

No. 31015/103/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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A Wing, Shastri Bhawan,
New Delhi 110 001

Order

1. This is an order on an application dated 19.12.2017 filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Piramal Enterprises Limited (hereinafter called the applicant) against notification S.O. No.3723(E), dated 23.11.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling prices of Sevoflurane Inhalation.

2. The petitioner has contended as under:

2.1 National Pharmaceutical Pricing Authority (hereinafter referred to as NPPA) under the Department of Pharmaceutical, Ministry of Chemicals and Fertilizers, Government of India issued notification no S.O. 3723(E) dated 23rd November, 2017 (fixing prices of Sevoflurane Inhalation at Sr. No.1 under the provisions of Para 6 of Drugs (Prices Control) Order (hereinafter referred to as DPCO), 2013.

2.2 AND WHEREAS, the worksheet for calculation of ceiling price of formulations notified vide S.O. 3723 (E) dated 23rd November, 2017 failed to consider their formulation having Moving Annual Turnover (MAT) for the period ending August, 2015 of greater than 1% Market Share. Against the total MAT value considered of Rs.1,642.87 lakhs company's formulations have the MAT value of Rs.232.89 lakhs.

2.3 AND WHEREAS, NPPA had correctly consider the Ceiling price calculation under para 4 of DPCO, 2013 Vide S.O. No. 2850(E) Dated 20th September, 2013 along with its Working Sheet.

2.4 AND WHEREAS, NPPA had specifically requested information regarding out MAT Value as of August, 2015 wide their letter dated 12th April, 2017 to which company duly replied by letter dated 18th April, 2017.

2.5 AND WHEREAS, the company submits a certificate from Chartered Accountant to certify that Sevoflurane Inhalation has Moving Annual Turnover (MAT) for the period ending August, 2015 of greater than 1% Market Share, constituting 12% of the total MAT Value.

2.6 AND WHEREAS, NPPA has inadvertently erred by not considering their formulation Sevoflurane Inhalation in the calculation of ceiling price.

2.7 AND WHEREAS, Para 4 of DPCO, 2013 clearly states that the government shall include Prices to retailer of all the brands and generic versions of the medicine having market share more than or equal to one percent of the total market turnover on the basis of Moving Annual Turnover of that medicine.

Under the circumstances:

- a. NPPA should reinstate the ceiling price for Sevoflurane Inhalation under the provisions of Para 4 of DPCO, 2013.
- b. NPPA must consider company's formulations, having Market share greater than 1% based on MAT of August, 2015, for arriving at the ceiling price for captioned formulation.
- c. NPPA must renotify the prices of Sevoflurane urgently to avoid undue hardship on company.

2.8 Under the circumstances, The applicant hereto prayed as under:

- a. To consider and conclude that NPPA had inadvertently erred in pricing of Sevoflurane Inhalation under Notification no. S.O. 3723(E) dated 23.11.2017.
- b. To direct NPPA to include their SKUs in revising the ceiling price of Sevoflurane Inhalation under the provisions of Para 4 of DPCO, 2013.
- c. Pass a speaking order in respect hereof.
- d. Any other order in interest of this manufacturer.

3. Comments of NPPA:

3.1 Ceiling price of Sevoflurane Inhalation was notified as Rs. 24.12 per ml vide S.O. 3723 (E) dated 23.11.2017 as per para 4,6,10,11,14,16,17, and 18 of DPCO, 2013.

3.2 The company has stated that correct methodology was not followed in arriving at the ceiling price of Sevoflurane Inhalation. 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: -

Company's Grievances	NPPA's comments
<p>Petitioner company stated that NPPA fixed the ceiling price of Sevoflurane Inhalation under the provisions of Para 6 of DPCO 20 13 and failed to consider their formulation (having moving annual turnover (MAT) for the period August 2015 greater than 1% market share) in the price calculation sheet. Company also claimed that NPPA did not consider the MAT value of their product which is Rs 232.89 lakhs, instead considered the MAT value of RS 1642.87 lakhs.</p> <p>Company stated that NPPA had correctly considered the ceiling price calculation under Para 4 of DPCO,</p>	<p>NPPA fixed ceiling price of Sevoflurane Inhalation as Rs.24.12 per ml vide S.O. 3723 (E) dated 23.11.2017 considering the data submitted by Pharmatrac for the period of August 2015.</p> <p>Since, there is only one brand available for fixing the ceiling price, the application of Para 6 of DPCO, 2013 is correct.</p> <p>NPPA Fixed ceiling price at Rs. 27.99 under para 4 of DPCO, 2013 vide S.O. 2850(E) dated 20.09.2013 considering the data submitted by IMS for the</p>

2013 vide S.O. 2850 (E) dated 20.09.2013. NPPA had specifically requested information regarding our MAT value of August, 2015 vide their letter date 12.04.2017 to which we duly replied by our letter dated 18.04.2017.

