

No. 31015/57/2014-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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B Wing, Janpath Bhawan, New Delhi

O R D E R BY REVIEWING AUTHORITY UNDER PARA.31 OF DPCO, 2013

Subject: Review application of M/s. Zydus Healthcare Ltd. against fixation/revision of ceiling prices of Ciprofloxacin HCl tablet 250 mg vide NPPA notification S.O. No. 2352(E) dated 15/9/2014 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013).

Ref. 1) Applicant Review application dated 7.10.2014
2) NPPA notification under review S.O. No.2352(E) dated 15/9/2014
3) Record Note of discussions held in the personal hearing held in the matter on 24.11.2014

Whereas National Pharmaceutical Pricing Authority (NPPA), Government of India, vide price fixation Order S.O. No.2352(E) dated 15/9/2014 fixed/revised ceiling price of Ciprofloxacin HCl tablet 250mg under DPCO, 2013 included at section 8.2.2.3 in Schedule-I of the order.

2. And whereas aggrieved by the above notification, M/S Zydus Healthcare Ltd. (hereinafter referred to as the Petitioner) submitted review application dated 7.10.2014 under para.31 of DPCO, 2013 for the review of NPPA Price fixation Order S.O.No.2352 (E) Dated 15.9.2014 fixing Ceiling price of Rs. 2.02 per tablet of Ciprofloxacin HCl tablet 250 mg under DPCO, 2013.

3. The grievance of the Petitioner raised in their review application dated 7.10.2014 were sent to NPPA and the comments of NPPA thereon were given to the Petitioner through the record note of discussions held in the hearing on 24.11.2014. Record note of discussion is made integral part of the review order. After considering the comments of NPPA the Petitioner has raised the following points, on which comments given by NPPA representative during the hearing and Department's comments on the issue is recorded subsequently against each point:

4. **Petitioner:**

The petitioner representative mentioned that their brand Ciprobid 250 mg tablet with PTR of Rs.2.71 per tablet has not been considered by NPPA. The company representative, therefore, requested that the price fixation may be reconsidered by NPPA by considering their brand Ciprobid 250 mg tablet having PTR of Rs.2.71 per tablet which has a market share of 23% as per AWACS.

The petitioner representative provided a photocopy of strip of Ciprobid 250 mg tablet manufactured in July 2013 (batch No.ZHN 2943) substantiating that Ciprobid 250 mg tablet was/is existing in the market.

5. **NPPA comments:**

NPPA representative stated that data as provided by IMS Health has been considered in price fixation which did not include data of Ciprobid 250mg tablet of M/s Zydus Healthcare.

6. **Government's decision:**

Para 9(1) of DPCO 2013 empowers NPPA to revalidate data by appropriate survey or evaluation. NPPA may be directed to revalidate the data.

Based on the above and other documents on record, the Government has decided as under:

“Para 9(1) of DPCO 2013 empowers NPPA to revalidate data by appropriate survey or evaluation. NPPA is directed to revalidate the data.”

Issued on this date 6th February, 2015

(Anil Jain)

Under Secretary to the Government of India
For and on behalf of the President of India

To

1. The Member Secretary,
National Pharmaceutical Pricing Authority,
YMCA Cultural Centre Building, New Delhi-110001
2. M/s Zydus Healthcare Ltd.,
Zydus Tower,
Satellite Cross Road,
Ahmedabad-380 015

Copy to :

1. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.
2. Sr. PPS to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
3. T.D. (NIC) for uploading order on Department Website.