

**No. 31015/49/2016-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 USV Private Ltd. against price fixation of “Amlodipine 5 mg, Clopidogrel 75 mg tablets” vide NPPA order No. S.O. 1686(E) dated 09.05.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).**

**Ref: 1) Review application dated 07.06.2016**  
**2) NPPA notification under review S.O. No.1686(E) dated 09.05.2016**  
**3) Record Note of discussions held in the personal hearing held in the matter on 19.7.2016.**

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s USV Private Ltd. (hereinafter called the petitioner) against notification S.O. No.1686(E) dated 09.05.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Amlodipine 5 mg, Clopidogrel 75 mg tablets Tablet.

2. The petitioner has contended as under:

(1) It is apparent that the exercise of the revision of the ceiling price has been undertaken only in view of the revision of the NLEM. At the outset they submitted that the power to re-fix the existing ceiling price of Amlodipine 5mg and Clopidogrel 75 mg tablets has not been exercised in accordance with the letter and spirit of DPCO, 2013 and particularly of the provisions of paragraph 18 of the DPCO-2013 read with paragraph 4 thereof, and read with the clause 4(xi) of the National Pharmaceutical Pricing Policy, 2012 (NPPP-2012) issued on 07.12.2012.

(2) **Paragraph 18. of DPCO-2013**

**18. Revision of ceiling price on the basis of moving annual turnover (MAT).-** 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;

(ii) when the number of manufacturers of a scheduled formulation, having price of a scheduled formulation more than or equal to seventy five percent of the ceiling price fixed and notified by the Government, has decreased by twenty five percent or more than the number of manufacturers as existing on the reference date;

(iii) when the number of manufacturers of a scheduled formulation, having prices of their scheduled formulation equal to or lower than twenty five percent of the ceiling price fixed by the Government, has increased by twenty five percent or more than the number of manufacturers as existing on the reference date.

**Explanation.- For the purpose of items (ii) and (iii) the “reference date” shall be for first revision of ceiling price May, 2012 and for second or subsequent revision the date of previous revision of the ceiling price.**

(3) **Clause 4(xi) of NPPP-2012**

4. PRINCIPLES FOR DRUGS PRICE CONTROL AND DETERMINATION IN NPPP-2012

(xi) The Simple Average Price of all the brands of the medicine having market share (on the basis of Moving Annual Turnover) more than and equal to 1% of the total market turnover of that medicine - the Reference Prices for calculation of Simple Average Price - may also change on an annual basis due to changes in the MAT value. However, there would be no annual revision of Ceiling Prices on the basis of MAT. 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.

(4) It is clear from a reading of the aforesaid clause 4(xi) of NPPP-2012, that the re-fixation in the existing ceiling prices can be carried out only in the following circumstances:

(i) Under DPCO-2013, a ceiling price calculation is based on the simple averaging of the market prices of different brands of medicines having a market share of 1% and above, based on the Moving Annual Turnover (MAT). Over a period of time, these market shares (based on MAT values of different brands) undergo change - change in the "market structure" of a medicine. This would be due to new brands entering the market and / or some of the existing brands exiting the market and / or the inter-se changes in the market shares (collectively referred herein as "market competition"), thereby necessitating a re-fixation of the existing ceiling prices.

(ii) When the National List of Essential Medicines (NLEM) is updated/ revised (leading to updation / revision of the Schedule-I of DPCO-2013, some of the brands may get reclassified into different therapeutic groups/ sub-groups, thereby changing the "market structure" of certain medicines, and thereby necessitating re-fixation of the ceiling prices of such medicines.

(iii) From the above analysis, the intent of the NPPP-2012 is clear, that any "re-fixation" of an existing ceiling price could be initiated ONLY due to changes in the "market structure" of such medicine, caused either by "market competition" and / or updation / revision of the NLEM; and that such "re-fixation" of an existing ceiling price could be initiated for **no other reasons / factors**.

