

No. 31015/57/2017-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 "Paracetamol Sustained Release 1000mg tablet" vide NPPA order No. S.O. 1335(E), dated 27.04.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 05.05.2017
2) NPPA notification under review S.O. No.1335(E), dated 27.04.2017
3) Record Note of discussions held in the personal hearing on 21.09.2017.

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.1335(E), dated 27.04.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of their formulation Paracetamol Sustained Release 1000mg tablet.

2. The petitioner has contended as under:

(i) The Retail Price fixed by NPPA for Paracetamol Sustained Release 1000mg vide notification S.O. 1335(E) dt 27.4.2017 is not correct. The details of the price fixed vide above referred notification is as below:

Sl. No.	Name of the Scheduled Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company respectively	Retail Price (Rs.)
1	2	3	4	5	6
1	Paracetamol Sustained Release 1000mg tablet	Each uncoated bilayered tablet contains: Paracetamol 300mg (as immediate release) Paracetamol 700mg (as sustained release)	1 Tablet	M/s Lincoln Pharmaceuticals Ltd/ M/s Cadila Healthcare Ltd.	3.28

(ii) Company further submitted that Draft Working sheet related to the 9 relevant packs was placed on NPPA's website on 23.11.2016 and company had represented against the same vide their letter 28.11.2016. Draft version of Proposed Price Calculation Sheets for 9 packs involving Paracetamol 1000mg tablets shows that NPPA has erred in recognizing their Paracetamol 1000 SR tablets. NPPA has computed the Retail Price of their Paracetamol 1000mg SR tablets on the basis of PTR data of all the formulations of Paracetamol 1000mg including conventional immediate release tablets.

(iii) Pyrigesic 1000mg tablet manufactured by East India Pharmaceutical Works Ltd. has been considered in calculation sheet. This formulation is 1000mg conventional immediate release tablet. This should not have been considered by NPPA.

(iv) Opara Tablet manufactured by Wallace Life style Pharmaceuticals Pvt. Ltd has also been considered in calculation sheet. This formulation is also a conventional Acetaminophen Tablet 1000mg. This pack should also not have been considered by NPPA

Sum of MAT value considered for price calculation (Rs. In Lakhs)	
Sum of PTR per unit considered for price calculation	21.96
Number of Packs considered	7
Average PTR	3.14
Add : 16% Retailer Margin	0.50
Retail Price (without local taxes)	3.64

(v) With consideration of 7 packs only the Retail Price works out to be Rs.3.64 per tablet.

(vi) Further company submitted that explanation note to schedule -1 of DPCO 2013 also clearly indicates that prices of novel drug delivery systems like...Sustained release will be treated differently.

“Innovation in medicine must be encouraged. The formulations developed through incremental Innovation or novel drug delivery systems like lipid/liposomal formulations, sustained release/controlled release etc. should be considered as included only if specified in the list against any medicine. Such different formulations should be considered differently for purposes such as procurement policy, pricing etc.”

(vii) Company submitted that NPPA is not correct in stating that there is no separate mention in the NLEM regarding the Drug Delivery System, all versions of the Schedule Drug in question are required to be clubbed irrespective of the Drug Delivery System. In their case company have sought the price for Paracetamol 1000mg SR tablets. NPPA has wrongly clubbed all the formulations of Paracetamol 1000mg whether, immediate release or sustained release. NPPA should have used the PTR values of only SR/MR/TR/DR formulations to arrive at the average price. Such prolong release tablets have distinct therapeutic advantages over the conventional immediate release tablets. A SR preparation is an innovative and new drug delivery system which by passes the acidic environment of the stomach and releases the active ingredient for a prolonged period. This gives the therapeutic advantage of less frequent dosing, higher efficacy and minimal side effects. NPPA has erred in recognizing the above therapeutic benefits and has treated our proposed SR formulation as any other conventional and immediate release formulation of Paracetamol 1000mg.

(viii) Company highlighted that DPCO 2013 under NPPP 2012 does not recognize the API or the Bulk Drug for inclusion in NLEM or Schedule 1 of DPCO. Specified strength and dosage forms are recognized under NLEM and schedule 1 of DPCO 2013.

In view of above, company has requested as under:-

a. NPPA may be directed to recalculate the Retail Price of Paracetamol sustained release 1000mg Tablet of company based on PTR data of only those formulations which are SR/TR/MR/DR. Conventional immediate release tablets should be excluded and not be considered for calculating the average price as per the provisions of DPCO 2013.

