

**No. 31015/4/2014-PI.I**  
**GOVERNMENT OF INDIA**  
**MINISTRY OF CHEMICALS & FERTILIZERS**  
**DEPARTMENT OF PHARMACEUTICALS**

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B Wing, Janpath Bhavan, New Delhi

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

**Subject:** Review application of M/s. Aristo Pharmaceutcals Ltd. against fixation/revision of retail prices of Ilaprazole + Domperidone capsules (Checkcid-D SR) vide NPPA notification S.O. No.3151 (E) dated 10.12.2014 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013).

**Ref.** 1) Applicant Review application dated 23.12.2014  
2) NPPA notification under review S.O. No. 3151(E) dt. 10.12.2014  
3) Record Note of discussions held in the personal hearing held in the matter  
on 2.2.2015

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Whereas National Pharmaceutical Pricing Authority (NPPA), Government of India, vide price fixation Order S.O. No. 3151(E) dated 10.12.2014 fixed/revised retail price of Rs.4.37 per capsule of the above referred formulation under DPCO, 2013 included in Schedule-I of the order.

2. And whereas aggrieved by the above notification, M/s Aristo Pharmaceutcals Ltd., (hereinafter referred to as the Petitioner) submitted review application dated 23.12.2014 under para.31 of DPCO, 2013 for the review of NPPA Price fixation Order S.O.No. fixing Ceiling price of Ilaprazole + Domperidone capsules (Checkcid-D SR) under DPCO, 2013.

3. The grievance of the Petitioner raised in their review application dated 23.12.2014 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 2.2.2015. 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 Government's comments on the issue is recorded subsequently against each point:

**Petitioner's submission during personal hearing**

Petitioner: The petitioner representative mentioned that NPPA notified the price of this combination under para 6 based on the monopoly criteria treating Ajanta Pharma as the only manufacturer/marketer of the product. In the review application, details of 5 brands manufactured /marketed by different companies have been given by the petitioner. The price, therefore, should have fixed under para 5 based on the criteria in para 4 (1) of DPCO taking into consideration the average PTR of all the manufacturers/marketers. The rates given by the petitioner for different brands available in the market are between Rs.99 to 109.

NPPA comments: The NPPA representative stated that the price was fixed by applying monopoly condition as per para 6(1). As per pharma Trac, only one company was manufacturing the formulation and thus monopoly condition has been applied.

Department's comments:

4. The petitioner representative mentioned that there are 5 brands manufactured/marketed by different companies and, therefore application of para 6 based on monopoly criteria treating Ajanta Pharma as the only manufacturer of the product is not correct. NPPA representative mentioned that the price was fixed applying monopoly condition under para 6(1) as the data providing company i.e. Pharma Trac in this case, has mentioned that only one company was manufacturing the said formulation. But there are sufficient provision under para 9 (1) of DPCO 2013 under which NPPA may revalidate the data by appropriate survey or evaluation.

Government Decision :

5. NPPA may revalidate the data under para 9(1) of DPCO 2013 by appropriate survey or evaluation and revise the price.

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

“NPPA may revalidate the data under para 9(1) of DPCO 2013 by appropriate survey or evaluation and revise the price.”

Issued on this date 14<sup>th</sup> May, 2015.

( A.K.Sah )

Under Secretary to the Govt. of India  
For and on behalf of the President of India

To

1. M/s. Aristo Pharmaceuticals Ltd. Ltd.,  
Mercantile Chambers, 3<sup>rd</sup> floor,  
12, J.N. Heradia Marg, Ballard Estate  
Mumbai-400 001
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. Sr. PPS to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
3. TD, NIC for uploading the Order on Department's Website.