No.31015/42/2023-Pricing (E-23437) GOVERNMENT OF INDIA MINISTRY OF CHEMICALS & FERTILIZERS DEPARTMENT OF PHARMACEUTICALS

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Room No. 340-B, A Wing, Shastri Bhawan, New Delhi-110001.

Order

M/s Alembic Pharmaceuticals Limited (hereinafter called the "Applicant") filed a Review Application dated 28.02.2023 under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against price fixation order issued vide S.O. No. 484 (E) dated 02.02.2023 by the National Pharmaceutical Pricing Authority (NPPA). Vide its aforesaid Order, NPPA, inter alia, fixed the ceiling price of Azithromycin 250 mg and Azithromycin 500 mg Tablet.

2. On the aforesaid plaint, reference was invited by the Department of Pharmaceuticals from NPPA. Both the parties entered appearance on 25.07.2023 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 In spite of the detailed representation filed by the Applicant on 15.12.2022 against the draft working sheets published by NPPA on its website on 02.12.2022 along with relevant pack shots evidencing the error in calculation of ceiling price of the said formulation of various companies. NPPA, while calculating the ceiling prices of the Formulations, has not taken into consideration the MRPs of the formulations available in the market at the time of Price Calculation.

3.2 NPPA did not consider the revised PTR of the following brands, having more than or equal to one per cent market share, for the ceiling price calculation:

Sr. No.	Brand	1 0	Unit		9			
				Manufacturing Month				
AZITHROMYCIN 500 Tab								
1.	ATM 500	Indoco Remedies Ltd.	17.07	18.91	Jun - 22			
2.	AZILIDE 500	Micro Labs Ltd.	17.07	18.91	Jun - 22			
3.	HHAZI 500	Hegde & Hegde	17.07	18.90	Apr - 22			
4.	13 CM8029N2325 - PM53252 - PI	Hetero Healthcare Ltd.	16.33	18.07	Aug - 22			

5.	ZADY 500	Mankind	15.94	17.66	Apr - 22			
AZITHROMYCIN 250								
1.	ATM 250	Indoco Remedies Ltd.	8.46	9.38	May - 22			
2.	AZILIDE 250	Micro Labs Ltd.	8.46	9.38	Jul - 22			
3.	HHAZI 250	Hegde & Hegde	8.46	9.37	Apr - 22			
4.		Hetero Healthcare Ltd.	7.66	8.13	May - 22			
5.	ZADY 250	Mankind	7.86	8.71	Apr - 22			

3.3 Para 16(2) gives the companies the unfettered right to avail of the benefit of the increased WPI, without any prior intimation or approval of the NPPA/Government. Thus, the said benefit, once availed of by the company, cannot be denied by NPPA. Having said so, as stipulated in the said Para itself, availing of the benefit of the increased WPI by the company without filing Form-II, exposes the said company to overcharging liability and nothing else.

3.4 Therefore, once the products of the companies are available for sale at the increased WPI, and the said product have a market share of 1% or above, the NPPA is mandated by law to take them in consideration for the purpose of ceiling price fixation, an exercise which effects the entire industry. Failure or delay in filing Form-II by companies, cannot prejudice the rights of industry at large.

3.5 Accordingly, the Applicant contended that the calculation of ceiling price of the formulation mentioned in table above are incorrect as the PTR data of the brands mentioned in Para 3.2 has not been correctly considered for the said purpose.

4. Gist of clarifications made by NPPA:

NPPA on the other side argued that the instant review is not tenable on the following grounds:

4.1 As per the provisions of DPCO [Para 16(2)], the manufacturers may increase the MRP of scheduled formulations once in a year, in the month of April on the basis of WPI. Further, as per para 16(3), information about the revision, if carried out shall be forwarded to the Government in Form-II within a period of 15 days of such revision. This implies that Form-II for price revision based on WPI may be submitted latest by 15th May. Accordingly, NPPA has considered price revision in all cases where any representation is received and Form-II/V has been filed by the company on or before 15th May, 2022.

4.2 In this regard, it is stated that NPPA has considered the PTR as appearing in Pharmatrac database for July 2022 whereas the Applicant has mentioned a derived PTR based on MRP. Such derived PTR may not be considered for ceiling price calculation. Further, the details of PTR have been verified from Form-V and Form-II submitted by the companies within the prescribed timelines of DPCO. The status in this regard is as below:

(i) M/s Indoco Remedies Ltd. did not file Form-V and Form-II filed on 17.05.2022. Hence, the revision has not been considered.

(ii) M/s Micro Labs Ltd. did not file Form-II and Form-V filed on 25.07.2022. Hence, the price revision has not been considered.

(iii) M/s Hedge & Hedge did not file Form-II and Form-V. Hence, the price revision has not been considered.

(iv) M/s Hetero Healthcare Ltd. did not file Form-II and Form-V filed on 16.06.2022. Hence, the price revision has not been considered.

4.3 In the view of above, it is clear that NPPA has taken PTR for ceiling price calculation of the formulation Azithromycin 250 mg and Azithromycin 500 mg as available in market based data i.e. Pharmarac database. Further, NPPA has also ascertained from the Form-II and Form-V that none of the brands flagged by the Applicant had filed the revised price as per the timelines provided under DPCO. And that any increase in price after the period so provided in DPCO is not permissible and hence cannot be considered in fixation of ceiling price.

5. Examination:

5.1 In fixing the ceiling price of Scheduled formulations, NPPA has followed the due provisions of DPCO. Thus, in the instant case, market based data available with Pharmarac was used by NPPA as per the provision under Para 9 and fixed the ceiling price as per the methodology laid down under Para 4 of the DPCO. Further, NPPA has taken due cognizance of the provisions under Para 16(2) and 16(3) of DPCO which provides that manufacturers may avail the increase in MRP of scheduled formulations once in a year, in the month of April, on the basis of the WPI; and, that such information about the revision, if carried out, shall be forwarded to the Government on IPDMS in Form-II and Form V within a period of fifteen days. DPCO also expressly maintains that non-submission of information under Para 16(3) shall be construed as non-revision of MRP. Accordingly, NPPA re-ascertained the prices from the Form-II/V of companies indicated that none of the brands referred to by the Applicant had taken the price increase as per the provisions of Para 16(2) and 16(3) of DPCO. Accordingly, the relevant prices as per the extant provisions of DPCO has been taken by NPPA for fixing the ceiling prices of the formulation Azithromycin 250 mg and Azithromycin 500 mg.

5.2 Therefore, in view of the facts cited above, arguments and logics given by NPPA are acceptable.

6. Decision:

The action of NPPA fixing the ceiling prices of scheduled formulations is upheld and the Review Applications under consideration is accordingly rejected.

Issued on this, the 04th day of October, 2024.

(Awadhesh Kumar Choudhary)

(Awadhesh Kumar/Choudhary) Sr. Economic Adviser to the Government of India [For and on behalf of the President of India]

To:

M/s Alembic Pharmaceuticals Limited Prithvi Mansion, 4/8, Asaf Ali Road, New Delhi-110002.

Copy to:

- 1.
- 2.
- Chairperson, NPPA, New Delhi PSO to Secretary (Pharma), Shastri Bhawan, New Delhi Technical Director, NIC for uploading the order on DoP's Website. 3.
- Guard File 4.