

**No. 31015/32/2017-Pricing**  
**GOVERNMENT OF INDIA**  
**MINISTRY OF CHEMICALS & FERTILIZERS**  
**DEPARTMENT OF PHARMACEUTICALS**

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A Wing, Shastri Bhawan,  
New Delhi 110 001

**Subject:** Review application of M/s IPCA Laboratories Limited against price fixation of "Chloroquine Phosphate 150mg Tablets (150mg base=250mg) (Lariago Tablets 10's)" 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 held in the matter on 04.07.2017.

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. 443(E), dated 14.02.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Chloroquine Phosphate 150mg Tablets (150mg base=250mg) (Lariago Tablets 10's).

2. The petitioner has contended as under:

I. Company has referred their representation letter dated 25<sup>th</sup> January, 2017 against draft worksheet dated 20<sup>th</sup> January, 2017 of Chloroquine Phosphate 250mg Tablets displayed on the NPPA website. NPPA has failed to carry out the rectification and hence this review application.

II. The grounds of review, Inter alia are as under: -

(i) Under Sr. No. 2 and 3 of worksheet for S.O. 443(E) dated 14.02.2017 M/s. Bayer is shown to be marketing *Resochin Tablets* in pack of 24's & 12's respectively which is not correct. Bayer is marketing *Resochin Tablets* in pack of 10's only and as such artificial packs and data have been used by NPPA. As mentioned in their representation letter they are manufacturing *Resochin Tablets* in pack of 10's on behalf of Bayer in one of their Plants. This also shows that the data adopted is incorrect. Bayer has stopped marketing *Resochin Tablets* in pack of 12's. They have discontinued this pack since Apr-2011. Bayer has never marketed *Resochin Tablets* in pack of 24's. Further the PTR of *Resochin* 250mg Tablet 10's was Rs. 6.72 during Aug-2015.

- (ii) Under Sr. No. 5 they are shown to be marketing *Lariago Tablets* in pack of 50's which is totally incorrect. Company has not marketing this pack more than a decade and as such the data used for this pack is also incorrect.
- (iii) The company understand that M/s Bayer have also made a representation towards draft worksheet dated 20.01.2017. They have also pointed out to NPPA that they are no longer marketing Resochin Tablets in pack of 12's & 24's. Further they have provided all the data pertaining to Resochin Tablets 10's.
- III. Impact of incorrect packs of Resochin Tablets (Bayer) and Lariago Tablets (Ipca) on Ceiling Prices of Chloroquine Tablets 250mg notified vide S.O.443(E) dated 14.02.2017 as shown in the below table:-

<i>Particular</i>	<i>PTR Rs./unit</i>
Sum of PTR per unit considered for price calculation as per worksheet published on 14.02.2017	3.17
Less: Sr. No.2 Resochin Tablets 24's Rs.(0.27)	
Sr. No.3 Resochin Tablets 12's Rs.(0.54)	(1.32)
Sr. No.5 Lariago Tablets 50's Rs.(0.51)	
Add: Estimated PTR of Resochin Tablets 10's with MRP 8.18 (August-2015)	0.67
Sum of PTR per unit after due correction	2.52
Number of packs now considered ( <i>From earlier 6</i> )	4
Average PTR (2.52 /4)	0.63
Add: @16% Retailer Margin to Average PTR	0.10
<i>Ceiling price before WPI</i>	0.73
Less: WPI @-2.7105%	(0.02)
<i>Correct Ceiling price per Chloroquine Phosphate 250mg Tablet</i>	0.71
<i>Incorrect Ceiling price of Chloroquine 250mg Tablets published by NPPA vide Notification No. S.O. 443(E) dt. 14.02.2017</i>	0.59
<i>Ceiling Price impact due to incorrect packs taken by Pharmatrac in August-2015</i>	(0.12)
<i>Ceiling Price Impact due to incorrect packs taken by Pharmatrac in August-2015%</i>	(20.34%)

- IV. The Ceiling price notified by NPPA is totally incorrect and they have totally ignored their representation letter dated 25<sup>th</sup> January, 2017 duly acknowledged by them on 30.01.2017. There needs to be a mechanism to compensate the manufacturers against wrong acts of NPPA as producers are forced even to implement wrong prices despite bringing the facts to the notice of NPPA.
- V. The company had also submitted:-
- (a) summary of all the invoice issued during the month of August-2015 for Lariago Tablets in strip of 10's duly attested, signed and sealed,
- (b) Chartered Accountant certifying summary of invoice statement

(c) sample invoice copies for the month of August-2015 showing PTR's of Lariago Tablets 10's with our letter dated 07<sup>th</sup> February, 2017 duly acknowledged by them on 09<sup>th</sup> February, 2017.

