

**No. 31015/100/2016-PI.I**  
**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 India Limited against price fixation of "Pheniramine Injection 22.75 mg/ml" vide NPPA order No. S.O. 3431(E), dated 10.11.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).**

**Ref: 1) Review application dated 30.11.2016  
2) NPPA notification under review S.O. 3431(E), dated 10.11.2016  
3) Record Note of discussions held in the personal hearing held in the matter on 17.1.2017.**

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Sanofi India Limited (hereinafter called the petitioner) against notification S.O. No.3431(E), dated 10.11.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Pheniramine Injection 22.75 mg/ml

2. The petitioner has contended as under:-

- I. The ceiling prices for the above product have been fixed by considering the PTR of August 2015 and applying the WPI decrease of 2.7105% as per the annual wholesale price index (WPI) for preceding calendar year. Since the price fixation of the above formulation is not in consonance with the NPPP 2012 and the relevant provisions of the DPCO 2013.
- II. They further submitted that Paragraph 4 (xi) of NPPP 2012 prescribing the principles for drug price control states as follows "Revision of Ceiling Prices on the basis of MAT value would be carried out only once in five years or as and when NLEM is updated/revised. However, the Government will revise the ceiling price of a medicine under NLEM, if there is a significant change in the market structure of the particular medicine even in between 5 years."
- III. From the above the intent of the Government is very clear that:-
  - (i) Ceiling price of every Scheduled Formulation needs to be fixed when it is included in Schedule I.
  - (ii) Once ceiling price is so fixed, it will be valid for 5 years, subject to increase or decrease due to change in WPI.
  - (iii) If any new formulation is added to the Schedule during the 5 years, only ceiling price of such scheduled formulation need to be fixed while the ceiling price of other scheduled formulations whose ceiling price was already fixed would not need to be re-fixed on the basis of MAT until expiry of 5 years.

- (iv) During the 5 years, if there is a significant change in the market structure, the ceiling price needs to be re-fixed.
- IV. The price of the above product was fixed for the first time under DPCO 2013 vide S.O. No. 2360(E) dated 15.9.2015 in accordance with Para 4 calculating the Average Price to Retailer on the basis of moving annual turnover for this medicine. They submitted that the price under **Para 18(i) on the basis of MAT can only be fixed after 5 years i.e. after 15.9.2020.**
- V. Para 18 (1) of DPCO 2013 reads as follows:-

The revision of ceiling prices on the basis of moving annual turnover value shall be carried out,-

- (i) as and when the National List of Essential Medicines is revised by the Ministry of Health and Family Welfare or five years from the date of fixing the ceiling price under this Order whichever is earlier;  
The phrase "whichever is earlier" in Para 18(i) when applied for re-fixing the ceiling prices formulations whose ceiling prices has already been fixed under DPCO, 2013 before the expiry of 5 years, would be clearly against the intent of the NPPP 2012. There cannot be any rationale to re-fix the ceiling price of any scheduled formulation for the mere reason that some other formulation has been added or deleted from the Schedule I. This can also lead to huge price instability for such scheduled formulations, as the prices of any scheduled formulation would get affected whenever any other formulation gets added to the schedule. Obviously such instability and unpredictability cannot be the intent of NPPP 2012, whose stated objective is to ensure availability of essential medicines at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of industry, thereby meeting the goals of employment and shared economic wellbeing for all.
- VI. The ceiling price for the medicines added in the first schedule on the basis of amendments or revision, if required, in the first schedule are required to be notified and fixed as per the provisions of Para 17 of the DPCO 2013 within a period of sixty days from the date of the notification amending the First Schedule. Accordingly, the provisions of Para 17 are only to be made applicable when NLEM has been updated/revised vide SO 701(E) dated 10.3.2016 as per the intention in para 4(xi) NPPP 2012. Thus, on a harmonious construction and a rational interpretation, the phrase "whichever is earlier" appearing in para 18(1) can only mean that it would permit
- (a) Fixing ceiling price of formulations which are newly added to the Schedule I as and when they are added and
- (b) Re-fixing the ceiling prices of those scheduled formulations, whose ceiling prices have already been fixed under DPCO, 2013 only after lapse of 5 years from the date of fixing its ceiling price.
- (c) It may also be seen from the Working Sheet Related to Price Notified on 10th price has been done under Para 4 of DPCO 2013 taking into account of WPI Reduction wef November, 2016 regarding Pheniramine Injection 22.75mg/ml that Computation of Ceiling 1.4.2016 @ -2.7105%.
- (d) Without prejudice to our contention that ceiling price for the above formulation ought

not to have been fixed under para 18(1), they stated that the reduction of 2.7105% is not in accordance with provision of para 9(5), which reads as follows:-

