

**No. 31015/33/2017-Pricing**  
**GOVERNMENT OF INDIA**  
**MINISTRY OF CHEMICALS & FERTILIZERS**  
**DEPARTMENT OF PHARMACEUTICALS**

A Wing, Shastri Bhawan,  
New Delhi 110 001

**Subject: Review application of M/s Cadila Healthcare Limited against price fixation of their formulation "Co-Trimoxazole Tablets" vide NPPA order No. S.O. 443(E), dated 14.02.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).**

**Ref: 1) Review application dated 01.03.2017**  
**2) NPPA notification under review S.O. No.443(E), dated 14.02.2017**  
**3) Record Note of discussions held in the personal hearing on 13.05.2017.**

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Cadila Healthcare Limited (hereinafter called the petitioner) against notification S.O. No.443(E), dated 14.02.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of their formulation Co-Trimoxazole Tablets.

2. The petitioner has contended as under:

- I. The price fixed by NPPA for schedule formulation Co-Trimoxazole Tablets vide ceiling price order no. S.O. 443(E) dated 14/02/2017 at sr. no. 15 of the order is not correct.
- II. The ceiling prices fixed and notified by NPPA for Co-Trimoxazole (Sulphamethoxazole 800mg + Trimethoprim 160mg) Tablets vide notification no. 443(E) dated 14/02/2017 is without considering PTR of their company's brand Oriprim DS Tablet. Further company also submitted that PTR considered for SEPTRAN DS 800/160 MG TABLET 10 is not correct.
- III. There is gross error in the working sheet of Co-Trimoxazole (Sulphamethoxazole 800mg + Trimethoprim 160mg). More over with the incorrect price declared by NPPA, the product becomes non-viable. The formulation Co-Trimoxazole (Sulphamethoxazole 800mg + Trimethoprim 160mg) Tablets was under price control under DPCO 1995 and continued to remain in DPCO 2013 which has resulted the reduction in the price by 26.5%, while input cost has gone up substantially.
- IV. In view of above, company prayed as under:
  - (i) Ceiling Price for Co-Trimoxazole (Sulphamethoxazole 800mg + Trimethoprim 160mg) Tablets should be reworked by NPPA considering the correct PTR and notify the revised price.

- (ii) Company requested this Department to consider the above facts favorably and direct the NPPA to re-notify the ceiling price for Co-Trimoxazole (Sulphamethoxazole 800mg + Trimethoprim 160mg) Tablets.

3. Comments of NPPA:

- I. Ceiling price of Rs. 0.98/tablet for Co-trimoxazole tablet (Sulphamethoxazole 800mg + Trimethoprim 160mg) was notified vide S.O. 443(E) dated 14.02.2017 as per para 4, 10, 11, 14, 16, 17 & 18 under DPCO 2013.
- II. Company has stated that correct methodology was not followed in arriving at the ceiling price for Co-trimoxazole tablet (Sulphamethoxazole 800mg + Trimethoprim 160mg). The points raised by the company are not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013 and as per the decisions of 27<sup>th</sup> Authority meeting held on 29.3.2016. Details are as follows:-

Sl. No.	Company's Grievances	NPPA's comments
1.	Company has stated that NPPA has not considered PTR of their formulation Oripim DS Tablet in calculation of the ceiling price for Co-trimoxazole tablet (Sulphamethoxazole 800mg + Trimethoprim 160mg). Company has also pointed out that PTR considered for SEPTRAN DS 800/160 MG TABLET 10 is not correct.	NPPA has considered the PTR for Co-trimoxazole tablet (Sulphamethoxazole 800mg + Trimethoprim 160mg) as per data provided by Pharmatrac for the month of August, 2015 and fixed the ceiling price Rs. 0.98 per tablet as per the provisions of DPCO, 2013.

Company has not challenged any notification in respect of Co-trimoxazole tablet (Sulphamethoxazole 800mg + Trimethoprim 160mg) in the Court.

4. During the personal hearing, the company further submitted that :-

- NPPA Notified the Ceiling Price for Co-Trimoxazole (Sulphamethoxazole 800mg + Trimethoprim 160mg) tablet vide Notification No. S.O. No. 443(E) dated 14.2.2017. The Ceiling Price notified is Rs. 0.98 per tablet. NPPA has considered 2 packs while arriving at the above Ceiling Price.
- While computing the price for Co-Trimoxazole (Sulphamethoxazole 800mg + Trimethoprim 160mg) Tablet NPPA has relied on the August 2015 data of AWACS. This data is inaccurate and incorrect. NPPA has relied on 2 packs namely Sepmax of Glaxo and Septran DS of Glaxo.
- The company stated as follows :

- a) Following 3 brands of Co-Trimoxazole (Sulphamethoxazole 800mg + Trimethoprim 160mg) Tablet existed in August 2015 namely :
- Sepmax- Glaxo
  - Bactrim DS – Abbott Healthcare
  - Oriprim DS – Zydus Alidac
- The above 3 brands exist today also.
- b) Ceiling Price considering the PTR values existing in August 2015 works out as follows :

SKU	Corporate	PTR
SEPMAX DS TABLET 10	GLAXOSMITHKLINE PHARMACEUTICALS LTD.	1.18
BACTRIM DS TABLET 10	ABBOTT HEALTHCARE	1.11
ORIPRIM DS 800 MG TABLET	ZYDUS ALIDAC	1.11
Sum of PTR per unit		3.39
Average		1.13
Add : 16% Retailer Margin		0.18
Ceiling Price w.e.f.14.2.17		1.31

