

**No. 31015/19/2018-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

A- Wing, Shastri Bhawan,
New Delhi 110 001

Order

1. This is an order on an application dated 13.02.2018 filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s IPCA Laboratories Limited. (hereinafter called the applicant) against notification S.O. No. 544(E), dated 06.02.2018 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling prices of Paracetamol 500mg + Dicyclomine HCL 20mg Tablets (Pacimol Spas Tablets) and Paracetamol 650mg + Caffeine 50mg Tablets (Pacimol Active Tablets).

2. The applicant has contended as under:-

2.1 **In respect of Paracetamol 650mg + Caffeine 50mg Tablets (Pacimol Active Tablets) vide S.O.544(E) dated 06.02.2018.**

(i) Retail price of the said product was notified on 6th Feb, 2018 vide S.No.6 of the notification at Rs. 1.88 per tablet excluding GST. Normally working sheet as per instructions based on which price is to be fixed is displayed on the website to invite objections, if any, before announcement of price. However, in the instant case the worksheet of 54th meeting got displayed on NPPA website on 06.03.2018 with date 05.03.2018. Therefore, there is a deprivation of the data even for filing a comprehensive review application against the settled position under DPCO, 2013.

(ii) In the worksheet displayed only 3 players in the market are mentioned as under:

Company Name	Brand Name	Market Share	PTR per Tablet	PTR Considered
Glaxosmithline Pharmaceuticals Ltd.	Crocic Pain Relief	0.43%	Rs.2.15	No
Ranbaxy Laboratories Ltd.	Doliza Plus	Nil	Rs.1.22	No
Sanofi India Ltd.	Novalgin NU	99.57%	Rs.1.69	Yes

(iii) It would be observed that the use of data (claimed to be of March, 2017) is contrary to the letter and spirit of paragraph 4 of DPCO, 2013 as only data(PTR) of those having market share of more than 1% can be used for working out average PTR. The source of data and the computations made as such are not correct.

- (iv) The above position is supplemented by the fact that Pharmatrac data of March, 2017 shows that excluding Ipca, there were two players, who have market share of 1% or more and their average PTR was Rs. 1.98 per tablet and retail price excluding GST was Rs. 2.20 per tablet against which a retail price of Rs. 1.88 per tablet was fixed.
- (v) Sanofi India has two brands, namely Combiflam Plus (2 pack i.e. 4T & 8T) & Novalgin NU with pack size of 10T.
- (vi) Glaxosmithkline Pharmaceuticals Ltd. which markets Crocin Pain Relief in pack of 15T. Crocin Pain Relief pack of 10T seems to be discontinued as per Pharmatrac.
- (vii) Market share of M/S Sanofi as shown in the worksheet is also as such is not correct in view of the above revelations.

2.2 Based on these observations, the worksheet published by NPPA seems to be grossly incorrect and needs a review. Company submitted Pharmatrac data of March, 2017 to show and support their contention that incorrect data have been used. These facts are confirmed to the company by Pharmatrac.

Company enclosed the working of correct retail price based on Pharmatrac, March-2017 MAT.

The summarized table of Retail price published by NPPA & Pharmatrac is as under:

Sr. No.	Particular	Retail Price	MRP per 10T
1.	Retail Price Fixed by NPPA	Rs.1.88 per Tablet	Rs.21.05
2.	Retail Price based on Pharmatrac	Rs.2.20 per Tablet	Rs.24.64
Difference in Retail Price →		Rs. 0.32 per Tablet	Rs. 3.59

2.3 After publication of the worksheet, it is amply clear that information published by NPPA is grossly incorrect resulting in a low retail price for our product Pacimol Active Tablets. Keeping in view the letter and spirit of Paragraph 15(5) of DPCO, 2013 revised price need to be fixed with effect from 6th Feb, 2018.