- (5) **They further submitted that the process followed by NPPA for the re-fixing of the existing ceiling price does not strictly adhere to the aforesaid intentions of the NPPP-2012.** This process does not exclude the impact of factors which cause an **unintended reduction** in the existing ceiling prices, as explained below:

#### **Case-1**

- (6) In terms of the provisions of paragraph 13(2) of DPCO-2013, the existing prices of brands which are below a ceiling price, cannot be raised upto the ceiling price, whereas those brands having prices above the ceiling price will need to reduce their prices upto the ceiling price. As a result, in the market there will be only two sets of brands –
1. those having prices equal to the ceiling price; and
  2. those having prices less than the ceiling price.
- (7) In such circumstances if the ceiling price is re-fixed as per the process stated under paragraph 4 of DPCO-2013, it would only cause an inevitable **unintended reduction** from its previous level, merely due to the mechanical following of the process as per paragraph 4 of DPCO-2013. This would take place without there being any change in the "market structure", and would take place due to the averaging of prices of even those manufacturers who have been forced to keep the prices below the ceiling price level; thereby violating the intentions of the NPPP-2012.

#### **Case-2**

- (8) In terms of the provisions of paragraph 4 of DPCO-2013, the ceiling price calculation process involves the averaging of the market PTRs (Price to Retailer) and adding 16% thereof towards Retailers' Margin. Under the provisions of Drugs (Prices Control) Order, 1995, there was a specific mandatory provision under paragraph 19(1) which required the giving of a fixed margin to Retailers @ 16% of the Retail Price. However, there is no such provision under the DPCO-2013, for enforcing such Retailers' Margin of 16% of the PTR. As a result, the actual Retailers' Margin gets fixed based on the relative negotiating capacities of the manufacturers and the trade associations, of which such retailers are members. At present, in most cases this Retailers margin has been fixed at 20% of the Maximum Retail Price (MRP), which effectively works out to 25% of the PTR, as opposed to the Retailers' Margin of 16% of the PTR which is used for ceiling price calculation. In such circumstances if the ceiling price is re-fixed as per the process stated under paragraph 4 of DPCO-2013, it would only cause an inevitable **unintended reduction** from its previous level, merely due to the mechanical following of the process as per paragraph 4 of DPCO-2013. This would take place without there being any change in the "market structure", and would happen due to the erroneous presumption that the manufacturers are giving only 16% of the PTR as the margin to Retailers, and thereby violating the intentions of the NPPP-2012.
- (9) It is, thus, clear that the impact of the above two factors has to be excluded while re-fixing any ceiling price in terms of the provisions of paragraph 18(i) of DPCO-

2013. They submitted that from the "Working Sheet" provided by NPPA (as displayed on its website on 10.05.2016) in support of the ceiling prices re-fixed vide notification no. S.O. 1686(E) dated 09.05.2016, it is evident that no such provision has been made for the exclusion of the impact of above stated factors.

- (10) They, therefore, requested NPPA to take into account our aforesaid submissions for a review the re-fixation of the ceiling prices vide the said notification dated 09.05.2016 in respect of their subject formulations so that the above explained unintended reduction in the ceiling prices, which is in violation of the objectives of the NPPP-2012, is avoided.

### **Comments of NPPA:**

- (i) NPPA has fixed the ceiling price of Rs. 2.33 & Rs. 6.44 per tablet for **Amlodipine 5mg and Clopidogrel 75mg tablet** vide S.O. 1686(E) dated 09.5.2016 in the 30<sup>th</sup> Authority meeting of NPPA held on 09.5.2016 based on pharma-trac data for the period August, 2015 as per existing practice under para 4, 10, 11, 14, 16, 17 & 18 of DPCO, 2013.
- (ii) Para 18(1) clearly states that revision of ceiling prices on the basis of Moving Annual Turnover (MAT) shall be carried out as and when the National List of Essential Medicines (NLEM) is revised by Ministry of Health & Family Welfare or five years from the date of fixing the ceiling under this order, which-ever is earlier.
- (iii) Ceiling price for above mentioned formulations were fixed under NLEM, 2011 based on the data available during the period May, 2012 while the same are re-fixed under NLEM 2015 based on the data available for the period August, 2015.
- (iv) The Hon'ble Supreme Court in GlaxoSmithKline vs UOI reported in SCC (2014) volume –II has held that DPCO is a beneficial legislation in case of Union of India vs Cynamide Ltd., reported in (1987) 2 SCC 720, at page 736, this Hon'ble Court as been pleased to observed as follows:

“Profiteering, by itself, is evil. Profiteering in the scarce resources of the community, much needed life sustaining food-stuffs and life-saving drugs is diabolic. It is a menace, which hat to be fettered and curve. One of the principal objectives of the Essential Commodities, 1955 is precisely that it must be remembered that art. 39(B) enjoins a duty on the state towards securing “that the ownership and control of the material resources of the community are so distributed as best to sub serve the common good.” The Essential Commodities Act is Legislation towards that end. ”

- (v) The Hon'ble Supreme Court in the Cynamide case supra at page 736 –

“A price fixation measure does not concern itself with the interests of an individual manufacturer or producer. It is generally in relation to a particular commodity or class of commodities or transactions. It is a direction of a general character, no directed against a particular situation. It is intended to operate in the future. It is conceived in interests of general consumer public. The right of the

citizen to obtain essential articles as fair prices and the duty of the state to so provide them are transformed into the power of the state to fixed prices and the obligation of the producer to charge no more than the price fixed.”

- (vi) Holding in respect of price fixation under EC Act, the apex court has held that public interest is with prime consideration.
- (vii) NPPA do not agree with the basic premise that price fixation primarily affect manufacturers and producers. Those who are most vitally affected are the consumer public. It is for their protection that price fixation resorted to and any increase in the price affect them as serially as any decrease does a manufacturer, if not more.
- (viii) In view of foregoing, it is stated that review application filed by M/s USV Pvt. Ltd. is devoid of any merit and deserves to be rejected.

4. During the personal hearing, the company representative further submitted that at every re-fixation of the Ceiling Price, an unintended price reduction takes place due to the mechanical and without application of mind observing of the Ceiling Price calculation process as per paragraph 4 of DPCO.

The following are the two causes of such unintended reduction at each occasion of re-fixation of the existing Ceiling Prices.

**A.**

Actual Retail Margin being higher than the Retail Margin reckoned by NPPA for the calculation of Ceiling Price:

- Calculation of the Ceiling Price under Paragraph 4 assumes that the Retail Margin, i.e. the difference between Ceiling Price and PTR, is 16% of the PTR.
- However, there is no provision in the DPCO-2013, compelling the manufacturers and the dealers to restrict this margin to 16% of PTR; and consequentially, the actual Retail Margin prevailing in the market is much higher at 20% of the Ceiling Price, which works out to 25% of PTR.
- Due to this situation, at each re-fixation of the Ceiling Price, the PTR post such higher Retail Margin is taken as a basis, causing the revised Ceiling Price to get re-fixed at reduced level, unintendedly.
- This unintended reduction needs to be avoided, and the Ceiling Price revision should be allowed to be affected only by factors like new entrants in the market at prices lower than the Ceiling Price, or like existing player's market share getting reduced below 1%, etc.

**B.**

Companies having their prices below the Ceiling Prices, and who can not raise their prices to Ceiling Price level, as per DPCO-2013 provisions:

- The prices of Companies, which are kept below the Ceiling Price level due to legal provisions, get reckoned again for working out average PTR, at each re-fixation of Ceiling Price thereafter.

- As a consequence, at each re-fixation of the Ceiling Price, the same gets reduced unintendedly.
- This unintended reduction needs to be avoided, and the Ceiling Price revision should be allowed to be affected only by factors like new entrants in the market at prices lower than the Ceiling Price, or like existing player's market share getting reduced below 1%, etc.

NPPA representative submitted that the ceiling prices have been calculated on market based price under the provisions of DPCO 2013, which may result in increase or decrease of ceiling price. Therefore, the submission made by the company has no relevance under the provisions of DPCO 2013.

