

**No. 31015/79/2016-PI.I**  
**GOVERNMENT OF INDIA**  
**MINISTRY OF CHEMICALS & FERTILIZERS**  
**DEPARTMENT OF PHARMACEUTICALS**

B Wing, Janpath Bhawan,  
New Delhi 110 001

**Subject:** Review application of M/s Sanofi-Synthelabo (India) Pvt. Ltd. against price fixation of "Sodium Valproate 200 mg. and 500 mg. tablets, Amiodarone tablets 100 mg. and Leflunomide 10 mg. and 20 mg. tablets" vide NPPA order No. S.O. 2193(E) [corrected SO No.2195(E)] dated 23.06.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref:** 1) Review application dated 14.07.2016  
2) NPPA notification under review S.O. No.2193(E) [corrected SO No.2195(E)] dated 23.06.2016  
3) Record Note of discussions held in the personal hearing held in the matter on 22.9.2016.

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.2193(E)[corrected SO No.2195(E)] dated 23.06.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Sodium Valproate 200 mg. and 500 mg. tablets, Amiodarone tablets 100 mg. and Leflunomide 10 mg. and 20 mg. tablets.

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. The price fixation of the above formulations are 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 as follows:-

- (i) vide S.O. No. 1564(E) dated 14.6.2013 for Leflunomide 20 mg
- (ii) vide S.O. No. 1874(E) dated 28.6.2013 for Leflunomide 10 mg
- (iii) vide S.O. No. 1571(E) dated 14.6.2013 for Sodium Valproate 200mg
- (iv) vide S.O. No. 1911(E) dated 28.6.2013 for Sodium Valproate 500mg
- (v) vide S.O. No. 1628(E) dated 14.6.2013 for Amiodarone Tablets 100 mg

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 14.6.2018.**

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. They submitted that once the Ceiling price has been fixed under DPCO 2013, the revision on the basis of MAT for the same formulation can be done **only once in five years.**
- VII. 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.**

- VIII. Secondly, it may be seen from the Working Sheet Related to Price Notified on 23<sup>rd</sup> June, 2016 regarding the above mentioned products that Computation of Ceiling price has been done under Para 4 of DPCO 2013 taking into account of WPI Reduction w.e.f. 1.4.2016 @ -2.7105%.
- IX. without prejudice to their contention that ceiling price for the above formulation ought not to have been fixed under para 18(1), we state 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”.**

- X. 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.
- XI. In view of the position as explained above, there is no justification for price fixation of Sodium Valproate 200mg & 500mg Tablets, Amiodarone Tablets 100 mg and Leflunomide 10 mg & 20mg tablets on MAT basis and also considering the WPI decrease for calendar year 2015 which is against the NPPP 2012 and the provisions of the DPCO 2013. They requested that the ceiling price of Sodium Valproate 200mg & 500mg Tablets, Amiodarone Tablets 100 mg and Leflunomide 10 mg & 20mg tablets notified vide SO 2193(E) **{corrected S.O. No. 2195(E)}** dated 23/06/2016 may be withdrawn immediately.
- XII. **They also confirmed that as required under para 31 they have implemented the ceiling price notified under S.O. 2193(E) {corrected S.O. No. 2195(E)} dated 23/06/2016 before filing the Review Application and they also attach a copy of the relevant Form V.**

#### **Comments of NPPA:**

- (1) NPPA has fixed the ceiling price of Rs. 3.07/ tablet for **Sodium Valproate 200mg tablet** vide S.O. 1571(E) dated 14.6.2013 and the same was revised to Rs. 3.26, Rs. 3.39 & Rs. 3.30 per tablet vide S.O. 1156(E), 619(E) & 644(E)

dated 28.4.2014, 26.02.2015 & 02.3.2016 respectively under NLEM 2011 and the same was revised to Rs. 2.75/tablet vide S.O. 2193(E) dated 23.6.2016 under para 18(1) of DPCO, 2013 under NLEM 2015. The ceiling price of Rs. 7.18/ tablet for **Sodium Valproate 500mg tablet** vide S.O. 1911(E) dated 28.6.2013 and the same was revised to Rs. 7.63, Rs. 7.92 & Rs. 7.71 per tablet vide S.O. 1156(E), 619(E) & 644(E) dated 28.4.2014, 26.02.2015 & 02.3.2016 respectively under NLEM 2011 and the same was revised to Rs. 6.43/tablet vide S.O. 2193(E) dated 23.6.2016 under para 18(1) of DPCO, 2013 under NLEM 2015. The ceiling price of Rs. 6.52/ tablet for **Amiodarone Tablet 100mg** vide S.O. 1628(E) dated 14.6.2013 and the same was revised to Rs. 6.93, Rs. 7.20 & Rs. 7.00 per tablet vide S.O. 1156(E), 619(E) & 644(E) dated 28.4.2014, 26.02.2015 & 02.3.2016 respectively under NLEM 2011 and the same was revised to Rs. 5.30/tablet vide S.O. 2193(E) dated 23.6.2016 under para 18(1) of DPCO, 2013 under NLEM 2015 and the ceiling price of Rs. 15.10/ tablet for **Leflunomide 10mg Tablet** vide S.O. 1874(E) dated 28.6.2013 and the same was revised to Rs. 16.05, Rs. 16.67 & Rs. 16.22 per tablet vide S.O. 1156(E), 619(E) & 644(E) dated 28.4.2014, 26.02.2015 & 02.3.2016 respectively under NLEM 2011 and the same was revised to Rs. 9.30/tablet vide S.O. 2193(E) dated 23.6.2016 under para 18(1) of DPCO, 2013 under NLEM 2015 and the ceiling price of Rs. 28.63/ tablet for **Leflunomide 20mg Tablet** vide S.O. 1564(E) dated 14.6.2013 and the same was revised to Rs. 30.44, Rs. 31.61 & Rs. 30.75 per tablet vide S.O. 1156(E), 619(E) & 644(E) dated 28.4.2014, 26.02.2015 & 02.3.2016 respectively under NLEM 2011 and the same was revised to Rs. 18.13/tablet vide S.O. 2193(E) dated 23.6.2016 under para 18(1) of DPCO, 2013 under NLEM 2015.

- (2) The ceiling prices of the above mentioned formulation were fixed vide S.O. 2193(E) dated 23.6.2016 as NLEM 2011 was substituted by NLEM 2015 in the First Schedule of DPCO, 2013. Para 18 of DPCO 2013 states that revision of ceiling prices on the basis of Moving Annual Turnover (MAT) value shall be carried out:-
- (i) As and when the National List of Essential Medicines is revised by Ministry H&FW or five years from the date of fixing the ceiling price under this order, **whichever is earlier.**

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 representative of NPPA submitted that the prices have been fixed under para 18(i) of DPCO, 2013, as per existing practice.

#### 4. **Examination:**

The petitioner company has challenged the NPPA Order S.O. 2193(E)[corrected SO No.2195(E)] dated 23/06/2016 for price fixation of their formulations listed therein. The main contentions of the petitioner company are as under:

- a. The revision of ceiling price of those drugs whose prices had already been fixed, should not be fixed again before the expiry of 5 years from the date of original fixation of the ceiling price.
- b. The ceiling prices should not be fixed by taking basis PTR August, 2015 by deducting negative WPI as applicable as on 1<sup>st</sup> April, 2016.

**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 2.6.2016, 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 has no merit in the petitions and may be rejected.

**7. Government Decision:**

**“The issues raised by the petitioner company in the review petition have no merit and hence the review petitions are hereby rejected.”**

Issued on this date of 29<sup>th</sup> day of November, 2016.

**(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**