2.4 In respect of Paracetamol 500mg + Dicyclomine HCL 20mg Tablets (Pacimol Spas Tablets) vide S.O.544(E) dated 06.02.2018

- (i) Retail price of the said product was notified on 6th Feb, 2018 vide S. No. 1 of the notification at Rs. 1.64 per tablet excluding GST. Normally working sheet as per instructions based on which price is to be fixed is displayed on the website to invite

objections, if any, before announcement of price. However, in the instant case the worksheet of 54th meeting got displayed on NPPA website on 06.03.2018 with date 05.03.2018. Therefore, there is a deprivation of the data even for filing a comprehensive review application against the settled position under DPCO, 2013.

- (ii) Paraspas Tablets marketed by Cadila Pharmaceuticals Ltd. contains Dicyclomine 10mg + Mefenamic Acid 250mg. It does not contain **Paracetamol 500mg+ Dicyclomine HCL 20mg.** Company enclosed an extract obtained from M/s. Cadila Pharmaceuticals Ltd website as an evidence for the same. In addition company provided extract of four other websites. Company requested this Department to drop this product from the calculation of retail price for our product Pacimol Spas Tablets.
- (iii) Company provided table below where amendment is needed to be made to arrive at correct retail price:-

Particular	PTR Rs./unit
Sum of PTR per unit considered for price calculation as per worksheet published on 06.03.2018	13.26
Less: Paraspas Tablets PTR	(0.48)
Sum of PTR per unit after due correction	12.78
Particular	PTR Rs./unit
Number of packs now considered (From earlier 9)	8
Average PTR (12.78 /8)	1.60
Add: @16% Retailer Margin to Average PTR	0.26
Revised Retail Price (without local taxes)	1.86
Excise factor @ 0.95905 applied on above revised retail price	1.78
Retail price as per notification S.O.544(E) dated 06.02.2018	1.64
Difference in Retail price (Rs.1.78-Rs.1.64)	0.14

2.5 After publication of the worksheet, it is amply clear that information published by NPPA is grossly incorrect resulting in a low retail price for our product Pacimol Spas Tablets. Keeping in view the letter and spirit of Paragraph 15(5) of DPCO, 2013 revised price need to be fixed with effect from 6th Feb, 2018.

Company submitted their certificate certifying that **they have not yet launched Pacimol Spas Tablets.**

3. Comments of NPPA:

3.1 Retail prices of formulations fixed by NPPA, vide S.O. No. 544 (E) dated 06.02.2018 are detailed below:-

Sl. No.	Name of the Formulation	Company's Composition	Product	Notified Price (Rs)
1	Paracetamol 500mg + Diclomine HCL 20mg Tablets (Pacimol Spas)	Each uncoated tablet contains: Paracetamol IP 500mg Diclomine Hydrochloride IP 20mg		1.64
2	Paracetamol 650mg + Caffeine 50mg Tablets (Pacimol Active Tablets)	Each uncoated tablet contains: Paracetamol IP 650mg Caffeine Anhydrous IP 50mg		1.88

3.2 NPPA fixed the retail prices of the subject formulations vide SO 544 (E) dated 06.02.2018 as per para 5, 11 and 15 of DPCO, 2013 based on the Pharmatrac data and working sheets of the subject formulations are available at NPPA's website.

3.3 NPPA fixed the retail prices of Pacimol spas tablet based on the Pharmatrac data for the month of October, 2016. As per the Pharmatrac data the product "Paraspas tablets" of M/s Cadila Pharmaceuticals Ltd contains Paracetamol 500mg + Dicyclomine HCL 20mg. However based on the grievance of the company, the same was referred to Pharmatrac for verification. However the same will be considered based on the directives of the Reviewing Authority, Pharmatrac's reply and supporting document submitted by the petitioner company as per OM relating to Standard Operating Procedure (SOP) dated 13.04.2017.

3.4 With respect to **Paracetamol 650mg + Caffeine 50mg Tablets (Pacimol Active)**, NPPA fixed the retail prices of the subject formulations vide SO 544 (E) dated 06.02.2018 as per para 5, 11 and 15 of DPCO, 2013 based on the Pharmatrac data. However based on the grievance of the company, the same was referred to Pharmatrac for verification. However the same will be considered based on the directives of the Reviewing Authority, Pharmatrac's reply and supporting document submitted by the petitioner company as per OM relating to Standard Operating Procedure (SOP) dated 13.04.2017.