"The market based data for fixing the ceiling price of a scheduled formulation due to a revision in the first schedule shall be the data available for the month ending immediately before six month of notification of revision in the first schedule".

At the time of fixation of ceiling price, DPCO 2013 merely requires computation of Simple Average of Prices prevailing six months prior to the date of price fixation and nowhere does it require the same to be reduced by WPI reduction of the preceding calendar year.

Thus for all price fixations, the data prior to six months of the price notification ought to have been taken without reduction of 2.7105%, being the WPI change for calendar year 2015.

- e. There has been an ambiguity in fixation of the ceiling price that the price of multi-dose vials of 10ml has been averaged with the price of single dose ampoule of 2ml, which is not in conformity with the provisions of para 11(3) of DPCO, 2013.

Accordingly, 2ml and 10 ml are two distinct packs with different cost structures and usage and hence it is incorrect to fix a common ceiling price by taking the average of the prices of 2ml single dose ampoules and 10 ml multi-dose vials. A separate ceiling price for multi-dose vials and single dose ampoules ought to have been fixed by averaging the same with similar packs.

- f. Further the PTR of Avil 2ml pack for August 2015 has been wrongly considered as Rs 1.78 per 2ml instead of the correct PTR of Rs 2.50 per 2 ml. They attached copy of the Invoice showing the MRP of Rs 30.40 and corresponding PTR of Rs 24.96 for 10 packs of 2ml. They also enclosed as the scan copy of the Avil Injections carton of batch number 2415124 Mfg. Date Aug 2015 showing the correct MRP of Rs 30.40 for pack of 10 ampoules of 2ml each. Thus the correct MRP for 2ml pack is Rs 3.04 and correct PTR is Rs 2.50.
- g. It is also pertinent to note that Pheniramine was a Scheduled product under DPCO, 1995 and its price was also fixed under DPCO, 1995 and the price changes after DPCO 2013 were only to the extent of WPI changes. As such the products are incurring losses and any reduction in price of these products could lead to unavailability of the product.

- VII. In view of the position as explained above, there is no justification for price fixation of Pheniramine Injection 22.75mg/ml in the manner as adopted by the NPPA i.e. on MAT basis, considering the WPI decrease for calendar year 2015, averaging the PTR of multi-dose vial pack of 10 ml with the PTR of single dose ampoule pack of 2ml, which is against the NPPP 2012 and the provisions of the DPCO 2013. It is therefore requested that the ceiling price of Pheniramine Injection 22.75mg/ml notified vide S.O. 3431(E) dated 10th November 2016 may be withdrawn immediately or the price is refixed strictly as per the provisions of the DPCO 2013 as amended.

- VIII. They also confirm that as required under para 31 they have implemented the ceiling price notified under S.O. 3431(E) dated 10/11/2016 before filing the Review Application and they also attach a copy of the relevant Form V.

Comments of NPPA:

Point (a) of review petition-

- (i) NPPA has fixed the ceiling price Rs. 1.03/ml for Pheniramine 22.75mg/ml Injection vide S.O. 2360(E) dated 15.09.2015 and the same was revised to Rs. 1.07, Rs. 1.40 /Rs. 1.45 and Rs. 1.41 per ml for vide S.O. 619(E), 836(E) and 644(E) dated 26.02.2015, 25.3.2015 and 02.3.2016 under NLEM 2011. This was again revised to Rs. 1.03/ml vide S.O. 3431(E) dated 10.11.2016 under NLEM 2015 of DPCO 2013.
- (ii) Price fixation exercise was carried out by NPPA under para 18(1) of DPCO, 2013 which states that the revision of ceiling price on the basis of Moving Annual Turnover (MAT) value shall be carried out as and when the National List of Essential Medicines (NLEM) is revised by the Ministry of Health & Family Welfare or 5 years from the date of fixing the ceiling price under this order, which ever is earlier. Ministry of Health & Family Welfare notified NLEM 2015 in December, 2015. Therefore, the ceiling price of **Pheniramine 22.75mg/ml Injection** has been revised under para 18 of DPCO, 2013.