(b) NPPA may also be directed to give due weightage to therapeutic benefits of such new drug delivery systems which benefit the patients and consider them separately for calculating their Ceiling Prices or Retail Prices and not club the PTRs of such formulations with that of the conventional formulations to arrive at an average price.

Company submitted that company has implemented the Notified Price of Paracetamol sustained release 1000mg tablet. Company certified that Cadila Healthcare Limited is 100% compliant on IPDMS.

4. **Comments of NPPA:**

- I. Retail price of **Paracetamol Sustained Release 1000mg tablet** was notified as Rs.3.28 vide S.O. 1335(E) dated 27.04.2017 under para 5, 11, 15 of DPCO, 2013.
- II. The company has stated that correct methodology was not followed in arriving at the retail price of **Paracetamol Sustained Release 1000mg tablet**. The points raised by the company are not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013. Details are as follows:-

Sl. No.	Company's Grievances	NPPA's comments
1.	Company stated that retail price fixed by NPPA for Paracetamol Sustained Release 1000mg vide notification No. S.O. 1335(E) dated 27.4.2017 is not correct.	NPPA fixed retail price Rs.3.28 for Paracetamol 1000 mg sustained release tablet (Paracetamol 300 mg as immediate release), (Paracetamol 700 mg as sustained release 700 mg tablet) based on the data provided by AIOCD-AWACS for the month of April 2016.
2.	Based on Draft Working sheet placed on NPPA's website. Company represented against the same vide their letter 28.11.2016, by stating that NPPA has erred in recognizing their product Paracetamol 1000 mg SR tablet as NPPA has computed the retail price of their product Paracetamol 1000 mg SR tablet on the basis of PTR data of all the formulations of Paracetamol 1000 mg including conventional immediate release tablet. NPPA has considered the PTR of Pyrigesic 1000 mg tablet which is a	As per the principle adopted by the authority in its 27th meeting held on 29.03.2016, all variants of the product are to be taken while calculating the price fixation of the formulation unless different variants of the formulations are specifically mentioned against any formulation in NLEM, 2015. Accordingly, the retail price of the subject formulation was calculated.

	<p>1000mg tablet manufactured by East India Pharmaceuticals Works Limited in price calculation sheet for price fixation of the subject formulation. As per the opinion of company, NPPA should not consider the PTR of Pyrogesic 1000mg tablet and Opara tablet of M/s. Wallace Lifestyle Pharmaceuticals Pvt. Ltd. for calculating the retail price of the formulation under reference, as they are conventional tablets. As per company opinion, only 7 packs to be considered for working out the retail price of this pack. Company requested in the light of explanation note to schedule 1 of DPCO, 2013.</p> <p>Company challenged price notification in the light of explanation note to schedule-I. Company also stated that in their case, they have sought the price for Paracetamol 1000mg SR tablets. NPPA has wrongly clubbed all the formulations of Paracetamol 1000mg whether, immediate release or sustained release. They should have used the PTR values of only SR/MR/TR/DR formulations to arrive at the average price. Such prolong release tablets have distinct therapeutic advantages over the conventional immediate release tablets. A SR preparation is an innovative and new drug delivery system which by passes the acidic environment of the stomach and releases the active ingredients for a prolonged period. This gives the therapeutic advantage of less frequent-dosing, higher efficacy and minimal side effects.</p> <p>Company has also pointed out that NPPA has not considered the drug delivery system based formulation for inclusion in the working out the price fixation. NPPA considered the three criteria's i.e. The API of Bulk Drug, Route of Administration and The strength of formulation to differentiate between the schedule and non-schedule formulation and ignored the drug delivery system. As per company opinion, above mentioned criteria are applicable only for scheduled</p>	
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	formulation.	
3.	Company requested to recalculate the retail price of Paracetamol sustained release 1000 mg tablet based on PTR data of only those formulations which are SR/TR/MR/DR. Conventional immediate release tablets should be excluded for calculating the average price.	NPPA fixed the retail price as per the provisions of DPCO, 2013 and the principle adopted by the authority in its 27th meeting held on 29.03.2016, whereby all variants of the product are to be taken while calculating the price fixation of the formulation unless different variants of the formulations are specifically mentioned against any formulation in NLEM, 2015.

III. Company has not challenged any notification in respect of **Paracetamol Sustained Release 1000 mg tablet** in the Court.

