

**No. 31015/56/2016-PI.I**  
**GOVERNMENT OF INDIA**  
**MINISTRY OF CHEMICALS & FERTILIZERS**  
**DEPARTMENT OF PHARMACEUTICALS**

B Wing, Janpath Bhavan,  
New Delhi 110 001

**Subject: Review application of M/s Abbott India Limited against price fixation of “Amoxicillin + Clavulanic Acid Oral Liquid, Metformin Immediate Release tablet and Carbimazole” vide NPPA order No. S.O. 1351(E) [corrected SO No.1951(E)] dated 02.06.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).**

**Ref: 1) Review application dated 15.06.2016**  
**2) NPPA notification under review S.O. No.1351(E) [corrected SO No.1951)] dated 02.06.2016**  
**3) Record Note of discussions held in the personal hearing held in the matter on 23.8.2016.**

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Abbott India Limited (hereinafter called the petitioner) against notification S.O. No.1351(E)[corrected SO No.1951(E)] dated 02.06.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Amoxicillin + Clavulanic Acid Oral Liquid, Metformin Immediate Release tablet and Carbimazole.

2. The petitioner has contended as under:

I. Para 4 (xi) of NPPP 2012 contains the following

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.***

II. Based on the above para 18(1) 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”

III. From the wordings in NPPP 2012, at the time Market Based Pricing (MBP) was introduced for the first time in 2013, the understanding in the Industry and Policy makers was as follows:-

- a. Ceiling prices will be fixed first when a formulation is included in Scheduled I.
- b. It would be on the basis of the simple average of prices of brands having a market share of 1% or more.
- c. It would be increased or decreased every year to the extent of change in WPI.
- d. After five years, a fresh ceiling price would be fixed based on simple average of prices prevailing then.
- e. The intention behind re-fixing the ceiling price after 5 years was to take care of change in market structure due to new manufacturers entering or some of the existing manufacturers exiting over a period of time.
- f. It was also meant to give certain degree of predictability to prices which will enable manufacturers to commit investments to deliver quality products and capacity expansion. A reasonable stability of prices is absolutely essential in as much as there is absolutely no control on input costs of medicines.
- g. However, if any new formulation is added to NLEM in the intervening five years, ceiling price of such new formulation would be fixed based on the simple average prices of brands such new formulation having a market share of 1% or more. It was quite clear that any revision or updation of NLEM would not lead to re-fixation of ceiling prices of other scheduled formulations.

IV. While it is logical that if few medicines are added to NLEM, their ceiling prices should be immediately fixed, it does not look logical that ceiling prices of other medicines which were already in NLEM and whose price had been already fixed, is once again fixed without expiry of 5 years from the date of original fixation of the ceiling price.

V. Repeated re-fixing of the ceiling prices and consequent unpredictability of prices will not leave funds with the industry to do innovations, R&D and to maintain highest quality as well as for capacity expansion. Consumers may benefit in the short run due to lower prices but in the long run due to inadequate investment, availability of abundant supply of quality essential medicines will be at a serious risk.

VI. **Considering the above they requested this Department to advise NPPA not to re-notify ceiling prices of medicines which are already in NLEM and whose price have already been notified, is once again notified (before expiry of 5 years unless there is a significant change in the market structure of the particular medicine).**

3. **Comments of NPPA:**

- (i) DoP has amended DPCO, 2013 by substituting NLEM, 2015. As per para 18(1) of DPCO, 2013 ceiling prices of scheduled formulations are to be revised as and when NLEM is revised by Ministry of Health or five years from the date of fixing the ceiling price under DPCO, 2013, whichever is earlier, therefore, NPPA has fixed the ceiling price of Rs. 1.68 per ml for **Amoxicillin 200ml + Clavulanic**

**Acid 28.5mg/5ml Oral Liquid**, Rs. 1.39 per tablet for **Metformin Immediate Release 500mg tablet** and Rs. 1.76 per tablet for **Carbimazole 5mg tablet** as per para 18(1) of DPCO, 2013.

- (ii) Fixation of ceiling prices for above said formulations vide S.O. 1351(E) [corrected SO 1951(E)] dated 02.6.2016 as per the provisions of DPCO, 2013.
- (iii) Company's request to withdraw S.O. 1351(E) [corrected SO 1951(E)] dated 02.6.2016 is not tenable.

4. The company was given a personal hearing on 23.8.2016, and during the hearing, the company representatives further submitted that :-

- 1. The intent of para 18(i) was to ensure stable environment and prices for the scheduled drugs listed in NLEM 2011 for a period of five years. It was also submitted that para 18(i) should only be applicable to the medicines which have been included for the first time in NLEM 2015.
- 2. While fixing the ceiling prices in 2013 for the first time, NPPA considered PTR basis MAT September, 2012 and issued ceiling price notification without adding WPI as applicable as on 1<sup>st</sup> April, 2013 whereas while fixing the ceiling price in 2016, NPPA has issued notification basis PTR August, 2015 by deducting negative WPI as applicable as on 1<sup>st</sup> April, 2016 from the ceiling price.

**It is, therefore, submitted that while WPI was not added in 2013 ceiling price fixation, in the same spirit the negative WPI should not have been deducted while fixing ceiling price in 2016.**

5. NPPA representative submitted that the ceiling price, for the formulations for which the company submitted this review petition, have been fixed strictly within the provision of para 18(i) of DPCO 2013. DoP has revised the NLEM before the expiry of five years. Para 18(i) states that the refixation of ceiling prices can be made after five years or revision of NLEM whichever is earlier.

6. **Examination:**

The petitioner company has challenged the NPPA Order No.S.O. 1351(E)[corrected SO 1951(E)] dated 02.06.2016 for price fixation of their three 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 petition 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 petition is hereby rejected.**

Issued on this date of 19<sup>th</sup> day of September, 2016.

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

To

1. **M/s. Abbott India Limited,  
271, Business Park, 6<sup>th</sup> Floor,  
Model Industrial Colony,  
Off Aarey Road, Goregaon (E),  
MUMBAI-400 063.**
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**