Point (b) – (d) of review petition-

- (iii) Issue raised by company has no merit as earlier ceiling price was based on the data provided by IMS for May 2012 while latest ceiling price is based on the data provided by pharma-trac for the month of August, 2015. As para 9(5) of DPCO, 2013, para 9(5) states that *“the market based data for fixing the ceiling price of a scheduled formulation due to a revision in the First Schedule shall be the data available for the month ending immediately before six months of notification of revision in the First Schedule”*. Accordingly, data of August 2015 was taken as the basis for calculation of ceiling price under revised Schedule-I of DPCO, 2013. As August 2015 was taken for the purpose of calculation of ceiling price, the WPI of 2015 (-2.7105%) was applied for determination of ceiling price.
- (iv) DOP vide letter no. F. No. 31015/44/2016-PI.I dated 11.7.2016 gave the following, directions: *“NPPA to henceforth place a draft version of the Price Calculation Sheets for the proposed revised price notification, including wherever applicable, the Price to Retailer (PTR) and Moving Annual Turnover (MAT) values adopted for calculations, on the website of NPPA for 10 clear working days to invite comments from the affected pharmaceuticals firms. Only after taking into account the comments or any additional data thus received within the given time period, the NPPA shall finalize the Ceiling and the Retail Prices. This issues with the approval of Hon'ble Minister (Chemicals & Fertilizers)”*. Accordingly, NPPA uploaded draft working sheet of proposed ceiling price of this formulation also on its website. This was on the website of NPPA for 10 clear working days. M/s Sanofi India Limited did not make any representation against the proposed ceiling price uploaded on NPPA's website.

Point (e) of representation-

- (v) M/s Sanofi India Limited did not make any representation also under para 11(3 & 4) with reference to Pheniramine 22.75mg/ml Injection, when the detailed draft calculation sheet was put up on NPPA's website.

Point (f) of application-

- (vi) Company had not raised this point when the draft calculation sheet was uploaded on the website for 10 days.

Point (g) of application-

- (vii) The point raised by the company is not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013.
- (viii) As per information available with NPPA, company has not challenged any ceiling price notification with respect to Pheniramine 22.75mg/ml Injection in the Court of law.
- (ix) As per information available with NPPA (through IPDMS report), company is following the ceiling price notified vide S.O. 3431(E) dated 10.11.2016 for the above mentioned formulation. However, DoP is also requested to verify the same from the company by insisting on certified copies of the control sample and relevant invoices in support thereof.

3. During the personal hearing, the representatives of the company, in addition to their earlier submissions, stated that DPCO 2013, which is derived from NPPP 2012, has to be read in harmonious construction with NPPP 2012 and a rational interpretation of the provisions of DPCO 2013 should be done in alignment with the policy laid down in 2012.

Paragraph 4 (xi) of NPPP 2012 prescribing the principles for drug price control states as follows "Revision of Ceiling Prices on the basis of MAT value would be carried out only once in five years or as and when NLEM is updated/revised.

As per para 4(xi) of NPPP 2012 - *"The Government will revise the ceiling price of a medicine under NLEM, if there is a significant change in the market structure of the particular medicine even in between 5 years."*

It is clear from the above provision that revision of prices of drugs already included in NLEM would be triggered before 5 years only if there is a change in market structure.

When the ceiling prices were fixed for the first time in 2013, the average of prices prevalent in May 2012 were only considered without taking into account the WPI increase for the calendar year 2012. Hence, applying the same logic, the WPI decrease for 2015 should also not be considered.

Without prejudice to our contention that ceiling price for the above formulations ought not to have been fixed under para 18(1), the company representatives stated that the reduction of 2.7105% is not in accordance with provisions of para 9(5), which reads as follows :

“The market based data for fixing the ceiling price of a scheduled formulation due to a revision in the first schedule shall be the data available for the month ending immediately before six month of notification of revision in the first schedule”.