5. During the personal hearing, the company representative made the following additional submission :-

- NPPA Notified the Retail Price for Paracetamol Sustained Release 1000 mg Tablet vide Notification No. S.O. No. 1335(E) dated 27.4.2017. The Retail Price notified is Rs. 3.28 per tablet. NPPA has considered 9 packs while arriving at the above Retail Price.
- Draft Working Sheet related to the 9 packs was placed on NPPA's web site on 23.11.2016. Cadila Healthcare Limited had represented against the same vide letter dated 28.11.2016.
- In the representation, the company had categorically stated that out of 9 considered packs there are 2 packs namely Pyrigesic 1000 mg tablet manufactured by East India Pharmaceutical Works Ltd and Opara Tablet of Wallace Life Style Pharmaceuticals Pvt. Ltd, which are not Sustained Release Formulation packs and should not be considered while computing the average price.
- NPPA did not consider the company's representation and went ahead with Retail Price Notification on 27.4.2017. The company did not hear anything from NPPA in favour or against our representation.
- Through this additional submission, the company highlighted the following :
 1. As per Explanation note to Schedule-1 of DPCO 2013 (NLEM 2015) it is clearly stated that the Prices of novel drug delivery systems like Sustained Release will be treated differently.
"Innovation in medicine must be encouraged. The formulations developed through incremental Innovation or novel drug delivery systems like lipid/liposomal formulations, sustained release/controlled release etc. should be considered as included only if specified in the list against any

medicine. Such different formulations should be considered differently for purposes such as procurement policy, pricing, etc.”

2. Vide OM dated 6.12.2013 Ministry of Health and Family Welfare have categorically stated that dosage forms like modified release forms if specifically mentioned would be considered for price approval separately.
 3. The company representative further stated that NPPA considers such dosage forms like SR/TR/MR/DR if specifically mentioned in the NLEM, and the company's application in Form 1 was specifically for SR Form of Paracetamol 1000mg tablet.
 4. NPPA has erred and has considered sustained release forms as well as immediate release forms of 1000mg tablet of Paracetamol and has accordingly considered 9 such packs in totality. Pyrigesic 1000 mg tablet manufactured by East India Pharmaceutical Works Ltd and Opara Tablet of Wallace Life Style Pharmaceuticals Pvt. Ltd should not have been considered.
- Submission:
 - (1) NPPA may please be directed to rework the Retail Price for Paracetamol Sustained Release 1000 mg Tablet considering only the 7 packs of Modified Release Formulations as on August 2015. This is a case of Retail Price for Sustained Release Tablet. Therefore conventional tablets of Paracetamol cannot be considered for averaging the prices under Para 4 or Para 5 of DPCO 2013.

NPPA representative stated that they have no further submission in addition to as mentioned above.

6. Examination:

The grievance of the company is that NPPA has considered the PTR of two formulations, i.e. Pyrigesic 1000mg tablet 10 being manufactured by M/s East India Pharmaceutical Works Ltd. and Opara 1000mg tablet 10 being manufactured by M/s Wallace Pharmaceuticals Ltd., while calculating the ceiling price of this formulation. According to company, these two formulations are conventional immediate release tablets and the MAT value of these formulations should not be considered while arriving at the retail price of Paracetamol 1000mg tablet, which is having noval drug delivery system.

6.2 NPPA has fixed the retail price of Paracetamol 1000mg, which is 300mg as immediate release and 700mg as sustained release, by considering the data of similar formulations available in domestic market data provided by AIOCD-AWACS (Pharmatrac) for the month of August, 2015. As per the provisions of DPCO, 2013, all variants of the product are to be taken while calculating the price fixation of the formulation unless different variants of the formulations are specifically mentioned against any formulation in NLEM, 2015. The formulation of the petitioner company is not 100% Sustained Release formulation, therefore, NPPA has rightly fixed the retail

price as per the provisions of DPCO, 2013, by considering all variants of the product while calculating the price fixation. In view of the above, the grievance of the petitioner company has got no merit and may be rejected.

7. Government Decision:

“The grievance of the petitioner company cannot be accepted as the formulation of the petitioner company is not 100% Sustained Release formulation, and NPPA has rightly fixed the retail price as per the provisions of DPCO, 2013, by considering all variants of the product while fixing the retail price.”

Issued on this date of 1st day of January, 2018.

(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**