

No. 31015/68/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

B Wing, Janpath Bhawan,
New Delhi 110 001

Subject: Review application of M/s IPCA Laboratories Limited against price fixation of "Paracetamol 500 mg. tablet" vide NPPA order No. S.O. 1351(E)[corrected SO No.1951(E)] dated 02.06.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 17.06.2016
2) NPPA notification under review S.O. No. 1351(E)[corrected SO No.1951(E)] dated 02.06.2016
3) Record Note of discussions held in the personal hearing held in the matter on 08.09.2016.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s IPCA Laboratories Limited (hereinafter called the petitioner) against notification S.O. No. 1351(E)[corrected SO No.1951(E)] dated 02.06.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Paracetamol 500 mg tablet.

2. The petitioner has contended as under:

- I. This is with reference to above mentioned Notification, in which based on the provisions of para 4, 10, 11, 14, 16, 17 and 18 Of the Drugs Price Control order 2013, the NPPA has decided to further reduce the prices of paracetamol tablets 500 mg to **Rs.0.83 per tab** from the Revision given on March 2, 2016, **S O 644 (E) of Rs 1.01 per tab**, giving effect to the Whole sale price index changes of -2.7105%. Neither the PTR nor the basket of producers have changed but the above reduction has been brought about without any assignable reasons NPPA as provided in paragraph 31 of DPCO, 2013.
- II. The prices for Paracetamol Tablets of the said strength were changed on the following dates, and the following ceiling prices were announced:-

June 14, 2013	Rs.0.94 per tab
April, 28, 2014 (WPI @6.32%)	Rs.1.00 per tab
February 26, 2015 (WPI @3.849%)	Rs.1.04 per tab
April 2015 (adjusting for ED)	Rs.1.036 per tab
March 02, 2016 (WPI @-2.7105%)	Rs.1.01 per tab
June 2, 2016	Rs.0.83 per tab

- III. PTR cannot change overnight and in the instant case MAT values and brands taken into consideration do not reflect the correct position and NPPA is supposed to verify facts before working out prices. They highlight the following for your consideration:-

- (i) For the purpose of calculation even a 1000 jar pack has been considered for calculation of average PTR per tablet. This is a dispensing pack and not a consumer pack and the objective of both type of packs is different and cannot be clubbed together if saneness is the guiding factor. When your authority itself is clearly differentiating packing charges for “tablets packed in random” and “tablets packed in strip” and also packing material costs of both type of packs are different, how is it possible to compare the price of both for average cost. There is no rational of such an average and no rational person can think of the same and to expect such a thing from body of experts is nothing but acting against the make in India campaign of Government of India. The manpower requirements, and packing material cost is vastly different for packing 1000 tablets in jar and 1000 tablets in blisters of 10x10 and these aspects cannot be ignored by any sensible organization.

Average PTR & Ceiling Prices for Paracetamol Tablets in Strips & Bulk Pack

	PTR Total	No. of Packs	Average PTR	16% Margin	Ceiling Price (Excl Tax)	WPI @ - 2.7105%	Final Ceiling Price (excl Tax)
Strip	9.90	12	0.83	0.13	0.96	-0.03	0.93
Bulk	1.09	3	0.36	0.06	0.42	-0.01	0.41
Ceiling price revised by NPPA (Strip + Bulk)	10.99	15	0.73	0.12	0.85	-0.02	0.83
Difference in Ceiling Price between Strip & Ceiling price revised by NPPA (Strip + Bulk)							0.10

- (ii) They enclosed workings of 14th June, 2013 and workings of 2nd June, 2016. How the price can come down after three years when costs have gone up is really disturbing and there cannot be an average PTR of unlikes. It is sad that even this aspect has not been settled showing the efficiency of the Administration and the way things are moving. First IMS Health MARG data was used in June, 2013 as per Policy directive, later NPPA of its own switched to Pharmatrac data leading to inconsistencies.
- IV. They requested this Department to withdraw the notification as it is issued on a wrong basis and announce the correct price and the workings displayed on the website must show the officer who have prepared them and the officer who has checked them so that such instances are not repeated and correct guidelines are laid down and are followed. Major faults in the policy have not been corrected even after two years.
- V. They have uploaded Form V electronically in IPDMS and are following the ceiling price revised by NPPA.