With matter pertaining to fixing of the ceiling price, it was submitted that the DPCO 2013 merely requires computation of Simple Average of Prices prevailing six months prior to the date of price fixation and nowhere in DPCO 2013 does it require the same to be reduced by WPI reduction of the preceding calendar year.

Para 16, which mentions about WPI changes, is applicable only after one year of fixing of the ceiling prices and not at the time of determination of the ceiling price itself, which is mandated to be done under DPCO 2013 by taking the simple average of prices prevailing six months prior to the date of fixation. The company representatives requested the NPPA to specifically mention the para under which the WPI reduction while fixing the prices of scheduled formulations due to revision of Schedule I has been done.

The company representatives further pointed out that under DPCO 1995, cost based methodology, the price of Avil (Pheniramine) 2ml ampoules was fixed at Rs.3.58 vide SO 897(E), dated 28.4.2011. The MRP of Avil 2 ml, after notification SO 3431(E), dated 10.11.2016 has been reduced to Rs.2.16 per ampoule leading to huge losses on this product, which has become unviable.

Schedule I, as amended on 10<sup>th</sup> March, 2016, explanation 6, reads as follows:-

“For injectable preparation, the pack size (single and multi-dose pack) has not been mentioned. It is suggested that single and multi-dose pack be considered as separate entities for the purposes such as procurement, pricing etc.”

Avil (Pheniramine) 2ml ampoule pack is a single dose, while 10 ml vial pack is a multi-dose. In hospital setting, inhouse pharmacies, nurses can easily identify store and separate multi dose vials in emergency, when many doses may need to be given to save many lives. Avil is a life saving medicine in case of anaphylactic shock, a life threatening condition, if not managed with utmost emergency.

Vide Notification 836(E), dated 25.3.2015, the ceiling price of Pheniramine was fixed at Rs.1.45/ml w.e.f. from 1.4.2015. Accordingly, MRP of Avil 2ml was worked out as follows :

$(1.45 \times 2) + \text{VAT } 5\% = \text{Rs.}3.04$

MRP of 10 ampoules was Rs.30.40.

Invoice, dated 10.8.2015 mentioning the MRP of Rs.30.40 and PTR of Rs.24.96 has already been submitted. Copy of control samples showing MRP of Rs.30.40 were also given along with submission.

The company representative requested as follows:-

- a) Correct PTR of Rs.2.50 per 2ml be considered for Avil 2 ml instead of Rs.1.78 per 2ml wrongly taken in the calculation sheet.
- b) Separate average be taken for single dose 2ml ampoules and multi-dose 10 ml vials.

c) To note that Pheniramine was a scheduled drug under DPCO 1995 whose price was already fixed vide SO 897(E), dated 28.4.2011 and accordingly as per para 6(2) of DPCO, price reduction due to monopoly factor should not be applied.

4. The representative of NPPA submitted as follows:-

- (i) The ceiling prices of Pheniramine 22.75mg/ml injections have been fixed due to revision of NLEM as per para 18(i) of DPCO, 2013.
- (ii) Para 16 of DPCO 2013 states that WPI would be applicable on 1<sup>st</sup> day of April every year whenever there is a revision of ceiling price. Since, the revision of ceiling price of Pheniramine 22.75mg/ml was done as per para 18(i) of DPCO 2013 based on August, 2015 prices to be effective on or after April, 2016, the effect of WPI was given as on 1<sup>st</sup> April, 2016.
- (iii) As regards the request of the petitioner company to consider separate pricing for single and multi-dose pack, company may approach NPPA to consider the request under para 11(3) and (4) of DPCO 2013.
- (iv) As regards the issue of rectification of PTR, the company has not submitted any representation against the draft working sheet placed on website before the issue of notification. The company may approach NPPA regarding the PTR with supporting documents.

