

No. 31015/30/2023-Pricing (E-23317)
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

.....

Room No. 340-B, 'A' Wing, Shastri Bhawan,
New Delhi-110 001.

Order

M/s IPCA Laboratories Limited (hereinafter called the "Applicant"), filed a Review Application dated 03.02.2023 under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against price fixation order issued vide S.O. No. 194(E) dated 11.01.2023 by the National Pharmaceutical Pricing Authority (NPPA). Vide its aforesaid Order, NPPA, inter alia, fixed the ceiling price for Lariago Tablet containing Chloroquine Phosphate 150 mg.

2. On the aforesaid plaint, reference was invited by the Department of Pharmaceuticals from NPPA. Both the parties entered appearance on 14.09.2023 and presented their respective logics.

3. Major contentions raised by the Applicant:

It was contended on behalf of the Applicant that NPPA has erred in determining ceiling price of the above drug and hence may be directed to revise the same on the following grounds:

3.1 The company vide their letter dated 7.10.2022 has informed to NPPA in advance that the PTRs reflected in Pharmarack for Chloroquine Phosphate 150 mg tablet are grossly incorrect for Resochin tablet marketed by M/s Bayer Zydus Pharma.

3.2 Further, it was also informed to NPPA that Resochin tablets (Chloroquine Phosphate tablet 150 mg) has been discontinued by M/s Bayer Zydus Pharma and hence should not be considered in calculating the average PTR. The Applicant had also provided the list of approved Form IV intimation regarding discontinuation of scheduled formulation dated 31.03.2021 as per NPPA website, to NPPA.

3.3 Despite presenting the proof regarding revised prices and PTR, NPPA in draft worksheet uploaded on 12.01.2023 considered the old PTR of Resochin tablet as Rs. 0.65 per tablet.

3.4 The company claimed that they are sole manufacturers of Chloroquine Phosphate 150 mg tablets in India after discontinuation of Resochin tablet marketed by M/s Bayer Zydus Pharma and incorrect ceiling price fixed vide S.O.No.194 (E) dated 11.01.2023, will leave the company to apply Form -IV for discontinuation of the product Lariago tablets (Chloroquine Phosphate tablet 150 mg).

4. Gist of clarifications made by NPPA:

NPPA submitted the following:

4.1 The PTR of Resochin tablets marketed by M/s Bayer Zydus Pharma shown in Pharmatrac database is Rs.6.46 per 10 tablets which is without WPI increase. It is observed

that Form II is not filed by the company for the year 2022-23 and last Form II was filed on 20.04.2021 with PTR of Rs. 9.99 for pack of 10 tablets. Hence, the same needs to be amended.

4.2 It is also stated that in case of M/s IPCA Laboratories limited, the correct PTR is Rs.10.54 per 10 tablet i.e. Rs.1.05 per tablet on the basis of Form-II submitted by the company on 12.04.2022. However, NPPA has inadvertently considered the price of Rs. 13.83 per 10 tablets for M/s IPCA Labs. This also needs to be rectified so as to reflect the correct PTR of Rs. 10.54 per 10 tablets.

5. Examination:

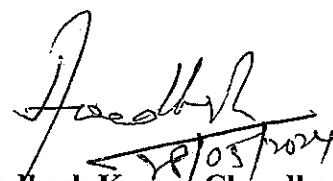
5.1 M/s Bayer Zydus Pharma had discontinued the scheduled formulation based on Form-IV filed with NPPA and submitted last Form II on 20.04.2021 with PTR of Rs. 9.99 for pack of 10 tablets. During the hearing, NPPA acknowledged that inadvertently, last Form-II filed of M/s Bayer Zydus Pharma was not considered. Further, the PTR of M/s IPCA Laboratories limited was also not considered correctly. Therefore, the ceiling price for the formulation Chloroquine Phosphate 150 mg required recalculation based on revised PTR.

5.2 NPPA may once again look out for all such possible errors in calculation of ceiling price.

6. Decision:

In the backdrop of above facts, the case is being referred back to NPPA for recalculation of Ceiling Price of Chloroquine Phosphate 150 mg tablet as per the extant provisions of DPCO, 2023.

Issued on this, the 28th day of May, 2024.


(Awadhesh Kumar Choudhary)

Sr. Economic Adviser to the Government of India
[For and on behalf of the President of India]

To:

IPCA Laboratories Limited,
125, Kandivli Industrial Estate,
CTS no. 328, Kandivli (West)
Mumbai-400067

Copy to:

1. Chairperson, NPPA, New Delhi
2. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi
3. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi
4. Technical Director, NIC for uploading the order on DoP's Website.
5. Guard File