

No. 31015/46/2017-Pricing
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 29/03/2017 under para 31 of DPCO against NPPA order No. S.O. 787(E) dated 10/03/2017 for price fixation of Methyldopa Tablet 500mg.

Ref: 1) Review application dated 29.03.2017
2) NPPA notification under review S.O. No.787(E) dated 10.03.2017
3) Record Note of discussions held in the personal hearings held in the matter on 04.07.2017.

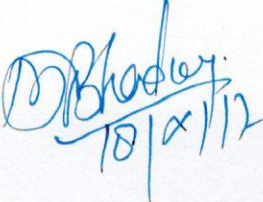
1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Wockhardt. Ltd. (hereinafter called the petitioner) against notification S.O. No.787(E) dated 10.03.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Methyldopa Tablet 500 mg.

2. The petitioner has contended as under:

- I. As per the 2017 Notification, the National Pharmaceutical Pricing Authority ("**NPPA**") has fixed the ceiling price of Methyldopa-500mg tablets at Rs. 4.33/ tablet for all manufacturers of the scheduled formulation.

Facts:

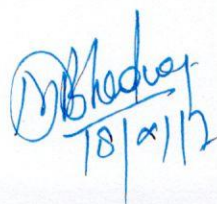
- a. M/s. Wockhardt Ltd. currently markets Alphadopa 500 mg tablets (which contain Methyldopa 500 mg). As per the National List of Essential Medicines 2011 ("**NLEM 2011**") under DPCO 2013 in Schedule I, Methyldopa-500mg was a non-scheduled formulation. Subsequently, pursuant to Notification S.O. 701 (E) dated 10 March 2016, Methyldopa 500-mg was added in Schedule I of DPCO 2013 by virtue of the National List of Essential Medicines 2015 ("**NLEM 2015**").
- b. Pursuant to its inclusion in NLEM 2015, by virtue of S.O. No. 1254 (E) dated 29th March, 2016, NPPA fixed the retail price of Methyldopa-500mg as a "new drug" under Paragraph 15 of DPCO 2013 at Rs. 4.46/ tablet. It is pertinent to note that this price was only fixed for the concerned manufacturers in that case i.e. M/s Medibios Lab. Pvt. Ltd. and M/s Wockhardt Ltd.
- c. Company applied for review against the above stated notification on 5 April 2016. Subsequently, they had three personal hearing on 29 April, 2016, 31 May, 2016 and 18 October, 2016 with the Department of Pharmaceuticals ("**DOP**") to explain their point of view regarding the fixation of the retail price of Methyldopa-500mg.
- d. The DOP, on 5 January 2017, issued their review order, directing the NPPA to re-examine the fixation of price of Methyldopa 500 mg. tablet and to re-fix the


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- ceiling price under Paragraph 4 (1) and Paragraph 6 of DPCO 2013, within a month's time from the date of the order i.e. 5 January 2015.
- e. Subsequently, the NPPA, by O.M. No. 8(34)/2016/DP/NPPA/Div.II dated 21.02.2017, proposed the ceiling price of Methyldopa-500mg to be set at Rs. 13.90/tablet. They made no representation against this price formulation by NPPA.
 - f. In its meeting on 9 March 2017, NPPA examined the draft calculation sheet of Methyldopa-500mg and the review order of DOP dated 5 January 2017. On the basis of this, NPPA took the retail price fixed by virtue of S.O. No. 1254 (E) dated 29th March, 2016 as the ceiling price, disregarding the ceiling price determined by the process stipulated in the DPCO 2013, and fixed the final ceiling price of the formulation after adjusting the wholesale price index ("WPI") of (-) 2.7105% at Rs. 4.33/ tablet.
 - g. This ceiling price was notified by the NPPA by virtue of Notification S.O. 787 (e) dated 10 March 2017.
 - h. Dissatisfied with the ceiling price fixed by the NPPA by virtue of Notification S.O. 787 (e) dated 10 March 2017, the company submitted this review application to request the NPPA to re-examine the price on the basis of the process established by the DPCO 2013.

