

No. 31015/72/2016-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 Abbott Healthcare Pvt. Limited against price fixation of "Propranolol 40 mg tablets" 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 27.06.2016
2) NPPA notification under review S.O. No.1351(E) [corrected SO No.1951(E)] dated 02.06.2016
3) Record Note of discussions held in the personal hearing held in the matter on 23.08.2016.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Abbott Healthcare Pvt. 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 Propranolol 40 mg tablets.

2. The petitioner has contended as under:

- I. It seems there are few calculation errors in the working sheet published by NPPA. They have revised the calculation and as per their calculation the **revised ceiling price should be Rs.2.86 per tab.**
- II. Further, they brought this Department's attention that CIPLAR LA 40mg Tablets 15' is not considered in working sheet. The details extracted from AIOCD-AWACS data is appended below.

SUBGROUP	BRAND	SKU	COMPANY	STRENGTH	PACK	MRP	PTR	PTS	MAT VAL AUG 15
PROPRANOLOL -C7A37	CIPLAR	CIPLAR LA 40 MG TABLET 15	CIPLA LTD.	40 MG	15	56.00	43.12	39.01	8.60

- III. They requested this Department to advise NPPA to clean up Pharmatrac data to reflect the correct position.
- IV. Considering the above facts, they requested this Department to revise the Ceiling price of Propranolol 40mg tablets. They have already implemented the ceiling price as per NPPA Notification S.O. 1351(E) {**corrected S.O. No.**

1951(E) dated 2nd June, 2016 for their SKU Inderal 40mg Tablets & Inderal LA 40mg Tablets.

Comments of NPPA:

- (i) NPPA has fixed the ceiling price of Rs. 2.56 / tablet for **Propranolol 40mg Tablet** vide S.O. 2528(E) dated 21.8.2013 and the same was revised to Rs.2.72, Rs.2.82 & Rs.2.47 vide S.O. 1156(E), 619(E), & 644(E) dated 28.4.2014, 26.02.2015 & 02.3.2016 respectively under NLEM 2011. The ceiling price for this pack was fixed at Rs. 2.59/tablet vide S.O. 1351(E) dated 02.6.2016 under NLEM 2015 as per Data provided by Pharma Trac for August, 2015.
- (ii) Concerned companies, viz. M/s Cipla and M/s Surien Pharmaceuticals Pvt. Ltd have not raised any issue or submitted any representation to NPPA.
- (iii) Company has submitted Form-V through IPDMS. On scrutinizing latest data reporting by company it could not ascertain the company has complied ceiling price based on S.O. 1951(E) dated 02.06.2016. DoP may verify the same from the company.

3. During the personal hearing, the representative of the company aggrieved by the notification, requested to advise NPPA to revise the ceiling price of Propranolol 40 mg after including the data/details of Ciplar LA 40 MG tablet 15's of Cipla Ltd. as the published working for Propranolol 40 mg does not have Ciplar LA 40 mg tablet 15's of Cipla Ltd.

NPPA representative stated that NPPA has fixed the ceiling price based on the data submitted by Pharma Trac for the period of August, 2015 and no representation of Cipla is pending with NPPA in regard to Ciplar LA 40 mg tablet.

4. Examination:

The petitioner company has contended that there are few calculation errors in the working sheet published by NPPA. The petitioner company has revised the calculation and as per their calculation the **revised ceiling price should be Rs.2.86 per tab.**

The company also contended that CIPLAR LA 40mg Tablets 15' is not considered in working sheet and submitted the details extracted from AIOCD- AWACS data. The company requested this Department to advise NPPA to clean up Pharmatrac data to reflect the correct position and also requested this Department to revise the Ceiling price of Propranolol 40mg tablets.

NPPA appears to have erred in considering the data and may be directed to examine the data furnished by the petitioner company on merit along with other relevant data/information and to re-fix the price of the product of the petitioner company within one month of the decision in this regard.

5. **Government Decision:**

NPPA is hereby directed to examine all the relevant data/information furnished by the petitioner company again on merits and to re-fix the ceiling price of Propranolol 40mg tablets within one month of the decision in this regard.

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. Abbott Healthcare Pvt. Limited,
D Mart Building,
Goregaon Mulund Link Road,
Mulund West, Mumbai-400 080.**
- 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**