

**No. 31015/3/2016-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 Boehringer Ingelheim India Pvt. Ltd. against price fixation of Paracetamol 325 mg + Hyoscine Butylbromide 10 mg tablets (Buscogast Plus Tablets) vide NPPA order No. S.O. 583(E) dated 24/02/2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref:** 1) Review application dated 09.03.2016  
2) NPPA notification under review S.O. No.583(E) dated 24.2.2016  
3) Record Note of discussions held in the personal hearing held in the matter on 18.4.2016.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Boehringer Ingelheim India Pvt. Ltd. (hereinafter called the petitioner) against notification S.O. No.583(E) dated 24.02.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Paracetamol 325 mg + Hyoscine Butylbromide 10 mg Tablets (Buscogast Plus Tablets).

2. The petitioner has contended as under:

- (i) Based on the worksheet placed on NPPA's website, it is evident that NPPA has not followed the correct methodology, whereas the price should have been fixed by following the methodology under Para 4, 5(1) and 9 (1) (4) of the DPCO, 2013. Relevant information/data provided by company vide reference no BI/NPPA/F-1/001/2014 dated 25/09/2014 was not considered while fixing the retail price was fixed for this pack;
- (ii) NPPA also ignored the **IMS data**, where more than one player was already in the market;
- (iii) The above mentioned formulation is not available in monopoly condition;  
and
- (iv) NPPA has notified price of Paracetamol 500mg tablet at Rs. 1.04 and Hyoscine Butylbromide at Rs. 3.13, the price still works out at Rs. 4.17 per tablet (i.e. sum of both the ceiling prices). It is illogical to have a retail price lower than the sum of individual price. Therefore, they requested to re-fix the price by allowing impact of an annual entry.

5. A copy of the review petition was sent to the NPPA, which submitted its comments vide its letter dated 13.4.2016, as under:

- (i) M/s Boehringer Ingelheim India Pvt. Ltd., marketing company of the said formulation vide its Form-I application dated 25/09/2014 (received in NPPA on 26/09/2014) has applied for price fixation of the above new drug formulation. The applicant company has claimed the retail price of Rs. 55.70 for a strip of 10's tablet and launched its product in December 2014, after the period of 60 days from the date of its application. The overcharging action for this being done separately.
- (ii) There are two other companies who have marketed product with the same composition, however, only the product of M/s Mankind was considered for fixing prices in the instant case as the product of M/s Acme Pharma (Manufacturer), marketed by M/s German Remedies (M/s Cadilla Healthcare i.e M/s Zydus Cadilla) was also launched in market without prior price approval of NPPA and hence was not considered. The overcharging action for this is also being done separately.
- (iii) During 26<sup>th</sup> Authority Meeting held on 24/02/2016, the Authority fixed the retail price of Rs. 3.76 per tablet as per para 5, 11, and 15 of DPCO, 2013 for M/s Boehringer Ingelheim Pvt. Ltd. and M/s Kemwell Biop Pharma Ltd. (manufacturer).
- (iv) During 27<sup>th</sup> Authority meeting (held on 29/03/2016), Authority also fixed the retail price of Rs. 3.76 per tablet for tablet containing Paracetamol 325mg + Hyoscine Butylbromide 10 mg manufactured by M/s Acme Pharmaceuticals and marketed by M/s German Remedies / Cadilla Healthcare, vide S.O. 1254(E) dated 29/03/2016.

6. The contentions of petitioner and the NPPA were heard on 18<sup>th</sup> April, 2016. The petitioner stated that they have submitted form 5 to NPPA on 2.4.2016 and are already complying with the relevant provisions of para 31 of DPCO 2013. The petitioner further informed that NPPA has not followed the provisions of para 9 (1) and (4) of DPCO 2013 wherein data and marketed products had to be taken into consideration, 6 months prior to fixation of price. Instead NPPA relied on data of 2012 price of only one product from one company. The petitioner further stated that besides Boehringer Ingelheim India Pvt. Ltd. there are two more players since 2012, M/s German Remedies India Pvt. Ltd. and ACME Pvt. Ltd. which have more than 1% market share (non-scheduled products). NPPA has not considered the PTR of these existing companies marketing the products under reference.

