

**No.31015/13/2023-Pricing (E-23270)**  
**GOVERNMENT OF INDIA**  
**MINISTRY OF CHEMICALS & FERTILIZERS**  
**DEPARTMENT OF PHARMACEUTICALS**

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Room No. 310, 'A' Wing, Shastri Bhawan,  
New Delhi-110 001.

**Order**

M/s RPG Life Sciences Limited (hereinafter called the “Applicant”) filed a Review Application dated 20.01.2023 under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against price fixation order issued vide S.O. No. 5938(E) dated 19.12.2022 by the National Pharmaceutical Pricing Authority (NPPA). Vide its aforesaid Order, NPPA, inter alia, fixed the ceiling price of Mofetyl 500 mg tablet 10’s containing Mycophenolate 500 mg.

2. On the aforesaid plaint, reference was invited by the Department of Pharmaceuticals from NPPA. Both the parties entered appearance on 22.06.2023 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 ceiling price as fixed by NPPA did not consider the revised PTR of the formulation Mofetyl 500 mg tablet 10’s containing Mycophenolate 500 mg. The revised PTR is based on WPI increases as permissible under para 16 of DPCO and was duly availed by the Applicant for the said formulation.

3.2 Despite presenting the proof regarding revised ceiling prices, NPPA did not upload the revised working sheets, which is in violation of para 6.8 of the Minutes of 105<sup>th</sup> Authority Meeting held on 15.12.2022.

3.3 Delay in the implementation of revised MRP or PTR based on WPI impact should not be construed as non-implementation of WPI based revision. Para 16

of DPCO, 2013 does enforce intimation of Form II but does not limit the implementation of the said WPI revision in case of an increase in the ceiling price of the formulation.

3.4 Non-reflection/ delayed reflection of PTR in the market-based data provided by Pharmatrac should not be construed as non-implementation of revised MRP, especially when pack shots of the relevant month are provided as documentary evidence in support of price revision.

3.5 The Applicant has contended that the permissible price increase under Para 16 of DPCO, 2013 for its brand 'Mofetyl 500mg Tablet 10's' was implemented by them in the month of April, 2022. However, incorrect Price-to-Retailer (PTR) data of the brand "Mofetyl 500mg Tablet 10's" was considered for the purpose of fixing of ceiling price of Mycophenolate mofetyl 500 mg. The same was shown/conveyed to NPPA by the submission of invoice and pack shot. The Applicant duly submitted their representation dated 07.12.2022 (within prescribed timeline of 10 working days) to NPPA. Hence, NPPA should have considered the revised PTR for 'Mofetyl 500mg Tablet 10's' at Rs. 624.30 and not Rs. 563.70 in calculating and fixing the ceiling price of 'Mycophenolate mofetyl 500 mg'.

#### **4. Gist of clarifications made by NPPA:**

NPPA submitted the following:

4.1. As per the provisions of para 16 (2) of the DPCO, 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) of the DPCO, 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 15<sup>th</sup> May.

4.2 In view of the provisions of DPCO, 2013, the variations in PTR claimed by the companies vis-à-vis PTR used in calculation of ceiling prices were cross verified with the Form-II/Form-V submitted by the companies till 15.05.2022 in IPDMS. Accordingly, revisions were carried out by NPPA in the PTR in case the representations are received within 10 working days of uploading of working sheets and Form-II/Form-V have been filed on or before

15.05.2022 in respect of the PTR of companies mentioned in the representation. (Reference 105<sup>th</sup> Authority meeting).

4.3 The decision taken in the 105<sup>th</sup> Authority Meeting (Para 6.8 of Minutes of the meeting) held on 15.12.2022, was in the context of 'Proposed Framework for undertaking Suo Moto corrections in the notified prices by NPPA'. As the instant case is not that of Suo Moto correction, the aforesaid decision of Authority Meeting is not applicable.

4.4 Para 16(3) maintains that non-submission of information with respect to WPI increase availed under para 16 (2) shall be construed as non-revision of maximum retail price (MRP) and the concerned manufacturer shall be liable to deposit the amount charged over and above the pre-revised maximum retail price (MRP), along with interest thereon from the date of overcharging. Hence, as per DPCO, 2013, delay in the implementation of WPI beyond April and the non-receipt of information about the revision within 15 days of such revision shall be construed as non-revision of MRP.

4.5 The Applicant, i.e., M/s RPG Life Sciences Limited, submitted Form-II on 04.04.2022 and Form-V on 28.05.2022. However, inadvertently the same was not considered.

## **5. Examination:**

5.1. M/s RPG Life Sciences Limited submitted Form-II on 04.04.2022 and Form-V on 28.05.2022. During the hearing, NPPA acknowledged that inadvertently, Form-II of the Applicant was not considered while taking the PTR of eligible brands for fixing the ceiling price for the formulation 'Mycophenolate 500 mg'. Therefore, the ceiling price for the formulation Mycophenolate mofetyl 500 mg requires recalculation based on revised PTR of 'Mofetyl 500 mg tablet 10's'.

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

## 6. Decision:

In the backdrop of above facts, the case is being referred back to NPPA for recalculation of ceiling price of Mycophenolate mofetyl 500 mg tablet as per the extant provisions of DPCO, 2013.

Issued on this, the 22<sup>nd</sup> day of February, 2024.



**(Awadhesh Kumar Choudhary)**

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

### To:

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### 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.