

No. 31015/95/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

A Wing, Shastri Bhawan,
New Delhi 110 001

Order

1. This is an order on an application, dated 08.12.2017, filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Abbott India 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 company has contended as under:

I. NPPA vide its O.M No. 8(35)/2016/DP/NPPA/Div-II dated July 21, 2017 put up the draft calculation sheet for proposed ceiling prices/retail prices of Sevoflurane Inhalation at Rs.23.13 per ml.

II. On August 1, 2017 Abbott filed representation against the draft calculation sheet by pointing the apparent errors in calculation, supported by documentary evidences, that NPPA has incorrectly applied monopoly-based reduction as well incorrect GST factor of 0.95905.

III. NPPA in its authority meeting on November 22, 2017 willingly did not consider the apparent calculation error of applying the monopoly-based reduction despite having pointed out the same by the company, supported by documentary evidences, vide its representation submitted on August 1, 2017. NPPA however, corrected the anomaly with respect to the GST factor.

IV. NPPA vide its Notification S.O. No. 3723(E) dated November 23, 2017 notified the incorrect ceiling price of Sevoflurane Inhalation at Rs 24.12 per ml by erroneous application of the monopoly reduction, which in this case is 10.85%.

V. Company submitted that Sevoflurane Inhalation is not a monopoly product. In addition to Abbott India Limited's brand Sevoflurane, there are many players in the market whose details are provided below:

S. No.	Company	Brand	MRP (Rs)	Remarks
1	Piramal Healthcare Ltd.	Sojourn	7145	Scan copy of product sample pack.
2	Baxter Ltd.	Sevoflurane	7892.14	Scan copy of product sample pack.
3	Troikaa Pharma	Sevotroy	7522	Scan copy of product sample pack.
4	Neon Pharmaceuticals	Sevura	7880	Scan copy of product sample pack.

VI. Further, company submitted that the drug was also under NLEM 2011. When NPPA had notified the ceiling price of Sevoflurane Inhalation on September 20, 2013, it had considered the competitors' prices and therefore, no monopoly criterion was applied.

VII. NPPA however, chose to willingly ignore the prices of these brands while notifying the ceiling price on November 23, 2017 despite having brought to its knowledge vide company's representation dated August 1, 2017 and applied the monopoly-based reduction which in this case is 10.85%.

VIII. Company has also taken up this matter with Pharmatrac who has acknowledged that they have "verified and found that in market there are products from Baxter and Piramal in this category".

IX. In view of the above, company request the DOP to direct the NPPA to revise the price of **Sevoflurane Inhalation** by not applying the monopoly-based price reduction.

3. **Comments of NPPA:**

I. 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.

II. 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>Company stated that NPPA vide OM No. 8(35)/2016/DP/NPPA/Div.-II dated July 21, 2017 put up the drug calculation sheet for proposed ceiling prices / retail prices of Sevoflurane Inhalation at Rs.23.13 per ml.</p> <p>On August 1, 2017 Abbott filed representation against the draft calculation sheet by pointing the apparent errors in calculation, supported by documentary evidences, that NPPA has incorrectly applied monopoly-based reduction as well incorrect GST factor of 0.95905.</p> <p>NPPA in its Authority meeting on November 22, 2017 willingly did not</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>The draft ceiling price was uploaded on the website @Rs. 23.13 per ml on 21.07.2017.</p> <p>The contention of the petitioner regarding GST factor was considered by the Authority and therefore, working out ceiling price Rs. 23.13 was revised to Rs.24.12 per ml by applying the GST factor of 1. NPPA notified ceiling price as Rs.24.12 per ml vide S.O. 3723 (E) dated 23.11.2017 in accordance with the provisions of DPCO, 2013.</p> <p>As regards considerations of other brands, the representation / documents</p>

considered the apparent calculation error of applying the monopoly-based reduction despite having pointed out the same by the company, supported by documentary evidences, vide its representation submitted on August 1, 2017.

Company also stated that vide its notification S.O. No. 3723(E) dated November 3, 2017 NPPA notified the incorrect ceiling price of Sevoflurane Inhalation at Rs.24.12 per ml by erroneous application of the monopoly reduction, which in this case is 10.85%. Company has submitted a table in support of their claim.

