

No.31015/91/2023-Pricing (E-25438)
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS
.....

Room No. 207, D Wing, Shastri Bhawan,
New Delhi-110 001.

Order

M/s Samarth Life Sciences Private Limited (hereinafter called the “Applicant”) filed a Review Application dated 28.04.2023 under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against the price fixation order issued vide S.O. No. 1577(E) dated 31.03.2023 by the National Pharmaceutical Pricing Authority (NPPA). Vide its aforesaid Order, NPPA, inter alia, fixed the ceiling price of Atrapure 100 mg injection 10 ml, Atrapure injection 25 mg injection 2.5 ml and Atrapure 50 mg injection 5 ml containing Atracurium injection 10 mg per ml.

2. On the aforesaid plaint, reference was invited by the Department of Pharmaceuticals from NPPA. Both parties entered appearance on 25.09.2023 and presented their respective logics.

3. Major contentions raised by the Applicant:

It was contended, on behalf of the applicant, that NPPA has erred in determining the ceiling price of the above drug and hence may be directed to revise the same on the following grounds:

3.1 M/s Samarth Life Sciences Private Limited is engaged in manufacturing and marketing of brand “Atrapure 100 mg injection 10 ml”, “Atrapure injection 25 mg injection 2.5 ml” and “Atrapure 50 mg injection 5 ml” containing “Atracurium injection 10 mg per ml”. NPPA issued a Notification S.O. No. 1577 (E) dated 31st March 2023, fixing ceiling prices of 127 Scheduled formulations, inter-alia, including Scheduled formulation “Atrapure 100 mg injection 10 ml”, “Atrapure injection 25 mg injection 2.5 ml” and “Atrapure 50 mg injection 5 ml”. The calculation of ceiling price for “Atracurium injection 10 mg per ml” in December, 2016 was based on a product pack of 10 mg/ml. The formulation “Atrapure 100 mg injection 10 ml”, “Atrapure injection 25 mg injection 2.5 ml” and “Atrapure 50 mg injection 5 ml” are not sold in packs of 10 mg but rather 10 mg/ml. Therefore, pricing a liquid injection on the basis of “each pack” is arbitrary.

Company	Product	Pack	Unit	Total Strength	Strength per ml
Samarth Life Sciences Private Limited	Atrapure 25 mg injection 2.5 ml	2.5	ml	25 mg	10 mg
Samarth Life Sciences Private Limited	Atrapure 50 mg injection 5 ml	5	ml	50 mg	10 mg
Samarth Life Sciences Private Limited	Atrapure 100 mg injection 10 ml	10	ml	100 mg	10 mg

3.2 Further, and against the provision of para 11(1) of DPCO 2013 which states as under:

The average price to retailer calculated as per the provisions in paragraphs 4, 5 and 6 shall be on the dosage basis, (per tablet, per capsule or injection in volume listed in first Schedule) and the ceiling price or retail price of a pack shall be reached by multiplying the same with the number or quantity in the pack as the case may be.

In the light of aforesaid, the company referred to section 1.4.1 of NLEM 2022 which specifies Atracurium injection 10 mg/ml and not a powder for injection which disregards the level of dilution. The ceiling price calculation of Atracurium injection 10 mg/ml must be on the basis of “each ml” and not “each pack”.

3.3 The following table shows that the strength of 4 mg/ml is considered (not being a scheduled strength) for the calculation of the ceiling price of Atracurium injection 10 mg per ml is beyond the scope of Para 4 of DPCO, 2013. So, The ceiling price calculation of Atracurium injection 10 mg/ml must only include injection brands having strength “10 mg/ml”.

TABLE -A

Company	Product	Pack	Unit	Total Strength	Strength per ml	Remark	Qualified
Gland Pharma Limited	Acris 10 mg injection 2.5 ml	2.5	ml	10 mg	4 mg	Not a scheduled strength	N
Fresenius kabi India Pvt. Ltd	Kabitrane 10 mg injection 2.5 ml	2.5	ml	10 mg	4 mg	Not a scheduled strength	Y
Troikaa Pharmaceuticals Ltd	Troycurium 10 mg injection 2.5 ml	2.5	ml	10 mg	4 mg	Not a scheduled strength	N

4. Gist of clarifications made by NPPA:

4.1 The ceiling price notified for Atracurium injection 10 mg/ml is Rs. 15.14 per ml (Rs. 16.97 w.e.f 1.04.2023 after WPI revision) vide S.O. No. 1577 (E) dated 31.03.2023. All the line items/brands considered in the draft working sheet have a strength of 10 mg/ml as mentioned in Schedule. However, the pack sizes are different i.e., 2.5 ml, 5 ml and 10 ml. Therefore, the data considered for ceiling price fixation is correct.