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

The petitioner company has challenged the NPPA Order S.O. 3431(E) dated 10.11.2016 for price fixation of their formulation Pheniramine Injection 22.75 mg/ml. The main contentions of the petitioner company are that the ceiling price for Pheniramine 22.75 mg/ml injection has not been fixed in accordance with the spirit of DPCO 2013 and with the NPPP 2012 and also the re-fixation of ceiling price has caused an unintended reduction which is not in accordance with para 9(5) of DPCO, 2013. The price of multi-dose vial of 10ml has been averaged with the price of single dose ampoule of 2ml which is not in accordance with the provisions of para 11(3) of DPCO, 2013. Company has also requested for separate ceiling price for multi dose vial and single dose ampoule. The company also contended that PTR of Avil 2 ml pack has been wrongly considered as Rs.1.78/2ml ampoule against the correct PTR of Rs.2.50/2 ml ampoule.

Para 18(i) of DPCO 2013 clearly states that the revision of ceiling prices on the basis of moving annual turnover value shall be carried out "as and when the National List of Essential Medicines is revised by the Ministry of Health and Family Welfare or five years from the date of fixing the ceiling price under this Order whichever is earlier." In view of this, NPPA has revised the ceiling prices of the formulations strictly as per the provision of DPCO 2013.

As regards the other point that negative WPI should not be taken while fixing the ceiling price vide notification dated 15.9.2016, since the drugs are not new drugs in NLEM 2015, the WPI impact has to be taken care of while fixing the ceiling prices. Therefore, the petitioner company's contention in this regard has got no merit.

Regarding the grievance of the company against the price of multi-dose vial of 10ml being averaged with the price of single dose ampoule of 2ml, para 11(3) & (4) reads as under –

*“(3) Notwithstanding anything contained in sub-paragraph (1) and (2), in the case of injections or inhalation or any other medicine for which dosage form or strength or both are not specified in the Schedule-I of the Drugs (Prices Control) Order, 2013, the Government may fix and notify separate ceiling price or retail price for such formulations with specified therapeutic rationale, considering the type of packaging or pack size or dosage compliance or content in the pack namely liquid, gaseous or any other form, in the unit dosage as the case may be, conforming to Indian Pharmacopeia or other standards as specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules made thereunder for the same formulation.*

*(4) The Government shall form a Committee of Experts, as it may deem fit, within a period of fifteen days from the date of issue of this order, to recommend fixing of separate ceiling price of scheduled formulations or retail price of a new drug as per the above parameter.”*

The company representative during the personal hearing submitted that Avil (Pheniramine) 2ml ampoule pack is a single dose, while 10 ml vial pack is a multi-dose. In hospital setting, inhouse pharmacies, nurses can easily identify store and separate multi dose vials in emergency, when many doses may need to be given to save many lives. Avil is a life saving medicine in case of anaphylactic shock, a life threatening condition, if not managed with utmost emergency. In view of the specified therapeutic rationale of the formulation, it is proposed that the NPPA may be directed to consider the fixation of ceiling price as per para 11(3) & (4) of DPCO, 2013.

As regards PTR of Avil 2 ml pack being wrongly considered as Rs.1.78/2ml ampoule against the correct PTR of Rs.2.50/2 ml ampoule, the company submitted scanned copy of the Avil Injections carton of August, 2015 showing the correct MRP of Rs.30.40 for pack of 10 ampoules of 2ml each. Thus, the correct MRP for 2ml pack is Rs.3.04 and correct PTR is Rs.2.50. In view of the above, NPPA may be directed to re-fix/revise the ceiling price of the formulation Pheniramine 22.75mg/ml Injection, considering the documentary proof submitted by the petitioner company on merit.

6. Government Decision:

**“The grievance raised by the petitioner company that negative WPI should not have been considered while fixing the ceiling price of formulation Pheniramine 22.75 mg/ml injection has got no merit and stands rejected as the formulation was already in NLEM 2011 and is not a new medicine.**

**NPPA is, however, directed to reconsider the fixation of ceiling price as per para 11(3) & (4) of DPCO, 2013. NPPA is also directed to re-fix/revise the ceiling price of the formulation Pheniramine 22.75mg/ml Injection within one month of the date of this order, considering the documentary proof submitted by the petitioner company on merit.”**

Issued on this date, the 10<sup>th</sup> day of March, 2017.

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



To

1. M/s. Sanofi India Limited  
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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