Grounds:

- i. The ceiling price fixed by NPPA in its meeting on 29 March 2017 is without application of mind, and is totally contrary to the rules and procedure stipulated under the DPCO 2013, specifically, Paragraphs 4 (1) and Paragraph 6.
- j. The final ceiling price fixed by the NPPA arbitrarily reduces the price of the formulation to Rs. 4.33/ tablet from the proposed ceiling price of Rs. 13.90/ tablet initially proposed by virtue of O.M. No. 8(34)/2016/DP/NPPA/Div.II dated 21.02.2017.
- k. The final ceiling price fixed by the NPPA reduced the price of the formulation by Rs. 9.57. The NPPA provided no reason or explanation for deviating from its own proposed price of Rs. 13.90/ tablet on the basis of its calculations. By disregarding the proposed price, and establishing an arbitrary price without justification vitiates the due process of law as laid down in DPCO 2013, and violates our rights.
- l. The NPPA has violated the procedure for price fixation under Paragraphs 4 (1) and Paragraph 6 of the DPCO 2013 by arbitrarily considering the retail price fixed *only* for M/s Medibios Lab. Pvt. Ltd. and M/s Wockhardt Ltd. on 29 March 2016 as the ceiling price for *all* manufacturers of Methyldopa-500mg.
- m. M/s Wockhardt Ltd. did not make any representation against the proposed price fixation for Methyldopa-500mg of Rs. 13.90/ tablet. As M/s. Wockhardt Ltd. is the only manufacturer of the said formulation and they have no existing competitors, there would have been no representations made to NPPA against the proposed price. If any representations were made to NPPA, these had to be reasoned and justified through the minutes of the meeting dated 9 March 2017. Recording the detailed reasoning and justification is required to establish the conformity of following due process of law and application of mind.



- n. The prices fixed for other formulations, as displayed on the NPPA website, have been finalised without any variation or reduction. The ceiling price of one other drug has even increased. Contrary to all the other drugs, the ceiling price of Methyldopa-500mg has been reduced by a significant margin, highlighting the discrimination of and bias against M/s Wockhardt Ltd, as well as non-application of mind by the authorities to single out the drug manufactured by M/s Wockhardt Ltd.
- o. Company has waited for complete one year to obtain relief against the retail price fixed on 29March 2016 and has continued marketing the product at the notified price in spite of incurring heavy losses.
- p. Company has served the notice period of six months of intimation to NPPA required under Paragraph 22 of DPCO 2013, by submitting an application as per Form IV for discontinuation of this product on 6 April 2016. They continued to sell the product awaiting a fair and a reasonable review order, fixing an acceptable price for this formulation. Unfortunately, as the review price is lower than the initial price, and significantly lower than their cost incurred by them, they will now be forced to discontinue the product.
- q. In view of above, company has requested this Department to direct NPPA to withdraw Notification S.O. 787 (e) dated 10 March 2017 which fixes the ceiling price of Methyldopa-500mg at Rs. 4.33/ tablet and to either re-evaluate and re-fix the ceiling price for the product as per provisions of DPCO, 2013, or re-fix the price of the product on the basis of the original draft calculation sheet of the NPPA dated 21 February 2017.

3. **NPPA's Comments:**

- I. Ceiling price of **Methyldopa 500mg Tablet** was notified as Rs. 4.33/tablet vide S.O. 787(E) dated 10.3.2017 and revised to Rs. 4.42/tablet vide S.O. 1039(E) dated 01.4.2017 as per para 4, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.
- II. The company has stated that correct methodology was not followed in arriving at the ceiling price for **Methyldopa 500mg Tablet**. The points raised by the company are not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013. Details are as follows:-

Sl. No.	Company's Grievances	NPPA's comments
1.	Company has pointed out that NPPA vide OM no. 8(34)/2016/DP/NPPA/Div.II dated 21.02.2017 supposed the ceiling price of Methyldopa 500mg tablet to be set at Rs. 13.90/tablet. Company did not submit representation against the proposed ceiling price.	NPPA has rightly fixed the ceiling price of Methyldopa 500mg tablet as Rs. 4.33/tablet by following the provisions of DPCO 2013. The Authority in its 42 nd meeting held on 09.3.2017 examined the draft calculation sheet of Methyldopa 500mg tablet and the review order no 31015/5/2016-PI.I dated 05.01.2017. The Authority noticed that retail price of this formulation had been fixed on 29.3.2016 as Rs. 4.46/tablet. The Authority decided

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		to consider the retail price fixed for the formulation as the ceiling price too, as the formulation had become scheduled. After adjustment of WPI (-) 2.7105%, this was approved as Rs. 4.33/tablet (copy enclosed)
2.	<p>Facts on following ground:-</p> <p>1. Ceiling price fixed by NPPA is without application of mind, and is totally contrary to the rules and processor stipulated under DPCO, 2013.</p> <p>Ceiling price fixed by NPPA arbitrarily price of formulation to Rs. 4.33 per tablet from the proposed ceiling price of Rs. 13.90/tablet.</p>	<p>Ceiling price fixed by NPPA is as per the provisions of DPCO, 2013.</p> <p>The Authority examined and analyze the data mentioned in proposed ceiling price calculation sheet. It may be noted that ceiling price of Rs. 2.30/tablet for Methyldopa 250mg Tablet had been fixed by NPPA vide S.O. 1039(E) dated 01.4.2017.</p> <p>Not related to the provisions of DPCO, 2013.</p>
3.	Company has also pointed out that they have served the notice period of 6 months of intimation to NPPA require under para 22 of DPCO, 2013 by submitting an application as per Form IV for discontinuation of this products on 06.4.2016.	No comments.

