

**No. 31015/99/2016-PI.I**  
**GOVERNMENT OF INDIA**  
**MINISTRY OF CHEMICALS & FERTILIZERS**  
**DEPARTMENT OF PHARMACEUTICALS**

A Wing, Shastri Bhavan,  
New Delhi 110 001

**Subject: The review application of M/s Wockhardt Ltd dated 22.11.2016 under para 31 of DPCO against NPPA order No. S.O. 3431(E), dated 10.11.2016 for price fixation of Dicyclomine Injection (Spasmoproxyvon)**

**Ref: 1) Review application dated 22.11.2016**  
**2) NPPA notification under review S.O. No.3431(E) dated 10.11.2016**  
**3) Record Note of discussions held in the personal hearings held in the matter on 03.01.2017**

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.3431(E) dated 10.11.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Dicyclomine Injection (Spasmoproxyvon).

2. The petitioner has contended as under:

I. As per Gazette Notification No. S.O 1192 (E) dated 22nd March'2016 with respect to amendment in the Drug (Prices Control) Order, 2013. In Paragraph-11 after sub paragraph (2) the following sub-paragraph were inserted.

“(3) Notwithstanding anything contained in sub-paragraph (1) and (2) , in the case of injections or inhalation or any other medicine for which dosage form or strength or both are not specified in the Schedule-I of the Drugs ( Prices Control ) Order , 2013, the Government may fix and notify separate ceiling price or retail price for such formulations with specific therapeutic rationale , considering the type of packaging or pack size or dosage compliance or content in the pack namely liquid , gaseous or any other form , in the unit dosage as the case may be , conforming to Indian Pharmacopeia or other standards as specified in the Drugs and Cosmetics Act , 1940 ( 23 of 1940 ) and the rules made thereunder for the same formulation.”

II. **The ceiling price of the above said formulation has been worked out considering average price of 1 ml, 2 ml, 10 ml and 30 ml packs taken together. This is in contravene with above notification no S.O. 1192 (E) which clearly states that in case of Injections separate ceiling price should be fixed for each pack size.**

III. The previous ceiling price of this formulation was also fixed by NPPA vide notification no. 2064(E) dated 05-07-2013 considering average price of all different packs resulting in reduction in price by 65.4 % as compared to the highest price considering MAT value as on May, 2012.

- IV. By virtue of the directives dated 05.05.2016 issued by DoP, NPPA has by its notifications issued in June 2016 **{(S.O. 2209(E) and S.O. 2210(E)}** has re-fixed the ceiling prices of glucose injection, sodium chloride injection as well as glucose plus sodium chloride injection based on MAT value of September-November, 2013. They are also expecting similar directives from DoP to NPPA.
- V. They further stated that for calculation of ceiling price, spasmo proxyvon 10 mg injection 30 ml is included. **they stated that they have discontinued to manufacture the stated pack of 30 ML in the year 2005. Hence price of this pack should not be consider. Same in case of Cyclopam 10 mg injection 30 ML, they doubted that they are also selling the said pack.**
- VI. They further submitted that subsequent to notification no. S.O. 1192 (E) dated 22<sup>nd</sup> March, 2016. Most of the companies manufacturing injection in multiple packs applied for review against price revision/ fixation order of NPPA. Again in most of such cases DoP has directed NPPA to re examine and re fix the price on merit. Whereas NPPA takes their own time in re fixing the price resulting in margin losses to the industry. **In case of their product Wepox injection also DoP has directed NPPA to issue order within one month of the discussion dated 4<sup>th</sup> July, 2016 based on relevant data on merit but still there is no action from NPPA.**
- VII. They requested this Department to direct NPPA to withdraw of the notification related to above formulations and re-fix the ceiling price based on directives dated 05.05.2016 issued by DoP.
3. A copy of the review petition was sent to the NPPA, which submitted its comments vide its letter dated 06.01.2017, as under:
- (i) NPPA has fixed the ceiling price of Rs. 2.95/ml vide S.O. 2064(E) dated 05.7.2013 and the same was revised to Rs. 3.14, Rs. 3.26 & 3.17 per ml vide S.O. 1156(E), 619(E) & 644(E) dated 28.4.2014, 26.02.2015 & 02.3.2016 respectively under NLEM 2011 and Rs. 2.44/ml vide S.O. 3431(E) dated 10.11.2016 under NLEM 2015 based on the data provided by pharmatrac for the month of August, 2015 as per existing practice.
- (ii) **Representation submitted by M/s Wockhardt Ltd. under para 11(3 & 4) in this case is under examination.**
- (iii) DOP vide letter no. F. No. 31015/44/2016-PI.I dated 11.7.2016 gave the following, directions: *"NPPA to henceforth place a draft version of the Price Calculation Sheets for the proposed revised price notification, including wherever applicable, the Price to Retailer (PTR) and Moving Annual Turnover (MAT) values adopted for calculations, on the website of NPPA for 10 clear working days to invite comments from the affected pharmaceuticals firms. Only after taking into account the comments or any additional data thus received within the given time period, the NPPA shall finalize the Ceiling and the Retail Prices. This issues with the approval of Hon'ble Minister (Chemicals*

& Fertilizers)". Accordingly, NPPA uploaded draft working sheet of proposed ceiling price of this formulation also on its website. This was on the website of NPPA for 10 clear working days. **M/s Wockhardt Ltd. did not make any representation against the proposed ceiling price uploaded on NPPA's website.**

(iv) As per information available with NPPA, company has not challenged any notification in respect of Dicyclomine 10mg/ml Injection in the Court.

4. The contentions of petitioner and the NPPA were heard on 03.01.2017, wherein the representatives of the company stated that they have nothing more to submit in addition to written submissions already made. **The representatives of the company confirmed that they are following the ceiling price notified by NPPA and also submitted copy of Form-V.**

5. **Examination:**

The grievance of the company that NPPA has clubbed the PTR of 1ml, 2ml, 10ml and 30 ml packs while calculating the ceiling price of this formulation, in the absence of mention of any particular pack size in NLEM, 2015, the clubbing of PTR by NPPA is justified. However, the company submitted its representation under para 11(3&4), which states that "Government may fix and notify separate ceiling price or retail price for such formulations with specified therapeutic rationale, considering the type of packaging or pack size or dosage compliance or content in the pack namely liquid, gaseous or any other form, in the unit dosage as the case may be, conforming to Indian Pharmacopeia or other standards as specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules made thereunder for the same formulation." NPPA confirmed that the representation submitted by M/s Wockhardt Ltd. under para 11(3&4) is under examination. The company also stated that NPPA has considered the PTR of their 30ml pack, which was discontinued manufacturing in the year 2005.

The Hearing Authority is of the opinion that NPPA may be directed to examine the representation submitted by Wockhardt Ltd. under para 11(3&4) and relevant document/information submitted by the petitioner company about discontinuation of their 30ml pack, and to re-fix the ceiling price of **Dicyclomine Injection (Spasmoproxyvon)**, on merit.

6. **Government decision:**

**"NPPA is hereby directed to examine the representation submitted by Wockhardt Ltd. under para 11(3&4) and relevant document/information submitted by the petitioner company about discontinuation of their 30ml pack, and to re-fix the ceiling price of Dicyclomine Injection (Spasmoproxyvon) on merit, within 30 days of this Order and to send the compliance report to the Department".**

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

Issued on this 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. 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