Comments of NPPA:

- (i) NPPA has fixed the ceiling price of Rs. 0.84/tablet vide S.O. 1555(E) dated 14.6.2013 and the same was revised to Rs. 1.00, Rs. 1.04 & 1.0 per tablet vide S.O. 1156(E), 619(E) & 644(E) dated 28.4.2014, 26.02.2015 & 02.3.2016 respectively under NLEM 2011 and Rs. 0.83/tablet vide S.O. 1351(E) dated 02.6.2016 under NLEM 2015.
- (ii) Company's request to withdraw S.O. 1351(E) dated 02.6.2016 is not tenable as per para 18(1) of 2013.
- (iii) As per information available with M&E division (through IPDMS report), company is following ceiling price notified vide S.O. 1351(E) dated 02.6.2016 for above mentioned formulation. DOP is also requested to verify the same from the company by insisting on verified copies of the control sample of price revision and relevant invoices in support.

3. During the personal hearing, the representatives of the petitioner further submitted that the stand being taken by NPPA is wrong, unjust and without any basis due to the following reasons:-

- (a) Average PTR has been worked out for unlike packs. This cannot be and is not the purpose of the NPPP-2012 and NPPA has been giving wrong interpretation to justify its actions. NPPA has to notify retail prices and it should take into consideration retail packs only and not the dispensing packs. Clubbing of both types of packs is not justified on any ground and reflects non application of mind. Neither it is mathematically correct nor technically correct. It is also against the NPPP-2012. In such matters views of Body of Experts need to be called instead of NPPA alone.
- (b) NPPA has been deliberately doing such acts which have no justification. They have been doing so on the ground that cost is not relevant under new policy. However, nothing moves without cost. At the same time, there is no mandate in the NPPP-2012 to club together unlikes for the purpose of working out average PTR. In the instant case out of 15 packs, three dispensing packs of plastic containers having 500 to 1000 tablets packed in random and 12 packs in strip/blister have been taken for arriving at PTR per tablet and PTR variance between two type of packs based on own working of NPPA is between Rs. 0.34 per tablet to Rs. 0.84 per tablet. When purpose of both type of packs is separate and such is the large difference in PTR's only an impractical man bent upon destroying everything can take the average. This clearly shows that there is no application of mind. As a result of such acts number of producers /packs have got reduced from 104 in June, 2013 to only 70 in August, 2015 based on NPPA's own data. This is an undesirable situation and Ministry should take cognizance of the same and stop/effectively intervene in such acts of NPPA which are contrary to the Policy.
- (c) Kind attention is invited to Notification S.O.No.2209(E) dated 24th June, 2006(copy enclosed). It would be seen that for Glucose Injection, Sodium Chloride injection and Sodium Chloride and Glucose injection different ceiling prices have been fixed for different packing materials used, quantity per pack and ceiling prices fixed are not only different but also show wide variations. This

also shows that NPPA has been using its discretion which again is not a desirable situation. The notification against which we have filed review is dated 2nd June, 2016 showing thereby that discrimination is willful as well.

- (d) The companies cannot afford to lose due to wrong acts of NPPA and as such these matters are required to be resolved once for all.

NPPA representative submitted that the ceiling price of Paracetamol 500mg tablet has been fixed based as per the existing practice and the provision of DPCO, 2013.

4. Examination:

In the instant case, as regards the contention of the petitioner company that the price of paracetamol tablets 500 mg. was revised as Rs.1.01/tablet on 2.3.2016 and again fixed at Rs.0.83/tablet vide SO 1951(E), dated 2.6.2016, **Para 18(i) of DPCO 2013** clearly states that the revision of ceiling prices on the basis of moving annual turnover value shall be carried out **“as and when the National List of Essential Medicines is revised by the Ministry of Health and Family Welfare or five years from the date of fixing the ceiling price under this Order whichever is earlier.”** In view of this, **NPPA has revised the ceiling prices of the formulations strictly as per the provision of DPCO 2013.** WPI impact has to be taken care of while fixing the ceiling prices. Therefore, the petitioner company has no merit in this contention.

As regards, considering different size of packs, para 4 of DPCO, 2013 clearly states that PTR of brands and generic versions of the medicines having market share more than or equal to one percent of total turnover on the basis of moving annual turnover is considered with fixing the ceiling price. There is no provision for considering different size of packs in DPCO, 2013. Hence, the contention of the petitioner company has got no merit.

In view of the above, the hearing authority is of the view that the contentions of the petitioner company have no merit, hence the review petition may be rejected.

5. Government Decision:

In view of the above, the petition of the company with regard to withdrawal of notification of ceiling price of Paracetamol 500 mg. tablet vide SO 1351(E)[corrected SO No.1951(E)] dated 02.06.2016 stands rejected.

Issued on this date, the 14th day of February. 2017.

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

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**

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**