

No. 31015/38/2016-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 “Amiodarone Tablet 200 mg.” vide NPPA order No. S.O. 1816(E) dated 18.05.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 03.06.2016
2) NPPA notification under review S.O. No.1816(E) dated 18.05.2016
3) Record Note of discussions held in the personal hearing held in the matter on 21.7.2016.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Sanofi-Synthelabo (India) Pvt. Ltd. (hereinafter called the petitioner) against notification S.O. No.1816(E) dated 18.05.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Amiodarone Tablet 200 mg.

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 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:-

- a. Ceiling price of every Scheduled Formulation needs to be fixed when it is included in Schedule I.
- b. Once ceiling price is so fixed, it will be valid for 5 years, subject to increase or decrease due to change in WPI.
- c. 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.

- d. 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 vide SO No. 1629(E) dated 14.6.2013 Amiodarone Tablet 200 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 5.7.2018.**

V. Para 18 (1) of DPCO 2013 reads as follows:-

- a. The revision of ceiling prices on the basis of moving annual turnover value shall be carried out,-
- b. 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;
- c. 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 Ias 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 9th May, 2016 regarding Amiodarone Tablet 200 mg. 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), the petitioner company state that the reduction of 2.7105% is not in accordance with provision of **para 9(5)**, which reads as follows
 - a. **“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 Amiodarone Tablet 200 mg. 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 Amiodarone Tablet 200 mg. notified vide SO 1816(E) dated 18th May 2016 may be withdrawn immediately.
- XII. **They also confirmed that as required under para 31 they have implemented the ceiling price notified under SO 1816(E) dated 18th May 2016 before filing the Review Application and they also attach a copy of the relevant Form V.**

Comments of NPPA:

- (i) NPPA has fixed the ceiling price of Rs. 6.44 per tablet for **Amiodarone 200 mg tablet** vide S.O. 1816(E) dated 18.5.2016 under para 4, 10, 11, 14, 16, 17 & 18 of DPCO, 2013 based on Pharmatrac data as per existing practice.
- (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) 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. ”

- (iv) 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.”

- (v) Holding in respect of price fixation under EC Act, the apex court has held that public interest is with prime consideration.
- (vi) NPPA do not agree with the basic premise that price fixation primarily apex 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 apex them as serially as any decrease does a manufacturer, if not more.
- (vii) In view of foregoing, it is stated that review application filed by M/s Sanofi-Synthelabo (India) Pvt. Ltd. is devoid of any merit and deserves to be rejected.

4. In the personal hearing on 21.07.2016, the company representatives further submitted 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.

- It is clear that the intent of the Government is as follows:
 - (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.
 - (ii) 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.
- 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.**

If a new medicine is added in Schedule I to meet the health needs, it does not mean that the prices of all other medicines already in Schedule I should be refixed based on the MAT value. The interpretation adopted by NPPA would lead to such an irrational outcome leading to huge instability in prices and will result in manufacturers not being able to make appropriate investment to make essential medicines available in the market and can eventually lead to shortage of essential medicines. This defeats the very purpose of NPPP 2012 and DPCO 2013 as access to medicine would be adversely affected.

Without prejudice to their contention that ceiling price for the above formulation ought not to have been fixed under para 18(1), the petitioner company state 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”.

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 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.

It may be recalled that 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.

The company representative referred to the comments of NPPA which were provided to them during the course of time wherein NPPA has referred to the decision of the Supreme Court in Glaxo Smithkline and Cynamide case. The company representatives humbly submitted that the rulings cited above are not relevant to the issue under consideration.

In conclusion, the company representatives submitted that there is no justification for price fixation of Amiodarone Tablet 200 mg. 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 Amiodarone Tablet 200 mg. notified vide SO 1816(E) dated 18th May 2016 may be withdrawn immediately.

NPPA representative submitted that the ceiling price of Amiodarone Tablet 200 mg. has been fixed due to revision of NLEM as per para 18(1) of DPCO 2013. NPPA representative further stated that the Authority decided to give WPI effect in the fixation of ceiling price of the formulation so as to pass on the impact of change in WPI to the manufacturers and consumers.

4. Examination:

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.

As regards contention of the Petitioner Company that ceiling price of the formulation, i.e. Amiodarone Tablet 200 mg. ought not to have been fixed by reduction of WPI of 2.7105% as the same is not in accordance with provisions of Para 9(5), which reads as under:-

“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.”

It is submitted that para 13(3) of the DPCO, 2013 provides inter-alia as under:

“Provided that in case of decline in wholesale price index, a corresponding reduction in the prices shall be made as per the provisions of sub-paragraph (4) of paragraph 16.”

From the above Para of DPCO, 2013, it may be seen that NPPA has correctly fixed the ceiling price of the aforesaid formulation under Para 4 of DPCO, 2013 taking into account of WPI reduction w.e.f. 1st April, 2016 @ minus 2.7105%.

5. **Government Decision:**

In view of the above, the petition of the company with regard to withdrawal of notification of ceiling price of Amiodarone Tablet 200 mg. vide SO 1816(E) dated 18th May 2016 stands rejected.

Issued on this date, the 6th day of October, 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**