

No.31015/90/2023-Pricing (E-25437)
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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Room No. 340 B, A Wing, Shastri Bhawan,
New Delhi-110 001.

Order

M/s Samarth Life Sciences Private Limited (hereinafter called the “Applicant”) filed a Review Application dated 25.04.2023 under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against 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 Dobustat 250mg injection 5ml containing Dobutamine injection 50 mg/ml.

2. On the aforesaid plaint, reference was invited by the Department of Pharmaceuticals from NPPA. Both the 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 “Dobustat 250mg injection 5ml” containing “Dobutamine injection 50 mg/ml”. NPPA issued Notification S.O. No. 1577(E) dated 31st March 2023, fixing ceiling prices of 127 Scheduled formulations, including that of the subject formulation under this review. Earlier, NPPA had issued a corrigendum to Order S.O. No. 1642(E) dated 14.06.2013 vide S.O. No. 3170(E) dated 12th December, 2014 relating to the ceiling price fixation of Dobutamine injection 50mg/ml stating that “each pack” should be read as “1 ml”. The Applicant has contended that its formulation “Dobustat 250mg injection 5ml” is not sold in a pack of 50mg but rather in pack of 5ml.

3.2 In the draft working sheet, it is clear that the formulation should have the strength of 50 mg/ml, and pricing a liquid injection on the basis of “each pack” is arbitrary 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.

Further, section 10.4.2 of NLEM 2022 specifies Dobutamine injection 50mg/ml and not a powder for injection which disregards the level of dilution. In the light of the aforesaid, the ceiling price calculation of Dobutamine injection 50mg/ml must be on the basis of “each ml” and not “each pack”.

4. Gist of clarifications made by NPPA:

NPPA on the other side argued that the instant review is not tenable on the following grounds:

4.1 The ceiling price notified for Dobutamine injection 50mg/ml is Rs. 8.05 per ml (Rs. 9.02 per ml w.e.f. 1.04.2023 after WPI revision). NPPA issued corrigendum to order S.O. No. 1642 (E) dated 14.06.2013 vide S.O. No. 3170(E) dated 12th December, 2014 relating to the ceiling price fixation of Dobutamine injection 50mg/ml stating that “each pack” should be read as “1 ml”. However, as per WPI notification S.O. 619(E) dated 26.02.2015, the prices were revised by WPI and notified again for each pack.

4.2 NPPA consider the Applicant’s product “Dobustat 250 mg injection 5 ml” as pack of 5ml making the effective strength of the formulation as 50mg/ml as mentioned in Schedule.

4.3 Further, the issues raised in the review petition are the same as raised in representation 24.02.2023 which were placed before the 111th Authority meeting held on 29.03.2023. After the detailed deliberation, the Authority approved the ceiling price for Dobutamine injection 50 mg/ml at Rs. 8.05 per ml.

5. Examination:

5.1 The Applicant has maintained that its formulation “Dobustat 250mg injection 5ml” is not sold in a pack of 50mg but rather pack of 5ml. NPPA clarified that it has considered the Applicant’s product “Dobustat 250mg injection 5ml” as pack of 5ml making the effective strength of the formulation as 50mg/ml as mentioned in Schedule-I of DPCO, 2013. Further, considering the representations received from the companies, NPPA has fixed the ceiling price of the subject formulation on per ml basis under NLEM, 2022.

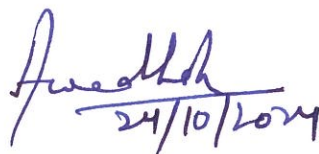
5.2 Para 4 of DPCO provides that the ceiling price of the scheduled medicines is to be fixed by calculating simple average of market prices of all brands of the drug which has market share of 1% or more. Further, under para 11(1), DPCO also provides that the average Price to Retailer (PTR) shall be on 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. Decision:

The action of NPPA fixing the ceiling prices of Dobustat 250mg injection 5ml containing Dobutamine injection 50 mg/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 24th day of October, 2024.

Handwritten signature in blue ink, with the date 24/10/2024 written below it.

(Awadhesh Kumar Choudhary)

Sr. Economic Adviser to the Government of India
[For and on behalf of the President of India]

To:

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Copy to:

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

