

**No.31015/12/2023-Pricing (E-23269)**  
**GOVERNMENT OF INDIA**  
**MINISTRY OF CHEMICALS & FERTILIZERS**  
**DEPARTMENT OF PHARMACEUTICALS**

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Room No. 207, D Wing, Shastri Bhawan,  
New Delhi-110 001.

**Order**

M/s RPG Life Sciences Limited (hereinafter called the “Applicant”) filed a Review Application dated 16.01.2023 under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against price fixation order issued vide S.O. No. 5939(E) dated 19.12.2022 by the National Pharmaceutical Pricing Authority (NPPA). Vide its aforesaid Order, NPPA, inter alia, fixed the retail price of Romilast tab 5 mg 15's Containing Montelukast 5 mg

2. On the aforesaid plaint, reference was invited by the Department of Pharmaceuticals from NPPA. Both the parties entered appearance on 25.09.2023 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 the retail price of the above drug and hence may be directed to revise the retail price of their formulation on the following grounds:

3.1 The formulation "Romilast Tab 5 mg 15's" was included in Schedule-I of DPCO with effect from 11<sup>th</sup> November, 2022. The formulation "Romilast Tab 5 mg 15's" was included in the draft calculation of ceiling price released by NPPA on 25.11.2022 under the provisions of Para 4, 6, 10, 11, 14, 16, 17 and 18 of DPCO. NPPA vide its OM 12(90)/2022/DP/NPPA/Div-II dated 25.11.2022 titled “Representations against ceiling prices fixed by NPPA under revised schedule- (NLEM, 2022) of DPCO, 2013” had requested representations against draft calculation of ceiling prices, if any. The representation had to be submitted with relevant information/documents within 10 working days. The Applicant agreed that it failed to do so. However, it has applied for the review of notification as provided under Para 31 of the DPCO, within the permissible timeframe.

3.2 The Applicant maintained that in the 105<sup>th</sup> Authority Committee Meeting dated 15.12.2022, it was clarified vide para 6.8 that in case of any revision in the draft calculation of ceiling prices, “the corrected working sheet shall be uploaded on NPPA website for 10 working days for comments, if any. In case of non-receipt of any comments or after addressing any issues received on the revised working sheets, the same shall be placed before the Authority for decision. In those cases where the data has been verified and confirmed by Pharmtrac, prices will be re-computed based on revised data. Accordingly, corrigendum/addendum/new price notifications will be issued.” The same has not been adhered to by NPPA and therefore, the notification S.O. 5939 (E) dated 19<sup>th</sup> December 2022, and specifically the ceiling price of formulation “Romilast Tab 5 mg 15's” containing “Montelukast 5 mg” at Sr. No, 9 should not have been notified without providing manufacturers another opportunity to review the revision in draft calculation of ceiling prices.

3.3 The Applicant contended that it has implemented the 10% price revision in the price of “Romilast Tab 5 mg 15's” in April, 2022. However, the price “Montelukast 5 mg” was calculated without taking into account the revised price of “Romilast Tab 5 mg 15's”, in violation of Para 4 and Para 16 of the DPCO 2013. Hence, the calculation of Montelukast 5 mg tablet must be rectified based on the PTR of ₹ 150.79 for the formulation “Romilast Tab 5 mg 15's” as submitted by the company in Form V and not the PTR of ₹130.57 taken in the calculation of the price of “Montelukast 5 mg”.

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

NPPA on the other side argued that:

4.1 The said formulation is added to Schedule-I for the first time. Therefore, Form-II is not applicable in this case. Further, in the case of newly added formulations, Form –V filled till 31.07.2022 is being considered. In the current case, M/s RPG Life Sciences Limited has filed the Form-V on 28.05.2022 revising their PTR to ₹ 150.79 for the pack of 15 tablets.

4.2 The decision taken in 105<sup>th</sup> Authority meeting held on 15.12.2022 (Para 6.8 of Minutes of 105<sup>th</sup> Authority Meeting), referred to by the Applicant (Para 3.2 above), was in the context of “proposed Framework for undertaking Suo Moto corrections in the notified prices by NPPA.” In other cases, where, based on the representation, the data has been verified and confirmed from/by Pharmatrac,

prices are recomputed based on the revised data, and corrigendum/addendum/new price notifications are issued, if required. As the instant case is not that of Suo Moto correction, the decision taken vide Para 6.8 of the Minutes of 105<sup>th</sup> Authority meeting held on 15.12.2022 regarding uploading the corrected working sheet for 10 working days on the website by NPPA for comments is not applicable.

4.3 The draft worksheet based on the Pharmatrac database was uploaded on NPPA's website on 25.11.2022 for 10 working days to invite comments, if any. However, no representation was made by the Applicant in respect of the revised PTR of the brand "Romilast Tab 5 mg 15's" to NPPA within the prescribed time limit of 10 working days. Therefore, the revised PTR was not considered.

## **5. Examination:**

5.1. The decision taken vide Para 6.8 of Minutes of 105<sup>th</sup> Authority meeting held on 15.12.2022 pertain to the Agenda Item No. 6 of the 105th Authority Meeting, which specifically pertained to cases of Suo Moto correction in notified prices by NPPA. Other cases are not covered by this Agenda, and hence the decision. Therefore, the submission made by NPPA is accepted.

5.2. Further, NPPA accepted that the applicant has filed the Form-V on 28.05.2022 revising their PTR to ₹.150.79 for the pack of 15 tablets, though its application was rejected on the ground that no representation was made by the company in respect of revised PTR of brand "Romilast Tab 5 mg 15's" to NPPA within prescribed time of 10 working days.

5.3. The Applicant has fulfilled all other conditions / provisions i.e. filling of requisite Forms as per the extant provisions of DPCO 2013, and providing the relevant information including the prices. The failure to represent within ten days against the ceiling price fixed by NPPA, may not deprive the Applicant of the legitimate prices of drugs manufactured by them.

## **6. Decision:**

6.1 In the backdrop of these facts, it is accepted that the practice of not uploading the corrected working sheet again on NPPA website for 10 working days, for comments in cases where based on the representation, the data has already been verified and confirmed, suffers no infirmity.

6.2 However, the contention regarding inaccurate fixation of price of Romilast tab 5 mg 15's containing Montelukast 5 mg raised by the Applicant is accepted. Accordingly, the case is referred back to NPPA for recalculation of the prices of the subject formulation as per the extant provisions of DPCO 2013.

Issued on this, the 19<sup>th</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:**

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

**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