

No. 31015/18/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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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" vide NPPA order No. S.O. 443(E), dated 14.02.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 03.03.2017
2) NPPA notification under review S.O. No.443(E) dated 14.02.2017
3) Record Note of discussions held in the personal hearing held in the matter on 09.05.2017.

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.443(E) dated 14.02.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Amiodarone Injection - 50mg/ml.

2. The petitioner has contended as under:

- I. Considering that there was an apparent error in the Draft Version of Proposed Price Calculation Sheet for proposed ceiling price of Rs 18.19 per ml. in respect of Amiodarone Injection-50mg/ml displayed on NPPA website which was uploaded on 6th December 2016, they made a detailed representation to NPPA vide our letter dated 15.12.2016 pointing out the following errors in working out the proposed ceiling price
 - Arithmetical error in computation of price per ml of one brand
 - Incorrect Application of price reduction due to Monopoly condition and
 - Non-inclusion of Sanofi brand Cordarone's price in working out the average.
- II. They also provided the PTR and MAT in respect of Sanofi Brand Cordaone Injection containing Amiodarone - 50mg/ml and also a Statement showing summary of Sales for August 2015, Copy of the Invoice showing PTR and MRP & Copy of Form V along with the said letter.
- III. Company, further, vide their letters dated 18th January, 2017 and 9th February, 2017 submitted additional documents/data in support of our case including certificate of IPDMS data submission along with copies of supporting IPDMS submission. However it seems that NPPA have not taken into account their submissions while notifying the ceiling price of Amiodarone injection - 50mg/ml.

IV. Grounds of review:

(i) The ceiling price has been worked out by NPPA considering the only 2 products namely Ritebeat 50 mg Injection 2ml having PTR of Rs 53.94 and also Ritebeat 50 mg Injection 3 ml having PTR of Rs 52.95, both being manufactured by Torrent Pharmaceuticals, products which have a market share of more than 1% and applying reduction as per monopoly condition. In the case of Ritebeat 50mg 2ml, price per ml would be $Rs\ 53.94/2 = Rs\ 26.97$ and not Rs 19.76 as considered by NPPA.

(ii) In the price calculation, average PTR has been computed at Rs 18,71, which is lower than the highest price of Rs 19.76 as per NPPA calculations (actually it works out to Rs 26.97 and not Rs 19.76).

(iii) Para 6 (1) of the DPCO, 2013 reads as follows:

"Ceiling price of a scheduled formulation in case of no reduction in price due to absence of competition.- (1) where the average price to retailer of a scheduled formulation, arrived at as per the formula specified in sub-paragraph (1) of paragraph 4, has the effect of,-

(a) no reduction in average price to retailer with respect to the prices to retailer of the schedule formulation; and

(b) there are less than five manufacturers for that formulation having one percent or more market share, the ceiling price shall be calculated as under:- "

(iv) It is thus clear that the price reduction as per monopoly condition can be applied **only if both** the conditions mentioned in para 6(1) have been fulfilled.

Since there has already been a reduction in the average PTR as compared to the highest PTR, there is no justification for applying 'Reduction as per Monopoly condition' as mentioned in Para 6 of the DPCO, 2013.

(v) Cordarone Injection 3ml marketed by Sanofi Synthelabo India Private Limited, containing Amiodarone (i.e. 50mg /ml) which has a MAT of Rs 5.8 crores as of August 2015 and PTR of Rs 56.90 per 3ml i.e. Rs 18.97 per ml has not been considered while working out the average price.

V. In view of above, there is no justification for price fixation of Amiodarone 50mg /ml Injection in the manner as adopted by the NPPA which is against the provisions of the DPCO, 2013.

VI. Company requested that the ceiling price of Amiodarone 50mg /ml Injection notified vide S.O. 443(E) dated 14.2.2017 may be withdrawn immediately.

3. **Comments of NPPA:**

NPPA has fixed the ceiling price based on the data submitted by pharma-trac for the month of August 2015. The representation submitted by M/s Sanofi-Synthelabo (India) Limited was not considered by the Authority as company could not submit the

sample of Amiodarone 50mg/ml Injection manufactured in August 2015 required as per OM no. 8(34)/2014/DP/Div.II/NPPA dated 07.02.2017. Moreover, IPDMS compliance was not up to 100% for M/s Sanofi-Synthelabo (India) Limited. As far as PTR 19.76 per ml is concerned the same was restricted based on S.O. 619(E) dated 26.02.2015 by NPPA as subject formulation was also a scheduled formulation under NLEM 2011 of DPCO, 2013. M/s Torrent has not made any representation against the price fixation of Amiodarone 50mg/ml Injection.

3. During the personal hearing, the representatives of the company, the company representatives did not submit any further comments in addition to the written submissions made in the review petition.

4. **Examination:**

The petitioner company has challenged the NPPA Order S.O. 443(E), dated 14.02.2017 for price fixation of their formulation **Amiodarone Injection – 50mg/ml** on the ground that their product containing Amiodarone (i.e. 50mg /ml) which has a MAT of Rs.5.8 crores as of August 2015 and PTR of Rs 56.90 per 3ml i.e. Rs 18.97 per ml has not been considered while working out the average price. The company also submitted that correct methodology was not followed in arriving at the ceiling price for **Amiodarone 50mg/ml Injection**.

As regards the grievance of the company that their product containing Amiodarone (i.e. 50mg /ml) which has a MAT of Rs.5.8 crores as of August 2015 and PTR of Rs 56.90 per 3ml i.e. Rs 18.97 per ml has not been considered while working out the average price, it is observed that NPPA has considered the Pharmatrac data of August 2015 while fixing the ceiling price of the formulation. Moreover, as stated by NPPA, the company could not submit the sample of Amiodarone 50mg/ml Injection manufactured in August 2015, in support of their claim. Since the company could not satisfy the requirement of their product being considered, the grievance raised by the company cannot be considered.

In regard to the objection of the company regarding correct methodology not being followed in arriving at the ceiling price for **Amiodarone 50mg/ml Injection, NPPA has restricted the ceiling price based on S.O. 619(E) dated 26.02.2015 by NPPA as subject formulation was also a scheduled formulation under NLEM 2011 of DPCO, 2013**. While fixing the ceiling price, based on Pharma Trac data, NPPA has considered two formulations (Ritebeat 50 mg injection 2 ml and Ritebeat IV 50 mg injection 3 ml) of Torrent Pharmaceuticals Ltd. In view of the above, the ceiling price fixed by NPPA is in accordance with the provisions of DPCO, 2013 and is in order. Moreover, M/s Torrent Pharmaceuticals Ltd., whose products have been considered for fixing the ceiling price, has not raised any objection to the price fixation.

In view of the above, the grievances of the company cannot be considered and the review petition may be rejected.

5. **Government Decision:**

“The grievances raised by M/s Sanofi-Synthelabo (India) Private Limited in their review petition cannot be considered and hence the petition stands rejected.”

Issued on this date of 10th day of October, 2017.

**(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**