(d) extract copy of IMS Health for August-2015. There is no mention of *Resochin 250mg Tablets 12's & 24's packs*. Further there is no unit and value shown against *Lariago 250mg Tablets 50's*.

**VI.** In view of above, company has requested this Department for corrective action in the matter.

**Comments of NPPA:**

- I. Ceiling price of Chloroquine Phosphate 150mg tablet (150mg base=250mg) was notified as Rs. 0.59/tablet vide S.O. 443(E) dated 14.02.2017 and revised to Rs. 0.60/tablet vide S.O. 1039(E) dated 01.04.2017 as per para 4, 6, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.
- II. The company has stated that correct methodology was not followed in arriving at the ceiling price of **Chloroquine Phosphate 150mg tablet (150mg base=250mg)**. 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 has pointed out that NPPA has considered incorrect data in calculating the ceiling price for Chloroquine Phosphate 150mg tablet. M/s Bayer is marketing Chloroquine Phosphate 150mg tablet (Resochin tablet) in a pack size of 10's tablet only. Resochin tablet in pack size of 12's and 24's are not available in Pharma market as M/s Bayer have discontinued the pack size of 12's since April, 2011 and they have never marketed Resochin tablet in a pack size of 24's. Similarly, in calculation sheet, NPPA has shown that we have been marketing Larigo tablet in pack size of 50's which is totally incorrect. We have been marketing Larigo tablet in a pack size of 10's only.	NPPA considered the data provided by AIOCD-AWACS for month of August 2015. The Authority notified the ceiling price of Chloroquine Phosphate 150mg tablet in terms of the decisions taken in its 41 <sup>st</sup> meeting held on 13.02.2017 vide S.O. No. 443(E) dated 14.02.2017. Company has not given any supportive documents regarding prices of Chloroquine tablet of M/s Bayer.

		<b>Detail of trade margin based on AIOCD-AWACS data as on August 2015:-</b> Trade Margin from PTS level of the product of IPCA Laboratories Ltd.:- 1. Lariago 250mg tablet 10's – 33.14% 2. Lariago 250mg tablet 50's – 32.28%
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3. During the personal hearing, the representatives of the petitioner company stated that they have nothing more to submit, in addition to submissions already made.

3.2 NPPA submitted that they may examine the same on submission of requisite documents.

#### 4. **Examination:**

The main contentions of the petitioner company are about wrongly considering data of Resochin tablets in pack size of 24's and 12's being marketed by Bayer and also the company's data of Lariago tablets in pack of 50's by NPPA while fixing the ceiling price of the subject formulation. NPPA considered the data provided by Pharmatrac. In support of their claim, the company has submitted documentary proof to NPPA. During the personal hearing, the company also submitted photocopies of various documents in support of their claim, including copy of e-mail confirmation of AIOCD-AWACS (Pharmatrac), dated 21.2.2017. In view of this, NPPA may be requested to examine the documentary proof submitted by the petitioner company, and re-fix the ceiling price of **Chloroquine Phosphate 150mg Tablets (150mg base=250mg) (Lariago Tablets 10's)**, after obtaining confirmation from Pharmatrac, on merit.

4.2 On perusal of the calculation sheets of Chloroquine Phosphate 150mg Tablets (150mg base=250mg) (Lariago Tablets 10's), it is observed that NPPA has also taken into account one formulation, Resochin 250mg tablet 24 of Bayer Pharmaceuticals Pvt. Ltd., having MAT value of less than 1%. NPPA may be directed to consider only those medicines/formulations having MAT value of more than 1% market share, as DPCO does not recognize a company for average PTR but only medicines / formulations.

#### 4. **Government Decision:**

**“NPPA is hereby directed to examine the documentary proof submitted by the petitioner company about actual pack size availability in the market, and re-fix the ceiling price of Chloroquine Phosphate 150mg Tablets (150mg base=250mg) (Lariago Tablets 10's), after obtaining confirmation from Pharmatrac, on merit.”**

**“NPPA is also directed to re-fix the ceiling prices of subject formulations by considering only those medicines / formulations having MAT value of more than 1% market share as DPCO does not recognize a company for average PTR but only medicines / formulations.”**

Issued on this date, the 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. 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**