4. Examination:

4.1 NPPA fixed the retail prices of formulations **Paracetamol 500mg + Dicyclomine HCL 20mg Tablet (Pacimol Spas Tablet) and Paracetamol 650mg + Caffeine 50mg Tablet (Pacimol Active Tablet)** vide SO 544(E), dated 06.02.2018. The retail price has been fixed on the basis of request made by M/s IPCA Laboratories Limited under para 2(u) of DPCO, 2013 and filed Form I for fixation of retail price for their subject formulations

4.2 As regards the product **Pacimol Spas Tablet (containing Paracetamol 500mg + Dicyclomine HCL 20mg Tablet)**, company stated that the formulation Paraspas tablet marketed by M/s Cadila Pharmaceuticals Limited containing Paracetamol 500mg + Mefenamic Acid 250mg was considered, which is of different combination. In support

of its claim, the company submitted documentary proof about the composition and active ingredients used by M/s Cadila Pharmaceuticals Limited in their product Paraspas Tablet, which was put by the company on its website. The same was submitted by the company to this office vide its letter dated 30.3.2018.

4.3 It is observed from the documentary proof submitted by the company that the product of M/s Cadila Pharmaceuticals Limited is of different combination and should not be considered in price calculation of Pacimol Spas Tablet. Therefore, the grievance of the company has got merit.

4.4 In view of the above, NPPA needs to examine and verify the documentary proof submitted by the company about the different composition of the product of M/s Cadila Pharmaceuticals Limited. After verification, the retail price of Pacimol Spas Tablets containing Paracetamol 500mg + Dicyclomine HCL 20mg tablets may be re-fixed by excluding that product in price calculation, on merit.

4.5 Regarding the product **Pacimol Active Tablets (containing Paracetamol 650mg + Caffeine 50mg Tablets)**, the company stated that while calculating the retail price of the formulation, NPPA has not considered the PTR of other companies having MAT percentage of more than 1%. Company stated that Crocin pain relief tablet marketed by Glaxosmithline in pack size of 15's is having market share is 20.37%; Anacin tablet marketed by Pfizer is having market share 29.81%; market share of Combiflame plus tablet marketed by Sanofi is 9.49% and Market share of Novalgin NU, which is shown as 99.57% in worksheet, whereas IMS Health shows a market share of 23.46%. In support of its claim, the company submitted statement of IMS Health data of the month of March, 2017. Company also submitted copy of statement of Pharmatrac data of the month of March, 2017, which also support the claim of the company.

5.6 On going through the documentary proofs submitted by the company, it is observed that the grievance of the company has got merit. Therefore, NPPA needs to examine and verify the documentary proofs submitted by the company about the market share of similar formulations of other companies. After verification and cross-checking the data, re-fix the retail price of Pacimol Active Tablets containing Paracetamol 650mg + Caffeine 50mg tablets, on merit.

6. **Decision:**

“NPPA is hereby directed to examine and verify the documentary proof submitted by the company about the different composition of the product of M/s Cadila Pharmaceuticals Limited. After verification, the retail price of Pacimol Spas Tablets containing Paracetamol 500mg + Dicyclomine HCL 20mg tablets may be re-fixed by excluding that product in price calculation, on merit.”

“NPPA is further directed to examine and verify the documentary proofs submitted by the company about the market share of similar formulations of other companies. After verification and cross-checking the data, re-fix the retail price of Pacimol Active Tablets containing Paracetamol 650mg + Caffeine 50mg tablets, on merit.”

“The above directions be implemented within a period of one month from the date of issue of the order and compliance report be submitted.”

Issued on this date, the 22nd day of June, 2018.

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

Copy to:-

1. M/s Ipca Laboratories Limited, 125, Kandivli Industrial Estate, CTS No.328, Kandivli (West), Mumbai-400 067.
2. The Member Secretary, National Pharmaceutical Pricing Authority, YMCA Cultural Centre Building, New Delhi-110001
3. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.
4. PS to MoS(C&F), Shastri Bhawan, New Delhi for information.
5. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
6. T.D., NIC for uploading the order on Department's Website.