#### 4. Examination:

The ceiling price of **Amlodipine 5 mg.** tablet was fixed of **Rs.3.06**/tablet vide S.O. 1809(E), dated 21.6.2013 and revised as per tabulation given below:

| Medicine   | Strength | Unit     | Ceiling Price (Rs.)           | SO No.  | Date of Notification | Remarks                   |           |
|------------|----------|----------|-------------------------------|---------|----------------------|---------------------------|-----------|
| Amlodipine | 5 mg     | Tablet   | 3.06                          | 1809(E) | 21.6.2013            | Fixation of ceiling price | NLEM 2011 |
|            |          |          | 2.83                          | 3773(E) | 20.12.2013           | Revision on review        |           |
|            |          |          | 3.01                          | 1156(E) | 28.4.2014            | Revision due to WPI       |           |
|            |          |          | 3.13                          | 619(E)  | 26.2.2015            | Revision due to WPI       |           |
|            |          |          | 3.05                          | 644(E)  | 2.3.2016             | Revision due to WPI       | NLEM 2015 |
| 2.33       | 1686(E)  | 9.5.2016 | Revision due to new NLEM 2015 |         |                      |                           |           |

On the same basis, the ceiling price of **Clopidogrel 75 mg.** tablet was fixed at Rs.10.03/tablet vide S.O. 2060(E), dated 5.7.2013 and revised as per tabulation given below:-

| Medicine    | Strength | Unit   | Ceiling Price (Rs.) | SO No.  | Date of Notification | Remarks                       |           |
|-------------|----------|--------|---------------------|---------|----------------------|-------------------------------|-----------|
| Clopidogrel | 75 mg    | Tablet | 10.03               | 2060(E) | 5.7.2013             | Fixation of ceiling price     | NLEM 2011 |
|             |          |        | 10.66               | 1156(E) | 28.4.2014            | Revision due to WPI           |           |
|             |          |        | 11.07               | 619(E)  | 26.2.2015            | Revision due to WPI           |           |
|             |          |        | 10.77               | 644(E)  | 02.03.2016           | Revision due to WPI           |           |
|             |          |        | 6.44                | 1686(E) | 9.5.2016             | Revision due to new NLEM 2015 | NLEM 2015 |

In this case, the petitioner company is taking the shelter of Clause 4(xi) of NPPP-12, which reads as under :-

#### 4. PRINCIPLES FOR DRUGS PRICE CONTROL AND DETERMINATION IN NPPP-2012

(xi) The Simple Average Price of all the brands of the medicine having market share (on the basis of Moving Annual Turnover) more than and equal to 1% of the total market turnover of that medicine - the Reference Prices for calculation of Simple Average Price - may also change on an annual basis due to changes in the MAT value. However, there would be no annual revision of Ceiling Prices on the basis of MAT. 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.

It is submitted here that NPPP-12 was the policy guidelines based on which DPCO, 2013 was formed. Hence, all the cases of price fixation are to be dealt with on the basis of DPCO, 2013.

NPPA has revised the ceiling prices of these products as per provision of para 18(i), which states that:

***“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.”***

In this particular case, revision of ceiling price has been done by NPPA on the basis of revision of NLEM and consequent revision in Schedule I. NPPA is fully within its powers to revise the ceiling prices. Hence, the contention of the petitioner company has no justification and the review petition may be rejected.

#### 5. **Government Decision:**

In view of the above, the petition of the company with regard to review of notification of **ceiling price of Amlodipine 5 mg and Clopidogrel 75 mg tablets vide SO 1686(E) dated 09<sup>th</sup> May 2016** stands rejected.

Issued on this date, the 22<sup>nd</sup> day of December, 2016.

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

To

1. **M/s. USV Private Ltd.**  
**Arvind Vithal Gandhi Chowk,**  
**B.S.D. Marg, Govandi,**  
**MUMBAI-400 088.**

**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**