase of 1.97186%	
24	Amiodarone	Tablet 200 mg	1 Tablet	10.72	1819 dated 18.5.2016
26	Amiodarone	Tablet 100 mg	1 Tablet	5.40	2195 dated 23.6.2016
25	Amiodarone	Injection 50 mg/ml 1	1 ml	18.55	443 dated 14.2.2017

(iii) Company stated that when the original ceiling price was notified on 18.5.2016, 23.6.2016 and 14.2.2017, the PTR as prevalent in August 2015 was considered in the working. As all formulations of Amiodarone 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. Company also refer to NPPA OM dated 19-6-2017, wherein NPPA had noted that ceiling prices of scheduled formulations which were exempted from Excise duty need not be revised. NPPA had also called for list of scheduled formulations with excise duty exemption along with relevant Excise duty Exemption as on August 2015.

(iv) Organisation of Pharmaceuticals Producers of India had filed a detailed list of all such scheduled formulations which were exempted as of August 2015 vide letter dated 21st June, 2017. The product Amiodarone was included in the said list.

(v) In response to Draft Ceiling prices uploaded by NPPA on 27th June, 2017, company had also submitted a letter dated 29th July 2017 to NPPA pointing out that Amiodarone was exempted from excise duty as of August 2015 and accordingly ceiling price of Amiodarone Injection and Tablets should be worked out by multiplying existing ceiling prices by a factor of 1.

(vi) Company confirmed that Amiodarone was exempted from Central Excise and CVD vide Customs Notification 12/2012 dated 17th March, 2012 and the same is listed in Serial Number 3 of List 3 appended to the said notification. As Amiodarone was exempted from Excise duty and CVD as of August 2015, the ceiling price ought to have been notified without applying the factor 0.95905 and company aggrieved by the error of NPPA in wrongly applying this factor.

(vii) Company stated that in view of the position as explained above, there is no justification for price fixation of Amiodarone 200mg Tablets, Amiodarone 100 mg Tablets and Amiodarone 50mg /ml Injection in the manner as adopted by the NPPA which is against the provisions of the DPCO 2013. Company requested that the ceiling price of Amiodarone 200 mg Tablet, Amiodarone 100 mg Tablet and Amiodarone 50mg /ml Injection, be fixed without applying factor 0.95905 to ceiling prices as notified in April, 2017.

(viii) Company confirmed that, company has implemented the ceiling price notified under above mentioned notification before filing the Review Application.

3. Comments of NPPA:

I. Ceiling price Rs. 17.79, Rs. 10.28 and Rs. 5.18 is notified for **Amiodarone Injection 50mg/ml, Amiodarone tablet 200mg and Amiodarone tablet 100mg**

respectively vide S.O. 2058(E) dated 30.06.2017 are 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 for their products vide S.O. 2058(E) dated 30.06.2017 has been done strictly in accordance with the provisions of DPCO, 2013. Details are as follows:-

Company's Grievances	NPPA's comments
<p>Company referred to the ceiling price notification for their products, which have been notified first time upon their inclusion in NLEM 2015 vide S.O. 701 (E) dated 10.03.2016 under DPCO 2013 and consequently their price was fixed vide S.O. No. 1039(E) dated 01.04.2017 for extending the WPI impact. Subsequently, these ceiling prices (after excluding excise duty levied prior to the GST regime) have been worked out for implementation after GST by applying the factor of 0.95905 on the ceiling prices notified earlier.</p> <p>Company has also pointed out that when the original ceiling price was notified on 14.02.2017, 18.05.2016 and 23.06.2016, all formulations of Amiodarone were exempted from excise duty and CVD during August, 2015, the PTR did not include excise duty element and as such there was no need to apply factor 0.95905. In response to draft ceiling price uploaded by NPPA on 27.06.2017, Company had submitted a letter dated 29.07.2017 to NPPA pointing out that Amiodarone was exempted from excise duty as of August, 2015 in the light of Custom's notification 12/2012 dated 17.03.2012. Amiodarone is listed in serial no. 3 of list 3 appended to the said notification.</p>	<p>Custom vide its notification no. 6/2016-Customs dated 28.01.2016 removed the excise exemption of Amiodarone based formulation. To give the effect of GST with effect from 01.07.2017, NPPA revised the ceiling price of Amiodarone 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.</p>

III. Company has not challenged in any court in respect of ceiling price fixation of their products vide S.O. 2058(E) dated 30.06.2017 in respect of Amiodarone Injection 50mg/ml, Amiodarone tablet 200mg and Amiodarone tablet 100mg.

4. During the personal hearing, the representative of the company submitted that, in case of those products which were exempt from excise duty as on August, 2015, the post-GST ceiling price should be worked out by multiplying pre-GST ceiling price by a factor of 1 and not .95905. Thus, in case of products which were exempt from excise duty in August, 2015, the pre-GST and post-GST ceiling prices would be identical.

4.2 The company had vide its letter, dated 29th July, 2017 informed NPPA that Amiodarone was exempted from excise as on 31st August, 2015 and had also given to

NPPA, copy of the relevant customs and excise notifications 12/2002, dated 17.03.2012.

4.3 In response to NPPA's contention stating that the excise exemption of Amiodarone was removed vide Custom Notification No.6/2016, dated 28.01.2016, the company representatives submitted that the removal of excise exemption in January, 2016 is irrelevant as the ceiling price was fixed based on the average of PTR prevalent in August, 2015. As the products were exempted from excise in August, 2015, the PTR considered for pre-GST ceiling prices did not include excise element and hence while computing the post-GST ceiling price, there is no rationale in using the factor of .95905, which is to be used only for those products which were subject to excise in August, 2015. It is further submitted that when the excise duty exemption was withdrawn in January, 2016, the pre-GST ceiling price was not correspondingly increased to the extent of applicable excise duty. Thus, applying a factor of .95905 will tantamount to double loss to the manufacturer. It is humbly submitted that the pre-GST ceiling price be multiplied by a factor of 1 to arrive at post-GST ceiling price.

5. **Examination:**

NPPA, vide its S.O. 2058(E), dated 30.06.2017 (pages 17-18/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 on 18.5.2016, the PTR as prevalent in August 2015 was considered in the working. As all formulations of Amiodarone 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 formulation Amiodarone from Central Excise and Counter Vailing Duty (CVD). NPPA for the first time fixed the ceiling price of the subject formulation vide its notification SO 1819(E), dated 18.5.2016 by considering the data of August, 2015. At that time, the drug/formulation was 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 Amiodarone based formulation.

5.3 Company contended that as the products were exempted from excise in August, 2015, the PTR considered for pre-GST ceiling prices did not include excise element and hence while computing the post-GST ceiling price, there is no rationale in using the factor of .95905, which is to be used only for those products which were subject to excise in August, 2015. Company also submitted that when the excise duty exemption was withdrawn in January, 2016, the pre-GST ceiling price was not correspondingly increased to the extent of applicable excise duty. Thus, applying a factor of .95905 will tantamount to double loss to the manufacturer.

5.4 The above contention of the petitioner company has got no relevance as levy/exemption of 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 the 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 fixing 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 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 the 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 fixing 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. Sanofi-Synthelabo (India) Pvt. Ltd.,
Sanofi House, CTS No.117-B,
L&T Business Park, Saki Vihar Road,
Powai, Mumbai-400 072.**
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**