Company opined that NPPA willingly ignore the prices of three brands while notifying the ceiling price on November 23, 2017 despite having brought to its knowledge vide their representation dated August 1, 2017 and applied monopoly-based reduction. Company has also stated that they have taken up this matter with Pharmatrac who has acknowledge that they have verified and found that there are products from Baxter and Piramal in this category. Company reiterated that they have achieved 100% IPDMS compliance and they are regularly filing the statutory forms in IPDMS from time to time.

submitted by the applicant was examined by NPPA and sent to Pharmatrac for verification. However, Pharmatrac informed that their data base do not have Sojourn (Piramal) and Sevoflurane (Baxter) products. Therefore, the contention of the petitioner to consider these products and working under Para 4 was not found tenable.

Since, there is only one brand available for fixing ceiling price, the application para 6 of DPCO, 2013 is correct. The contents of the company to fix the ceiling price under DPCO, 2013 was not found tenable.

III. Company has not challenged S.O. No. 3723 (E) dated 23.11.2017 in High Court.

4. During the hearing, the company representatives pointed out the additional following points:

- i. Company representatives submitted a CA certified copy of the MAT value of Piramal Enterprises Limited's Sevoflurane brand which was Rs 23,289,499 as on August 2015. As per this MAT data, Piramal Enterprises Limited Sevoflurane's market share is around 14.5% and establishes the presence of another major player in the market. Hence the monopoly criterion is not applicable in this case.

4.2 NPPA representative did not submit any further comments in addition to already submitted.

5. **Examination:**

The main grievance of the company is that NPPA fixed the ceiling price of Sevoflurane Inhalation under the provision of para 6 of DPCO-2013 and did not

consider the formulations of other market players, like Piramal Healthcare Ltd., Baxter Ltd., Troikaa Pharma and Neon Pharmaceuticals, having Moving Annual Turnover (MAT) for the period August 2015, and applied the monopoly-based reduction which, in this case, is 10.85%. NPPA incorrectly applied GST factor of 0.95905. However, NPPA corrected the anomaly with respect to the GST factor on the basis of their representation dated August 1, 2017.

5.2 On going through the papers on record, it is observed that the company could furnish only a certificate from Chartered Accountant, dated 19.12.2017 certifying that M/s Piramal Enterprises Limited is having MAT value of Rs.232.89 lakhs. The MAT value of M/s Piramal Enterprises Limited is around 12% against the total MAT value of Rs.1642.87 lakhs (of Abbott Healthcare Pvt. Ltd.), considered by NPPA while fixing the ceiling price. The company could not submit any documentary proof in support of their claim of having MAT value of other companies, viz. Baxter Ltd., Troikaa Pharma and Neon Pharmaceuticals.

5.3 NPPA stated that the representation / documents submitted by the applicant was examined by them and sent to Pharmatrac for verification. However, Pharmatrac informed that their data base do not have Sojourn (Piramal) and Sevoflurane (Baxter) products. Therefore, the contention of the petitioner to consider these products and working under Para 4 was not found tenable.

5.4 It may be worth mentioning here that NPPA fixed the ceiling price at Rs.27.99 under para 4 of DPCO 2013 vide SO 2850(E) dated 20.09.2013. On going through the calculation sheet of SO 2850(E), dated 20.9.2013, it is seen that at that time the MAT value of M/s Piramal Healthcare Limited was considered, which was having 27.73% market share. It proves that M/s Piramal Healthcare Limited has reasonable market share. The petitioner company also submitted a documentary proof (CA certificate) in support of its claim. However, company could not submit any documentary proof about the MAT value of M/s Baxter (which was having market share of 4.11% when the ceiling price was earlier fixed in 2013).

5.5 The other issue of the company about wrongly applying GST factor of 0.95905 has already been settled by NPPA based on the representation, dated 1st August, 2017, submitted by the company

5.6 In view of the above, NPPA may be directed to interact personally with the company, and on furnishing of necessary documents by the company and after verification, if the market share of M/s Piramal Healthcare Limited is found to be more than 1%, refix the ceiling price of Sevoflurane 250ml under para 4 of DPCO, 2013, on merit.

7. **Government Decision:**

“NPPA is directed to take into account the MAT data of Piramal Enterprises Limited’s Sevoflurane and if the market share of Sevoflurane brand of M/s Piramal Healthcare Limited is found to be more than 1%, refix the ceiling price of Sevoflurane 250ml under para 4 of DPCO, 2013, on merit, within a period of thirty days from the date of issue of this order.”

Issued on this date of 29th day of May, 2018.

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

Copy to :-

1. M/s. Abbott India Limited, 3-4, Corporate Park, Sion Trombay Road, Mumbai-400071.
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