In response to above submission, NPPA representative stated that the data provided by Pharmatech was considered as per the existing practice. The data of M/s German Remedies India Pvt. Ltd. and ACME Pvt. Ltd. were not considered as they were marketing their packs without price approval and, therefore, attracts the provisions

of overcharging under provision of DPCO 2013. NPPA has fixed the retail price at Rs.3.76 per tablet for Hyocimax plus tablet containing Hyoscine Butylbromide 10 mg and paracetamol 325 mg vide SO No. 1254(E) dt. 29.3.2016.

7. The petitioner further mentioned that the products marketed by M/s German Remedies India Pvt. Ltd. and ACME Pvt. Ltd are non-scheduled formulation marketed prior to DPCO 2013 notification. Hence the price of these products from the above mentioned companies should have been considered as per para 9(1) and (4) of DPCO 2013. Further, price and products having market share more than 1 % have not been correctly considered by NPPA for arriving at the retail price as per IMS data between March to September 2014 as per provision of para 9(1) (4) of DPCO 2013. Hyocimax plus tablet containing Hyoscine Butylbromide 10 mg and paracetamol 325 mg was already available in market more than 6 months prior to submission of our request in form I for price approval in September 2014.

NPPA representative stated that the company had now submitted some more information regarding MRP of Dolokind Spas Tablet of M/s Mankind Pharma Ltd. to Department of Pharmaceuticals without indicating the PTR, and the same was not endorsed by IMS / Pharmatech. Therefore, this data was not considered by NPPA while calculating retail price for this pack in the absence of supporting documents.

8. During the personal hearing, the petitioner also provided a copy of IMS data along with Form I in September 2014 in addition to packs available in market (scanned pictures of these packs were submitted with the form I application in Sept 2014) and requested for considering the IMS data for refixing the price of their product. Accordingly, the petitioner requested to reconsider the September 2014 application and revise the price for the mentioned product taking into consideration the data submitted by them.

**9. Examination:**

- (i) The price fixed vide S.O.583(E) is Rs. 3.76 per tablet is in favour of M/s Kemwell Biopharma Pvt. Ltd. & M/s Boehringer Ingelheim India.
- (ii) The contention of the petitioner is that NPPA has not considered the data provided by them during September 2014 as well as IMS data reflecting more than one manufacturer in the market for the formulation under reference. The petitioner also contended that the NPPA has notified prices for Paracetamol 500 mg tablet @ Rs. 1.04 and Hyoscine Butyl Bromide @ Rs. 3.13. Based on these prices the price @ Rs. 3.76 per tablet is inadequate.
- (iii) NPPA has contended that they have fixed price of the formulation as a **new drug** for the applicant company. It is also mentioned that other

companies quoted as marketing this formulation, did not have prior price approval and action is being separately initiated against them.

Based on the facts of the matter following observations are made:

- a) The tablet formulation containing Hyoscine Butyl Bromide 10 mg & Paracetamol 325 mg is a non-Schedule formulation and the price has been rightly fixed by NPPA as a New Drug in case the applicant has launched the product after implementation of DPCO 2013.
- b) The price was fixed by NPPA for the company considering the product as a new drug and monopoly formulation as no other company was marketing the said formulation with proper prior price approval.
- c) The IMS data provided by the company reflects presence of various manufactures of the same formulation and indicate that there are 5 brands of the same formulation being marketed in the country.

10. **Decision of the Government:**

**NPPA is directed to re-fix the ceiling price of “Paracetamol 325 mg + Hyoscine Butylbromide 10 mg tablets (Buscogast Plus Tablets)” after taking into consideration data furnished by the petitioner company on merit within a period of one month from the date of issue of this Order.**

Issued on this date, the 22<sup>nd</sup> day of July, 2016.

**(M.K. Bhardwaj)**  
**Deputy Secretary**

**For and on behalf of the President of India**

**To**

1. **M/s. Boehringer Ingelheim India Pvt. Ltd.,  
1002, 10<sup>th</sup> Floor, Hallmark Business Plaza,  
Gurunanak Hospital Road, Near Gurunanak Hospital,  
Bandra East,  
Mumbai - 400051**
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**