NPPA has inadvertently made error by not considering their formulation Sevoflurane Inhalation in the calculation of current ceiling price whereas Para 4 of DPCO, 2013 clearly state that the Government shall include prices to retailer of the brand and generic versions of the medicine having market share more than or equal to 1% of the total market turnover on the basis of moving annual turnover of that medicine.

period of May, 2012 under NLEM, 2011 of DPCO, 2013.

As regard consideration of the data of the company submitted by letter dated 18.04.2017, the data / information was not as per OM dated 10.10.2016. Hence the same was not considered. It may also be stated that based on the representation of M/S Abbott, verification of the product of M/S Piramal was sought from Pharmatrac. Pharmatrac in its reply did not mention the product of M/s Piramal, Accordingly the same was not considered.

4. During personal hearing company representative has submitted following:

- 1) NPPA Letter dated 12th April 2017 which did not request data or proof of sales as per OM dated 10.10.2016. It only requested data relating to MAT value as at August 2015 for the aforesaid formulation.
- 2) Company response vide letter dated 18th April, 2017 which clearly mentioned all details as requested by NPPA and in its prescribed format. Thus, NPPA's submission for not considering the aforesaid formulation of Piramal due to non-compliance with OM dated 10.10.2016 is unfounded and misleading.
- 3) The company representatives also submitted a copy of the NPPA worksheet and notification of ceiling price for the aforesaid formulation vide SO 2850(E) Dated 20th September 2013 which clearly mentions three manufacturers having market share more than 1% namely: Abbott, Baxter and Piramal.
- 4) The company representatives also submitted a copy of CA certificate for confirmation of MAT value of Sevoflurane as sold by Piramal Enterprises as at August 2015.
- 5) Finally, the company representatives also submitted proof of compliance with the ceiling price as notified vide S.O 3723(E) Dated 23.11.2017 and 100% compliance with IPDMS.

4.2 It is thus proved beyond doubt that the company has market share of over 1% as at August 2015 but NPPA has not considered their price despite evidence and submissions by the company proving the same. Therefore, NPPA has not followed the provisions of Para 4 of DPCO 2013 while calculating ceiling price of Sevoflurane vide S.O 3723(E) Dated 23.11.2017.

4.3 Further, the company representatives argued that Pharmatrac is an extrapolation of only certain wholesalers across India and does not exhaustively cover all wholesalers. Thus, NPPA must not exclude Piramal as a manufacturer of Sevoflurane and must also revise the notified ceiling price as per Para 4 of DPCO 2013.

5. Examination

5.1 On perusal of representation, dated 18.4.2017 submitted by the applicant to NPPA and other documentary proof submitted by M/s Piramal Enterprises Limited, it is observed that the MAT value of the company comes to around 12% of the total MAT value considered for ceiling price fixation of Sevoflurane Inhalation.

5.2 The calculation sheet of SO 2850(E), dated 20.9.2013 also reveals that the MAT value of M/s Piramal Healthcare Limited was considered at that time, being 27.73% of total market share, which proves that M/s Piramal Healthcare Limited has reasonable market share.

5.3 In view of the above, NPPA needs to examine the documents furnished by the company and refix the ceiling price of Sevoflurane 250ml considering the MAT value of all brands having more than 1% market share each.

6. Decision:

“NPPA is directed to examine the documents furnished by M/s Piramal Enterprises Limited and refix the ceiling price of Sevoflurane 250ml considering the MAT value of companies having more than 1% market share, within a period of thirty days of the issue of this Order.”

Issued on this date, 22nd day of June, 2018.

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

Copy to :

1. M/s. Piramal Enterprises Limited, Piramal Tower, Ganpatrao Kadam Marg, Lower Parel, Mumbai-400013,
2. The Member Secretary, National Pharmaceutical Pricing Authority, YMCA Cultural Centre Building, New Delhi-110001
3. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.
4. PS to MoS(C&F), Shastri Bhawan, New Delhi for information.
5. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
6. T.D., NIC for uploading the order on Department's Website