The company has not challenged any notification in respect of **Methyldopa 500mg Tablet** in the Court.

4. During the personal hearing, in addition to written submissions already made, the representatives of the company further submitted that the NPPA in other cases fixed price for products of different strengths having huge difference between the two prices. However, in the case of Methyldopa 500mg tablet, the NPPA fixed the price with the difference in the strength of the products being very low. For example, the company submitted a copy of sheet showing different prices fixed by NPPA for different products having different strengths with a huge difference.

4.2 In addition to this, the company further submitted that NPPA has gone against the order passed by the DoP on 5th of January, 2017 to refix the price of Methyldopa 500mg as per para 4(1) and para 6 of DPCO. NPPA has in fact disregarded their own calculation sheet which they had published in the OM dated 21.2.2017, which was Rs.13.90 per tablet and has fixed the price ad hoc in contradiction to para 4(1) and para 6 of the DPCO at Rs.4.33/tablet. NPPA has wrongly fixed the price of Methyldopa 500mg tablet taking the basis of the retail price of the earlier price fixed on 29.3.2016, which was actually challenged by us and directed by DoP to be revised as per para 6 of DPCO.

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5. NPPA representative submitted that earlier review order was against the retail price fixation of Methyldopa 500mg tablet for M/s Wockhardt Limited. With the addition of Methyldopa 500mg tablet in NLEM 2015, NPPA fixed the ceiling price of the subject formulation by the Authority in its 42nd Meeting held on 9.3.2017.

6. **Examination:**

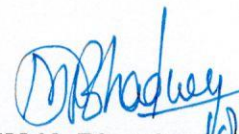
The price of Methyldopa 500mg was earlier fixed by NPPA vide SO No.1254(E), dated 29.3.2016, against which the company filed a review petition. DoP issued Review Order on 5.1.2017 directing NPPA to re-fix/revise the ceiling price of Methyldopa 500mg as per para 4(1) and para 6 of DPCO, 2013. Based on DoP's direction, NPPA, while revising the ceiling price of the subject formulation placed draft working sheet on its website on 21.02.2017 proposing the ceiling price as Rs.13.90/tablet. The company did not make any representation against the proposed ceiling price in draft working, as the company was fully satisfied with the proposed revision. However, before notifying the CP, the NPPA placed the matter before the Authority Meeting on 9.3.2017. In the Authority Meeting, a decision was taken to fix the ceiling price of the subject formulation as Rs.4.33/tablet, after giving negative WPI impact on the price of Rs.4.46/tablet, fixed earlier vide SO 1254(E), dated 29.3.2016. Based on the decision taken in the Authority Meeting, NPPA notified the price vide SO 787(E), dated 10.3.2017. In that way, NPPA has given no cognizance to the Review Order, dated 5.1.2017, issued by DoP. However, in the implementation report, NPPA stated that the Review Order stands implemented. M/s Wockhardt is the only company, which is manufacturing Methyldopa tablet 500mg and there is no other competitor. It may be worth mentioning here that the company has now already served a notice period of 6 months by submitting an application on 6.4.2016 as per Form IV for discontinuation of this product under para 22 of DPCO, 2013.

6.2 Keeping in view the facts mentioned above, it is seen that NPPA's Authority has taken an arbitrary decision in its meeting held on 9.3.2017, by not adhering to the direction issued by DoP on 5.1.2017. Therefore, NPPA may once again be directed to implement the Review Order No.31015/5/2016-PI.I, dated 5.1.2017 in its true spirit and fix the retail price of the formulation Methyldopa Tablet 500mg as per para 4(1) and para 6 of DPCO, 2013, and submit the compliance report.

7. **Government Decision:**

"NPPA is directed to strictly implement the Review Order No.31015/5/2016-PI.I, dated 5.1.2017 and fix the retail price of the formulation Methyldopa Tablet 500mg as per para 4(1) and para 6 of DPCO, 2013, and submit the compliance report."

Issued on this 18th day of October, 2017.


(M.K. Bhardwaj)
Deputy Secretary

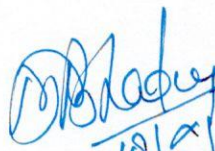
For and on behalf of the President of India

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


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