

**No. 31015/20/2016-PI.I**  
**GOVERNMENT OF INDIA**  
**MINISTRY OF CHEMICALS & FERTILIZERS**  
**DEPARTMENT OF PHARMACEUTICALS**

B Wing, Janpath Bhavan,  
New Delhi 110 001

**Subject:** The review application of M/s Wockhardt Ltd dated 04/05/2016 under para 31 of DPCO against NPPA order No. S.O. 1405(E) dated 12/04/2016 for price fixation of Erythropoietin Injection 2000 IU and 10000 IU.

**Ref:** 1) Review application dated 04.05.2016  
2) NPPA notification under review S.O. No.1405(E) dated 12.4.2016  
3) Record Note of discussions held in the personal hearings held in the matter 31.5.2016.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Wockhardt. Ltd. (hereinafter called the petitioner) against notification S.O. No.1405(E) dated 12.04.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Erythropoietin Injection 2000 IU and 10000 IU.

2. The petitioner has contended as under:

- (i) They are manufacturing and marketing the formulations Erythropoietin – 2000 IU/ml and Erythropoietin – 10000 IU/ml in three different packs under their trademarks WEPOX 2000 IU & WEPOX 10000 IU respectively.
- (ii) The said formulations are now scheduled formulations as per the NLEM, 2015 which is notified on 23<sup>rd</sup> December, 2015.
- (iii) They further submitted that now the ceiling price of above said formulation is fixed vide Notification no. S.O 1405(E) dated 12/04/2016 under para 4,10, 11, 14, 16, 17 and 18 of DPCO, 2013 viz.

a. Erythropoietin-2000 IU/ml	Rs. 562.49	For each Pack
b. Erythropoietin- 10000 IU/ml	Rs. 2349.76	For each Pack

- (iv) They submitted that Ceiling Price for Erythropoietin is not calculated in accordance with Para 4 of the DPCO, 2013. In working sheet of calculation of ceiling price of Erythropoietin 2000 IU/ml Sale of only three companies viz. LA RENON, MICRO LABS and SAMARTH Life Sciences Pvt. Ltd. is considered whereas for Erythropoietin 10000 IU/ml Sale of only two companies viz. LA RENON & MICRO LABS Ltd. is considered. Whereas it has not considered sale of major companies marketing Erythropoietin formulation, including sale of their company “Wockhardt limited”.

- (v) Further they submitted that the three different packs are as under:
- Vials (to be used with disposable injections)
  - PFS (Pre Filled Syringes)
  - PFS with safety mechanism (SAFE).
- (vi) They submitted that it is irrational and unscientific to fix single ceiling price for all packs. Each pack has different costing and pricing MRP of all packs cannot be the same. MRP of their formulation prior to above mentioned notification were as under:

Product	Pack	MRP
Wepox 2000 IU	PFS	779
Wepox 2000 IU	Vial	712
Wepox 2000 IU SAFE	PFS	930
Wepox 10000 IU	PFS	3236

They requested this Department to direct NPPA to withdraw the notification related to the above-said formulation.

3. A copy of the review petition was sent to the NPPA, which submitted its comments vide its letter dated 30.5.2016, as under:

- Erythropoietin injection 2000IU/ml and 10000 IU/ml are included under section 10.1.1 & 10.1.2 of NLEM, 2015. NPPA has fixed ceiling price Rs.562.49 for Erythropoietin injection 2000 IU per pack and Rs.2349.76 for Erythropoietin injection 10000 IU per pack. Company has not submitted any representation as per NPPA OM File No. 19(714)/2016/Div. II/DP/NPPA dated 11.4.2016 while other major Companies have submitted their representations along with supporting documents like copy of Invoices indicating Price to Retailer (PTR) and Moving Annual Turnover (MAT value) and samples of Aug. 2015 (dully self attested) as requested in OM dated 11/20.5.2016 (uploaded on NPPA website).
- NPPA will be able to consider the representation of M/s. Wockhardt while revising/refixing the ceiling price for subject formulation subject to the availability of required information of MAT as well as PTR.

4. In the personal hearing held on 31.5.2016, the petitioner stated that the data of various companies have not been considered while fixing the price of Erythropoietin Injection 2000 IU and 10000 IU. They submitted that M/s Wockhardt Ltd. itself is marketing Erythropoietin Injection in different dose forms that too have not been taken into account by NPPA for arriving at price fixation for the purpose. The Company also submitted that different doses form have different therapeutic advantages to the patients.

5. The NPPA representative requested the petitioner company to furnish the data / details as available with them in terms of NPPA OM No.F.No.19(714)/2016/Div.II/DP/NPPA, dated 11.4.2016 which states that

***aggrieved companies, by such price fixation, may make representations, if any, against the ceiling prices fixed by the NPPA by submitting their Price to Retailer (PTR) and Moving Annual Turnover (MAT) data along with supporting documents like copies of invoices to retailer and samples of August, 2015 in order to take necessary action in this regard.*** On receipt of information from petitioner company, the matter will be placed before the Authority Meeting. Similarly, the request of the petitioner company for giving differential prices to their different doses form i.e. vials, PFS and PFS with safety mechanism with different therapeutic advantages to the patients may be put up to the Authority Meeting.

6. The petitioner consented to furnish the relevant information / data as per NPPA OM No. F.No.19(714)/2016/Div.II/DP/NPPA, dated 11.4.2016, within a week's time, to enable NPPA to take further action in the matter.

7. **Government Decision:**

Any relevant data being furnished by the petitioner company to the NPPA may be examined by NPPA on merits and orders issues within one month of this decision.

In view of the above, the present review petition stands disposed off.

Issued on this date of, 4<sup>th</sup> of July, 2016.

(M.K. Bhardwaj)

Deputy Secretary

For and on behalf of the President of India

To

1. M/s. Wockhardt Limited,  
Wockhardt Towers,  
Bandra Kurla Complex,  
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