- c) WPI for the year 2016 may also be added to the above calculated Ceiling Price to arrive at a fresh Ceiling Price effective from 1.4.17.
- Cadila Healthcare Limited (CHL) had represented against the draft working sheet made available by NPPA on 26.10.16, vide letter dated 7.11.16. Company had brought to the knowledge of NPPA that their brand Oriprim DS Tablet which is a major brand in this category has not been considered by NPPA and the same should be considered in calculation of Ceiling Price. Company had also brought to NPPA's knowledge that the PTR considered for Septran DS of Glaxo is erroneous.
  - NPPA in response to their representation asked them to provide copies of sample invoices to Retailer and summary of all the invoices issued in August 2015. To which company had informed the NPPA that as a manufacturer, they do not invoice directly to the Retailer(s). Company provided the summary of Sales to Stockist(s) for the month of August 2015.
  - On further insistence, company had provided NPPA with a copy of Sample Retail Invoice dated 5.8.2015 which clearly showed the PTS and MRP.
  - NPPA did not take into account their representation and went ahead with Notification of the Ceiling Price with its incomplete and inaccurate data. Notification was made on 14.2.2017. It had more than 3 months time to verify the facts brought through our representation dated 7.11.16.
  - It clearly shows the following :

- a) NPPA has no clearly laid down SOP for disposing of the representations made to it against the draft working sheets which it has been made to put on website through a directive of DoP.
  - b) The manufactures/marketers never hear from NPPA regarding the status of their representation(s).
  - c) It appears that the facts brought out through such representations are not taken on record for independent verification.
  - d) Lack of technical expertise related to Pharmaceutical Industry is evident in many of the price notifications issued by NPPA. Costing principles are definitely important but over emphasis on mere costing and negligence to technical back up is leading to erroneous pricing calculations. This impacts the industry significantly. This also leads to over loading to the Reviewing Mechanism under DPCO 2013. There is a need to correct this situation on priority.
- Submission:
    - (1) NPPA may please be directed to rework the Ceiling Price for Co-Trimoxazole (Sulphamethoxazole 800mg + Trimethoprim 160mg) Tablet based on the data provided above. Copy of this additional submission is being handed over to the NPPA Representative(s) today. The same should be treated as evidence for reworking the Ceiling Price.
    - (2) NPPA may please be directed to withdraw its OM F.No. 8(34)/2014-Div.II/DP/NPPA dated 10.10.16 where under the manufacturers are compelled to provide Sample Retail Invoice(s) and Summary of such Retail Invoice(s). This is not possible for a manufacturer to comply with it as it does not supply its formulations directly to a retailer. Non receipt of above documents is being treated by NPPA as Non compliance and the representations are rejected. There is an urgent need to correct this situation by either withdrawing the above OM or by modifying the same.
    - (3) NPPA may please be sensitized to develop SOP for disposing of the representations. Manufacturers/Marketers should be kept informed about the status of the representations made.
    - (4) Documentary evidence available with the company to substantiate its claim including copies of packs available in the market have been submitted during the hearing to the Hearing Authority as well as the NPPA's representative. This is to expedite the action to be taken by the Hearing Authority as well as NPPA.

NPPA's comments:

NPPA representative submitted that the ceiling price of Co-Trimoxazole (Sulphamethoxazole 800mg + Trimethoprim 160mg) tablet was fixed based on the data available as per Pharmatrac for the month of August, 2015. NPPA representative further submitted that the matter may be examined on submission of documents by the company as per the extant OM.

**5. Examination:**

NPPA has fixed the ceiling price of Co-trimoxazole tablet (Sulphamethoxazole 800mg + Trimethoprim 160mg) by taking the average of per unit price of two formulations of Glaxosmithkline Pharmaceuticals Ltd. The company claimed that three more formulations of similar strength, viz. Sepmax DS tablet 10 of Glaxosmithkline; Bactrim DS tablet 10 of Abbott Healthcare and Oripim DS 800 MG tablet of Zydus Alidac, are also available in the market. In support of their claim, during the personal hearing, the company submitted documentary proof along with additional submissions, the copy of which is placed at pages 92-107/cors. The claim of the company made in the review application that the PTR considered for Septran DS 800/160 MG tablet of Glaxosmithdklin is not correct, has no relevance as the company could not provide any documentary proof in support of its claim. The company also raised various other issues, which are of administrative nature and has no relevance with the review of the petition.

6.2 Since the company has submitted sufficient documentary proof along with its review application and also during the personal hearing, it is proposed that NPPA may be directed to examine the documents submitted by the company and re-fix the ceiling price of the formulation Co-Trimoxazole Tablet, after getting confirmation from Pharmatrac, on merit.

**6. Government Decision:**

**“NPPA is hereby directed to examine the documentary proof submitted by the company and re-fix the ceiling price of the formulation Co-Trimoxazole Tablet, after verification, on merit.”**

Issued on this date of 24<sup>th</sup> day of August, 2017.

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

To

1. **M/s. Cadila Healthcare Limited,  
Zydus Tower, Satellite Cross Road,  
Ahmedabad-380015.**
2. **The Member Secretary,  
National Pharmaceutical Pricing Authority,  
YMCA Cultural Centre Building, New Delhi-110001**

Copy to :

1. **PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.**
2. **PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.**
3. **T.D., NIC for uploading the order on Department's Website**