

**No. 31015/5/2017-PI.I**  
**GOVERNMENT OF INDIA**  
**MINISTRY OF CHEMICALS & FERTILIZERS**  
**DEPARTMENT OF PHARMACEUTICALS**

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**A- Wing, Shastri Bhawan,  
New Delhi 110 001**

**Subject:** Review application of M/s Boehringer Ingelheim India Pvt. Ltd. against price fixation of “Hyoscine Butyl Bromide Injection 20 mg/ml” vide NPPA order No. S.O. 4128(E), dated 22.12.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref:** 1) Review application dated 05.01.2017  
2) NPPA notification under review S.O. 4128(E), dated 22.12.2016  
3) Record Note of discussions held in the personal hearing held in the matter on 07.03.2017.

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.4128(E), dated 22.12.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Hyoscine Butyl Bromide Injection 20 mg/ml

2. The petitioner has contended as under:-

- I. They observed that the working sheets uploaded on NPPA’s website capture the Ceiling Price calculation for Hyoscine Butyl bromide 20mg/ml. they submitted that the PTR mentioned for some brands has been rightly considered for the calculation, **like for Buscogast injection which is with Boehringer Ingelheim, the price considered is rightly taken however, for another product Hyocimax injection 20mg/ml from Zydus Cadila has been wrongly considered.** This is impacting the overall calculation of proposed ceiling price for Hyoscine butyl bromide injection 20mg/ml and hence affecting the price for their brand Buscogast injection as well.
- II. In view of above, they requested this Department to request NPPA to revalidate correct price for Hyocimax injection (Zydus Cadila) from Zydus Cadila to calculate the correct ceiling price and offer them relief on the right ceiling price.

**Comments of NPPA:**

- (i) Ceiling price of Rs. 9.67 per ml for **Hyoscine Butyl Bromide 20mg/ml Injection** was notified vide S.O. 4128(E) dated 22.12.2016 as per para 4, 10, 11, 14, 16, 17 & 18 under DPCO 2013.
- (ii) Company has stated that correct methodology was not followed in arriving at the ceiling price for **Hyoscine Butyl Bromide 20mg/ml Injection**. The points raised by the company are not relevant. Price fixation has been done strictly in

accordance with the provisions of DPCO, 2013 and as per the decisions of 27<sup>th</sup> Authority meeting held on 29.3.2016. NPPA also uploaded draft working sheet of proposed ceiling price of this formulation on its website. This was on the website of NPPA for 10 clear working days. **Neither M/s Boehringer Ingelheim India Pvt. Ltd. nor M/s Zydus Cadila made any representation against the proposed ceiling price uploaded on NPPA's website.**

(iii) Company has not challenged any notification in respect of **Hyoscine Butyl Bromide 20mg/ml Injection** in the Court.

3. During the personal hearing, the representatives of the company the working sheets uploaded on NPPA's website capture the Ceiling Price calculation for Hyoscine Butyl bromide 20mg/ml. further submitted that the PTR mentioned for some brands has been rightly considered for the calculation, **like for Buscogast injection which is with Boehringer Ingelheim, the price considered is rightly taken however, for another product Hyocimax injection 20mg/ml from Zydus Cadila has been wrongly considered.** This is impacting the overall calculation of proposed ceiling price for Hyoscine butyl bromide injection 20mg/ml and hence affecting the price for their brand Buscogast injection as well.

In view of above, it was further requested to this Department to request NPPA to revalidate correct price for Hyocimax injection (Zydus Cadila) from Zydus Cadila to calculate the correct ceiling price and offer them relief on the right ceiling price.

4. NPPA representative submitted that the ceiling price of Hyoscine Butyl bromide 20mg/ml. based on the data submitted by Pharmatrac for the month of August, 2015 as per existing practice. With respect of subject formulation Zydus Cadila has not raised any objection against draft working sheet uploaded on NPPA website regarding the PTR of its product.

#### **5. Examination:**

The petitioner company has challenged the NPPA Order S.O. 4128(E), dated 22.12.2016 for price fixation of their formulation **Hyoscine Butyl Bromide Injection 20 mg/ml** on the ground that correct methodology was not followed in arriving at the ceiling price of Hyoscine Butyl Bromide 20 mg/ml injection and the price of Hyocimax injection 20 mg/ml from Zydus Cadila has been wrongly considered. **The company has not submitted any documentary proof in support of their claim that NPPA has wrongly taken the data of Hyocimax injection 20 mg/ml.** NPPA has fixed the ceiling price based on the data provided by Pharmatrac for the month of August, 2015 and strictly in accordance with the provisions of DPCO 2013. Therefore, the grievance of the company has got no merit and the review petition may be rejected.

#### **6. Government Decision:**

**"The grievance raised by M/s Boehringer Ingelheim India Pvt. Ltd. in their review petition has got no merit and hence the petition stands rejected."**

Issued on this date, the 5<sup>th</sup> day of April, 2017.

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

To

1. M/s. Boehringer Ingelheim India Pvt. Ltd.  
1102, 11<sup>th</sup> Floor, Hallmark Business Plaza,  
Gurunanak Hospital Road, Gurunanak Hospital,  
Bandra East, Mumbai-400 051.
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