

No. 31015/53/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

A Wing, Shastri Bhawan,
New Delhi 110 001

Subject: Review application of M/s Pfizer Limited against price fixation of their formulation "Pitocin 0.5ml injection (containing Oxytocin Injection 10IU/ml." vide NPPA order No. S.O. 1009(E), dated 30.03.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 27.04.2017
2) NPPA notification under review S.O. No.1009(E), dated 30.03.2017
3) Record Note of discussions held in the personal hearing on 05.09.2017.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Pfizer Limited (hereinafter called the petitioner) against notification S.O. No.1009(E), dated 30.03.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of their formulations Pitocin 0.5ml injection (containing Oxytocin Injection 10IU/ml..

2. The petitioner has contended as under:

(i) NPPA had uploaded on its website the Draft Version of proposed price calculation Sheet in respect of 'Oxytocin Injection 10IU/ml vide Office Memorandum No. 8(35)/2016/DP/NPPA/Div.II dated 15.03.2017. Company stated that there was error in the above draft price calculation sheet issued on March 15, 2017.

(ii) Company had made a detailed representation in this respect to NPPA vide company's letter dated March 27, 2017 pointing out that the Price to Retailer for company's formulation Pitocin 10IU injection per 0.5 ml has been incorrectly considered by the NPPA in their draft price calculation sheet.

(iii) In spite of pointing out the errors in the draft price calculation sheet and providing valid supporting documents, NPPA ignored company's representation completely and without providing the company an opportunity in this regard arbitrarily fixed and notified the ceiling price of Pitocin 10IU Injection per 0.5 ml under S.O. 1009(E) dated March 30, 2017.

(iv) **Grounds:**

(a) In the price working sheet to the Notification No. S.O. 1009(E) dated 30.3.2017, NPPA has considered a Price to Retailer as Rs.17.23 whereas the Price to Retailer for this formulation was Rs.17.88. If the correct price of their formulation was taken into

consideration as above, the average ceiling price would have changed to Rs.38.67 per ml as against Rs.37.27 per ml i.e. after considering WPI increase of 1.97186%.

(b) In view of the above, Company requested to set aside the Price Notification No. S.O. 1009(E) dated March 30, 2017 and direct NPPA to rectify the errors as pointed out above and refix the ceiling price Oxytocin Injection 10IU/ml in accordance with the provisions of DPCO by considering the correct PTR.

Comments of NPPA:

- I. Ceiling price Rs. 37.27/ml is notified for Oxytocin injection & the same was revised to Rs. 35.74/ml vide S.O. 2058 (E) dated 30.06.2017 as per Para 4, 6, 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 of **Oxytocin injection 10IU/ml**. 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.	The company stated that based on the draft version of proposed price calculation sheet in respect of Oxytocin injection 10 IU/ml vide OM no. 8(35)/2016/DP/NPPA/Div.II dated 15.03.2017 uploaded in NPPA website. They made a representation that the PTR of their formulation Pitocin 10IU injection/0.5 ml has been incorrectly considered by NPPA.	NPPA examined the representation and documents submitted by the company. Company submitted representation after 10 working days from the date of uploading of the draft working sheet in NPPA's website. In addition, the ceiling price was approved by the authority in its meeting held on 29.03.2017 & the representation was received on 30.03.2017 (after the approval of ceiling price by the authority). Therefore, the representation of the company along with documents was not considered by the authority.
2.	In spite of pointing out the errors in draft price calculation sheet & providing valid supporting documents NPPA ignored the representation made by the company.	As company submitted representation along with supporting documents after 10 working days, therefore, authority did not consider their representation.
3.	Company is of the opinion that price fixation for Oxytocin injection 10IU/ml is not in consonance with the provisions of DPCO, 2013. Company has also pointed out that NPPA has considered PTR Rs. 17.23 for their formulation Pitocin 5 ml injection	

	<p>against the actual PTR Rs. 17.88. Company opined that in case, correct PTR as stated by company would be considered by NPPA. Average PTR will be worked out Rs. 38.67/ml as against Rs.37.27.</p>	
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3. Company has not challenged in any Court in respect of ceiling price fixation for Oxytocin injection 10 IU/ml S.O. 1009 (E) dated 30.03.2017.

4. During the personal hearing, the representative of the petitioner company did not make any further submission in addition to the earlier submissions made in the petition. NPPA also made no other submission in addition to the written submissions.

5. Examination:

In the instant case, the contention of the petitioner company is that NPPA has not considered the actual PTR of their formulation **Pitocin 0.5ml injection (containing Oxytocin Injection 10IU/ml.)** while fixing the ceiling price of **Oxytocin Injection 10IU/ml.** According to petitioner company, the actual PTR of their formulation is Rs.17.88 per 0.5ml whereas NPPA has considered PTR of Rs.17.23 per 0.5ml. In this connection, the company submitted all necessary supporting documents to NPPA, vide its letter dated 27th March, 2017, which was received by NPPA on 3.4.2017. During the personal hearing, a copy of the representation was also submitted.

5.2 In view of the above, NPPA may be directed to consider the information/documentary evidence submitted by the company and refix/revise the ceiling price of Oxytocin Injection 10IU/ml., after verification, on merit.

6. Government Decision:

“NPPA is hereby directed to consider the information/documentary evidence submitted by the company in respect of actual PTR of their formulation Pitocin 0.5ml injection and refix/revise the ceiling price of Oxytocin Injection 10IU/ml., after verification, on merit.”

Issued on this date of 30th day of October, 2017.

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

To

1. M/s. Pfizer Limited,
The Capital, 1802/1901,
Plot No.C-70, G Block, Bandra Kurla Complex,
Bandra (East), Mumbai-400 051.

**2. 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**