

**No. 31015/36/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

A Wing, Shastri Bhawan,
New Delhi 110 001

Subject: Two Review applications of M/s Abbott India Limited against price fixation of their formulations "Clomiphene 100mg and Clomiphene 50mg tablets" vide NPPA order No. S.O. 443(E), dated 14.2.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref: 1) Two Review applications dated 09.03.2017
2) NPPA notification under review S.O. No.443(E), dated 14.2.2017
3) Record Note of discussions held in the personal hearing on 23.5.2017.**

1. These are two petitions 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.443(E), dated 14.2.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of their formulations Clomiphene 100mg and Clomiphene 50mg tablets.

2. The petitioner has contended as under:

1. In respect of Clomiphene 100mg:-

- (i) They had already made their review petition representation dated 28.11.2016 to NPPA, wherein they have mentioned that the draft working sheet for ceiling price calculation of Clomiphene 100mg (vide 8(35)/2016/DP/NPPA/Div II dated 17.11.2016) were bearing anomaly in calculation.
- (ii) NPPA has considered PTR as Rs. 104.64 for Clome 100mg Tablet 10's of M/s Abbott India, whereas the correct PTR of Aug ' 15 is Rs. 107.56. (PTR per tablet is Rs. 10.76).
- (iii) NPPA has erroneously considered the same PTR for both FERTOMID 100mg Tablets 10's and FERTOMID 100mg Tablets 5's of M/s Cipla Limited. As per IMS data there is only FERTOMID 100mg Tablets 5's pack.

2. In respect of Clomiphene 50mg:-

- (i) They had already made their review petition representation dated 28.11.2016 to NPPA, wherein they have mentioned that the draft working sheet for ceiling price calculation of Clomiphene 50mg (vide 8(35)/2016/DP/NPPA/Div II dated 17.11.2016) were bearing anomaly in calculation.
- (ii) NPPA has considered PTR as Rs. 3.41 per Tab for Clome 50mg Tablet 10's of M/s Abbott India, where as they are not manufacturing and marketing this pack.

They have only one pack that is Clome 50mg Tablets 5's. They requested this Department to advise NPPA not to consider the Clome 50mg Tablet 10's for the purpose of calculation of ceiling price.

(iii) NPPA has erroneously considered the same PTR for both OVAFAR 50mg Tablets 10's and OVAFAR 50mg Tablets 5's of M/s Organon (India) Ltd. As per IMS data there is only OVAFAR 50mg Tablets 5's pack.

3. They appealed to the authority to advise NPPA to correct the apparent variance in calculation.

3. **Comments of NPPA:**

The ceiling price of Rs. 10.86/tab for **Clomiphene 100mg** and Rs. 6.91 /tablet for **Clomiphene 50mg** was notified vide S.O. 443(E) dated 14.02.2017 as per para 4, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.

2. Company has stated that correct methodology was not followed in arriving at the ceiling price for **Clomiphene 100mg & 50mg tablet**. The points raised by the company are not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013. Details are as follows:-

Sl. No.	Company's Grievances	NPPA's comments
1.	Company has stated that they have submitted representation against Draft working sheet and the same was not considered by NPPA.	NPPA has considered the representation submitted by the company but the representation not conclusively proved, hence rejected.
2.	Company has pointed out that NPPA has considered PTR Rs. 104.64 for their product Clome 100mg tablet against the correct PTR 107.56 for the period of August, 2015.	NPPA has considered the PTR as per data provided by PharmaTrac for the period of August, 2015.
3.	Company has also pointed out that NPPA has considered same PTR for Fertomide 100mg tablet and Fertomide 50mg tablet of M/s Cipla Limited. As per IMS data there is only Fortomide 100mg tablet 5 packs.	M/s Cipla has not submitted any representation to NPPA in this regard.

3. Company has not challenged any notification in respect of **Clomiphene 100mg & 50mg tablet** in the Court.

4. During the personal hearing the representatives of the company submitted that in respect of their formulation Clomiphene 100mg., in the calculation sheet, the PTRs of Cipla's brand Fertomid 100mg (10's & 5's packs) are the same, i.e. Rs.52.31, which looks evidently incorrect. The company also submitted documentary proof for Clome 100mg tablets to the effect that the correct PTR of August, 2015 is Rs.107.56.

As regards Clomiphene 50mg tablets, the company representatives submitted documentary proof in the form of CA Certification with regard to the fact that the company never manufactured Clome 50mg of 10's pack. The company also pointed out that the working sheet have the same PTR, i.e. Rs.33.31 for both Ovafar 50 mg tablets 10's and 5's pack, being manufactured by Organon (India) Ltd., which evidently looks incorrect.

The representatives of the NPPA stated that the documentary proof submitted by the company may be examined.

5. **Examination:**

In the case of Clomiphene 100mg, the petitioner company, in its review petition, stated that they had represented on 28.11.2016 against the draft working sheet. However, copy of representation dated 28.11.2016, although stated to be attached with the review petition, was not found to be there. During the personal hearing, the petitioner company submitted documentary proof (page 30/c) in support of their claim that the correct of PTR of their formulation Clome 100mg is Rs.107.56 for 10's pack (Rs.10.76 per tablet) instead of Rs.104.64 for 10's pack, considered by NPPA. The company also stated that NPPA has considered same PTR of FERTOMID 100mg tablet of 10's pack and 5's pack, being manufactured by M/s Cipla Limited. On going through the calculation sheet, it is seen that there is a merit in the submission of the company, as same PTR is shown against both 10's and 5's pack of M/s Cipla Limited. Company claimed that as per IMS data, there is only one data of FERTOMID 100mg in 5's pack.

5.2 Similarly, in the case of formulation Clomiphene 50mg also, copy of representation dated 28.11.2016 submitted against draft working sheet, stated to be attached with the review petition, was not found to be there. However, during the personal hearing, the company submitted a copy of CA Certificate, dated 22nd May, 2017 (page 27/c) in support of the claim that the company never manufactured and marketed Clome 50mg tablet 10's pack. The company manufactures and markets Clome 50mg tablets in 5's pack. The company also claimed that same PTR of OVAFAR 50mg, both for 10's pack and 5's pack, being manufactured by M/s Organon (India) Ltd., has been considered by NPPA. On going through the calculation sheet, it is seen that there is a merit in the submission of the company, as same PTR is shown against both 10's and 5's pack of M/s Organon (India) Ltd. The company claimed that as per IMS data, there is OVAFAR 50mg tablet in 5's pack only.

5.3 On perusal of the calculation sheets of Clomiphene 100mg and 50mg, it is observed that NPPA has taken into account certain formulations having MAT value of less than 1%, as per table given below:

	No. of Formulations to be considered for averaging purposes	No. of Formulations not to be considered having MAT value less than 1%
Clomiphene 100mg	9	2
Comiphene 50mg	10	3

NPPA may be directed to consider only those medicines/formulations having MAT value of more than 1% market share, as DPCO does not recognize a company for average PTR but only medicines / formulations.

6. Government Decision:

“NPPA is hereby directed to examine the relevant documents/ information furnished by the petitioner company, and after verification, to re-fix the ceiling prices of Clomiphene 100mg tablet and Clomiphene 50mg tablet, on merit.”

“NPPA is also directed to re-fix the ceiling prices of subject formulations by considering only those medicines / formulations having MAT value of more than 1% market share as DPCO does not recognize a company for average PTR but only medicines / formulations.”

Issued on this date of 24th day of August, 2017.

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

To

- 1. M/s. Abbott India Limited,
3-4, Corporate Park,
Sion Trombay Road,
Mumbai-400071.**
- 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**