

No.31015/25/2023-Pricing (E-23309)
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 RPG Life Sciences Limited (hereinafter called the “Applicant”) filed a Review Application dated 01.02.2023 under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against price fixation order issued vide S.O. No. 87(E) dated 06.01.2023 by the National Pharmaceutical Pricing Authority (NPPA). Vide its aforesaid Order, NPPA, inter alia, fixed the Ceiling price of Azoran 50mg tablet 10’s containing Azathioprine 50mg.

2. On the aforesaid plaint, reference was invited by the Department of Pharmaceuticals from NPPA. Both the parties entered appearance on 07.06.2023 and present 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 formulation “Azathioprine 50mg” was included in Schedule-I of DPCO, 2013 with effect from 11th November, 2022, and hence, the formulation “Azoran 50mg Tablet 10’s” was also included in the draft calculation of ceiling price released by NPPA on 01.12.2022 under the provisions of Para 4, 6, 10, 11, 14, 16, 17 and 18 of DPCO 2013. The Applicant submitted the representation in the prescribed format with required documents and within the prescribed time lines of 10 workings days to NPPA in pursuance to NPPA’s OM 12(90)/2022/DP/NPPA/Div-II dated 25.11.2022.

3.2 Azathioprine is a formulation which is indicated for auto-immune disease such as multiple sclerosis. The Applicant maintained that in view of the representation from IPC and medical community at large, the pack size of the said formulation was revised from 10’s to 20’s pack. Also, that the Applicant has never changed the formulation and did not sell 10’s and 20’s pack simultaneously in the market. Further, no batches of Azoran 10’s was manufactured on or after May 2021. Therefore, NPPA has erred by including their discontinued formulation “Azoran 50mg Tablet 10’s” in its calculation of ceiling price for “Azathioprine 50mg” tablets.

3.3 As per Para 4 of the DPCO 2013, the average Price to Retailer (PTR) is based on the total number of brands of generic version the medicine. The said formulation was only sold in a single brand namely Azoran 50mg. As the change in pack size is not mentioned in Para 4, when considering the price to retailer of the brand as on July 2022, the only price to be considered is of the continuing pack i.e. 20's.

3.4 Hence, the calculation of Azoran 50mg tablet 10's tablet is incorrect and must be rectified after removing the PTR of their erstwhile brand "Azoran 50mg Tablet 10's".

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 Pharmatrac database of July, 2022 has been considered for calculation of ceiling prices. As per this data, while Azoran 50mg tablet in pack size of 20 had 54.10% market share, its pack size of 10 tablets also had a market share of 26.30%. The confirmation regarding the accuracy of the data was received from the Pharmatrac on 17.04.2023.

4.2 Further, the argument that as per Para 4, only continuing pack sizes are to be considered is incorrect. Para 4 (methodology to fix ceiling price) and Para 9 (Reference data & source of market based data) does not differentiate between continuing and discontinued packs. Therefore, NPPA has taken data as per the provision of DPCO for ceiling price calculation of the above mentioned formulation as available in market based data i.e. Pharmatrac and fixed the ceiling price, based on PTR of brands under Para 4 of DPCO, 2013.

5. Examination:

5.1 It is noted that Para 9(5) of DPCO 2013 states that, "*The market based data for fixing the ceiling price of a scheduled formulation due to a revision in the first schedule shall be the data available for the month ending immediately before six months of notification of revision in the first schedule.*" It nowhere differentiates between continued and discontinued products.

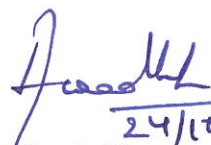
5.2 The Applicant did not dispute the fact that both of the pack sizes of the said formulation i.e., Azoran 50mg tablet, were available in the market in July 2022, which were captured by the Pharmatrac data and accordingly considered by NPPA for ceiling price calculation. Accordingly, NPPA had used the same for ceiling price calculation of the drugs being considered in the present case as per the provisions of DPCO, 2013.

5.3 Therefore, in view of the facts as at paras of 5.1 and 5.2 above, arguments and logics given by NPPA are accepted.

6. Decision:

The action of NPPA fixing the ceiling prices of the formulation Azathioprine 50mg vide S.O. No. 87(E) dated 06.01.2023 is upheld and the present Review Application is rejected.

Issued on this, the 24th day of October, 2024.


24/10/2024

(Awadhesh Kumar Choudhary)

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

To:

M/s RPG Life Sciences Limited,
RPG House, 463, Dr. Annie Besant Road,
Worli, Mumbai-400030

Copy to:

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