4.2 The other issues raised in the review petition are same as earlier raised by the company in their representation dated 24.02.2023 to NPPA which were examined and placed in the 111th Authority meeting held on 29.03.2023. The examinations are briefed as:

a. The subject formulation, i.e. Atracurium injection 10 mg/ml listed in section 1.4.1 in NLEM 2022, is a common formulation which was also covered in NLEM 2011 and NLEM 2015.

b. The ceiling price was notified under NLEM, 2011 as Rs.45.28 for “each pack” vide S.O. 1674 (E) dated 14.06.2013. The WPIs for 2013, 2014 and 2015 were applied and ceiling prices

were notified accordingly as Rs. 48.41, Rs. 49.99 and Rs.48.64 for each pack vide S.O. No 1156 (E) dated 28.04.2014, S.O. No 619 (E) dated 26.02.2015 and S.O. No 644 (E) dated 02.03.2016 respectively.

c. Further, under NLEM, 2015 the ceiling price was worked out on per pack basis and notified as Rs. 48.63 per pack vide S.O. 4128 (E) dated 22.12.2016. The pack sizes considered in the working sheet were 2.5 ml and 5 ml. Also, PTR restriction was applied on per pack basis.

d. The matter was placed in 43rd Authority meeting held on 29.03.2017 wherein a revised ceiling price of Rs.39.55 per ml was placed for consideration and approval against the notified price of 48.63 per pack based on the representations received from the companies. It was also proposed to issue a corrigendum/fresh notification in this respect. The matter was deliberated in detail & was rejected. The WPIs for 2017, 2018, 2019, 2020, 2021 & 2022 was applied accordingly notified as Rs. 49.59, Rs.47.56, Rs.49.20, Rs. 51.30, Rs.52.27, Rs. 52.55 and Rs. 58.21 for each pack vide S.O. 1039 (E) dated 1.04.2017, S.O. 2058 (E) dated 30.06.2017, S.O. 1461 (E) dated 2.04.2018, S.O. 1485 (E) dated 29.03.2019, S.O. 1213 (E) dated 25.03.2020, S.O. 1330 (E) dated 25.03.2021 & S.O. 1499 (E) dated 30.03.2012 respectively.

e. Further, M/s Sun Pharma Laboratories Limited filed a review application with DoP in this respect. Review Order dated 30.10.2017 was passed by DoP, wherein the request made by M/s Sun Pharma laboratories was rejected.

5. Examination

5.1 It has been claimed by the applicant that Non – Scheduled formulation of 4mg/ ml has also been taken for price calculations which has been denied by NPPA. The same has been confirmed from the draft working sheet uploaded by NPPA and the contention of NPPA is found to be correct.

5.2 Para 4 of DPCO provides that the ceiling price of the scheduled medicines is to be fixed by calculating simple average of market prices of all brands of the drug which has market share of 1% or more. Further, under para 11(1), DPCO also provides that the average Price to Retailer (PTR) shall be on a dosage basis (i.e per tablet, per capsule or injection in volume as listed in Schedule -I of DPCO).

5.3. NPPA has adhered to both these provisions of DPCO. It has taken prices of the available brands fulfilling the criteria as laid down by DPCO and also notified unit price on per ml basis for the aforesaid scheduled drug.

6. Conclusion

Through the detailed examination noted above, it is observed that, NPPA has appropriately followed the provisions of DPCO while fixing the ceiling price of Atrapure 100 mg injection 10 ml, Atrapure injection 25 mg injection 2.5 ml and Atrapure 50 mg injection 5 ml containing Atracurium injection 10 mg per ml.

7. Decision

The action of NPPA fixing the ceiling prices of Atrapure 100 mg injection 10 ml, Atrapure injection 25 mg injection 2.5 ml and Atrapure 50 mg injection 5 ml containing Atracurium

injection 10 mg per ml vide SO no. 1577(E) dated 31.03.2023 is upheld and the Review Application under consideration is accordingly rejected.

Issued on this, the 7th day of February, 2024.



(Awadhesh Kumar Choudhary)
Sr. Economic Adviser to the Government of India
[For and on behalf of the President of India]

To:

M/s Samarth Life Sciences Limited
Samarth House, 168, Bangur Nagar,
Off link Road, Near Ayyappa Temple,
Kallol Kali Temple,
Goregaon (West), Mumbai -400090.

Copy to:

1. Chairperson, NPPA, New Delhi
2. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi
3. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi
4. Technical Director, NIC for uploading the order on DoP's Website.
5. Guard File