

No.31015/38/2023-Pricing (E-23329)
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 Cipla Limited (hereinafter called the “Applicant”) filed a Review Application dated 08.02.2023 under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against price fixation order issued vide S.O. No. 194(E) dated 11.01.2023 by the National Pharmaceutical Pricing Authority (NPPA). Vide its aforesaid Order, NPPA, inter alia, fixed the ceiling price of Synclar 125mg Dry Syrup 30ml containing clarithromycin 125mg per 5ml.

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 “Clarithromycin 125mg per 5ml” was included in Schedule-I listed out in the final list of scheduled formulations with effect from 11th November, 2022, and hence, the formulation “Synclar 125mg Dry Syrup 30ml” was also included in the draft calculation of ceiling price as released on 20.12.22 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 requisite documents, and within the prescribed timelines of 10 workings days. However, correction in PTR of the brand “Synclar 125mg Dry Syrup 30ml” 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 invoices of sales and pack shots at revised MRP are provided as Documentary evidence. Hence, the ceiling price calculation of their brand “Synclar 125mg Dry Syrup 30ml” should have included the revised PTR of Rs. 112.80 and not Rs.101.95.

4. Gist of clarifications made by NPPA:

NPPA on the other side argued that:

4.1 As per the provisions of para 16(2) of the DPCO, 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) of the DPCO, information about the revision, if carried out, shall be forwarded to the Government in Form-II within a period of 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, the claims made in the representations received from companies are cross-verified with the Form-II / Form-V submitted by the companies till 15.05.2022 in IPDMS. Accordingly, revisions are 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 M/s Cipla Limited has submitted Form-II on 02.05.2022 and Form-V on 07.05.2022 with NPPA. However, the same were inadvertently not considered by NPPA while fixing the ceiling prices.

5. Examination:

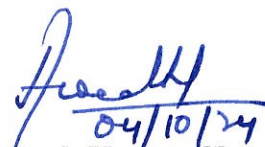
5.1 It is noted that Forms-II and Form-V were filed within stipulated time by M/s Cipla Limited. However, inadvertently, the same have not been considered in calculating the PTR. Accordingly, revisions may be carried out by NPPA in the PTR.

5.2 NPPA may once again look out for all such possible errors in calculation of ceiling price.

6. Decision:

In the backdrop of these facts, the case is being referred back to NPPA for recalculation of ceiling price for the formulation clarithromycin 125mg per 5ml as per 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]

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

