

No.31015/34/2023-Pricing (E-23323)
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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Room No. 340-B, A Wing, Shastri Bhawan,
New Delhi-110001.

Order

M/s Cipla Limited (hereinafter called the “Applicant”) filed a Review Application dated 02.02.2023 under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against price fixation order issued vide S.O. No. 87(E) dated 06.01.2023 by the National Pharmaceutical Pricing Authority (NPPA). Vide its aforesaid Order, NPPA, inter alia, fixed the ceiling price of “Advent 1.2gm injection Powder containing Amoxycillin 1000mg + Clavulanic Acid 200mg”.

2. On the aforesaid plaint, reference was invited by the Department of Pharmaceuticals from NPPA. Both the parties entered appearance on 22.06.2023 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 The formulation “Amoxycillin 1000mg + Clavulanic acid 200mg powder for Injection” was included in Schedule-I of DPCO with effect from 11th November 2022. Hence, “Advent 1.2gm injection powder” was included in the draft calculation of ceiling price released by NPPA on 05.12.2022 under the provisions of Para 4, 6, 10, 11, 14, 16, 17 and 18 of DPCO 2013.

3.2 The company had implemented the WPI under para 16 of DPCO, 2013 in the month of April, 2022. This was also proven to NPPA by the submission of Invoice, Form-V and snapshot of product pack.

3.3 The company submitted the representation in the prescribed format with the necessary documents, and within the prescribed timelines of 10 workings days. However, correction in PTR of the brand “Advent 1.2gm Injection Powder” was not made in the calculation of ceiling price.

3.4 Non-reflection of PTR in the market-based data should not be construed as non-implementation of revised MRP, especially when Form-II, invoices of sales and pack shots at revised MRP are provided as documentary evidence. Hence, calculation of Amoxycillin 1000mg + Clavulanic Acid 200mg powder for injection per vial is incorrect and must be rectified based on the revised PTR of Rs. 111.52 and not Rs. 100.69.

4. Gist of clarifications made by NPPA:

NPPA on the other side urged that:

4.1 As per the provisions of para 16 (2) of DPCO, 2013, the manufacturers may increase the MRP of scheduled formulations once in a year, in the month of April on the basis of WPI. Further, as per para 16 (3), information about the revision, if carried out, shall be forwarded to the Government in Form-II within 15 days of such revision. This implies that Form-II for price revision based on WPI may be submitted latest by 15th May.

4.2 In view of the provisions of DPCO, 2013, the claims made in the representations received from companies were cross verified with the Form-II / Form-V submitted by the companies till 15.05.2022 in IPDMS. Accordingly, revisions were carried out by NPPA in the PTR in case the representations are received within 10 working days of uploading of working sheets; and, Form-II / Form-V have been filed on or before 15.05.2022 in respect of the PTR of companies mentioned in the representation. (Reference 105th Authority meeting).

4.3 In the current case, two brands of M/s Cipla Limited are captured in July, 22 Pharmatrac database i.e. Advent 1000/200mg Inj 10ml and Novamox CV 1000/200mg Inj 10ml with PTR of Rs. 100.69 per vial. Both these brands had more than 1% market share and hence qualified for being considered in calculation of PTR.

4.4 M/s Cipla Limited had filed representation for only one brand i.e. Advent 1.2gm Powder Vial claiming revised PTR as Rs. 111.52 per vial. Further, M/s Cipla Limited filed two Form-IIs on 02.05.2022 i.e. one for Advent 1.2gm Inj Vial and one for Advent 1.2gm 20ml Inj claiming revised PTR of Rs. 111.52 for both. Company had also submitted two Form-Vs on 07.05.2022 in line with Form-IIs.

4.5 The brand appearing in database as shown in draft worksheet uploaded has 10ml pack size and the Forms submitted were for 20ml pack or for 1 vial. Further, the company has never represented that the pack size as appearing in the database is not correct. Based on the available data it was observed that no Form was filed by the company for the brand considered in draft worksheet. Hence, the price revision was not considered.

5. Examination:

5.1 It is noted that M/s Cipla Limited filed two Form-IIs on 02.05.2022 i.e. one for Advent 1.2gm Inj Vial and one for Advent 1.2gm 20ml Inj claiming revised PTR of Rs. 111.52 for both. Company had also submitted two Form-Vs on 07.05.2022 in line with Form-IIs.

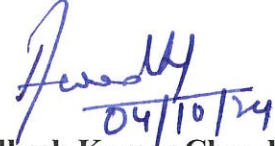
5.2. There is a difference in pack size as captured by Pharmatrac database and pack size reported by the Applicant in Form-II. As the pack size reported in Form-II was not reflected in Pharmatrac data, the price revision in pack sizes reported by the Applicant through Form-II was not considered for price calculation.

5.3. Therefore, in the present case, NPPA may relook into the issue and examine with respect to pack size as available in Pharmatrac and contention of the Applicant regarding pack size and revise the ceiling price on the basis of extant provisions of DPCO, 2013.

6. Decision:

In the backdrop of these facts, the case is referred back to NPPA for re-examination and re-calculation of the prices of the subject formulation as per the extant provisions of DPCO, 2013.

Issued on this, the 04th day of October, 2024.



(Awadhesh Kumar Choudhary)

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

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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

