

No.31015/74/2023-Pricing (E-24295)
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 Macleods Pharmaceuticals Limited (hereinafter called the "Applicant") filed a Review Application dated 20.06.2023 under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against price fixation order issued vide S.O. No. 2540 (E) dated 08.06.2023 by the National Pharmaceutical Pricing Authority (NPPA). Vide its aforesaid Order, NPPA, inter alia, fixed the ceiling price of Isoniazid 300 mg Tablet. The Applicant is engaged in manufacturing drugs, including 'Solonex 300 mg Tablet 10's containing Isoniazid 300 mg', price of which is affected by the aforesaid order of NPPA.

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 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 "Solonex 300 mg Tablet 10's" is included in Scheduled-I of the DPCO with effect from 11th November, 2022. The formulation "Solonex 300 mg Tablet 10's" was included in the draft calculation of ceiling prices released by NPPA on 11.05.2023 under the provisions of Para 4,6,10,11,14,16,17 and 18 of DPCO. The draft working sheet for the formulation "Solonex 300 mg Tablet 10's" shows that the maximum permissible PTR is higher than the actual PTR of the company by 0.09 paise i.e. 7.8%. Thus, a calculation of ceiling price under Para 4 of DPCO, 2013 would lead to a reduction in ceiling price 7.8%.

3.2 Para 6 of DPCO, 2013 is clearly applicable only when there is no reduction in the ceiling price of a scheduled formulation under Para 4. Since, there is a significant reduction in price for the subject formulation, a further reduction of 6.78% should not be implemented. Further, Para 4 (VIII) of NPPP 2012 clarifies that a reduction in a price of a medicine based on the same molecule with different dosage or strength or different therapeutic category will be applied only if there is no reduction in price.

3.3 Ceiling price calculation of Isoniazid 300 mg tablet must be recalculated under Para 4 for the said formulation, as the average PTR at Rs. 1.06 per tablet and not the level of maximum permissible PTR i.e. Rs. 1.15 is akin to application of both Para 4 and Para 6 of DPCO, 2013. Thus, NPPA has erred by:

- (i) Not considering the subject formulation only under Para 4.
- (ii) Further, reducing the average PTR by 6.78% under Para 6.
- (iii) Giving an effect of both Para 4 and Para 6 which is beyond the scope of DPCO, 2013.

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 DPCO provides the methodology of ceiling price fixation based on:

Para 4(1): Simple average of brand having market share equal or more than 1%.

Para 6(1): Under the condition where there is no reduction in the price calculated under 4(1) due to absence of competition.

Para 6(2): Non-applicability of para 6(1) of DPCO, 2013 for the formulations for which price has been fixed under DPCO, 1995.

4.2 Price fixation is undertaken under Para 6(1) on fulfilment of two conditions, viz.:

- (a) No reduction in average price to retailer with respect to the prices to retailer of the Scheduled formulation; and
- (b) There are less than five manufacturers for that formulation having one percent or more market share.

4.3 In the instant case, the Applicant is the sole manufacturing and marketing company of the product as per available market data. Also, no reduction in PTR is observed. As both the conditions for fixation of price under Para 6 of the DPCO are applicable, the reduction as per Para 6 (1) of DPCO is applied in the instant case.

4.4 The contention that Para 4 and Para 6 of DPCO can't be applied at the same time is not valid. The Para 6 of DPCO provides for the reduction on the prices calculated under Para 4(1) where no reduction in average price is registered and market has less than five manufacturers.

5. Examination:

5.1. The contention of NPPA regarding the applicability of provisions under Paras 4 and 6 of DPCO in the instant case is appropriate. The provisions of Para 6 of the DPCO comes into effect when there is no reduction in the average price to retailer of

scheduled formulation as arrived at by using para 4 (1) of DPCO, and, there is absence of competition.

5.2. Both these conditions are germane to this case. As per market based data available with NPPA, the Applicant is the sole manufacturing and marketing company for the product. Also, no reduction in PTR is observed. Hence, NPPA applied the reduction as per extant provisions of DPCO 2013 with respect to fixation of ceiling price of a scheduled formulation in case of no reduction in price due to absence of competition. Hence, application of reduction as per provisions of Para 6 of DPCO is in order.

6. Decision:

The action of NPPA fixing the ceiling prices of 'Isoniazid 300 mg tablet' vide S.O. No. 2540 (E) dated 08.06.2023 is upheld and the Review Application under consideration is accordingly rejected.

Issued on this, the 14th day of March, 2024.



(Awadhesh Kumar Choudhary)

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

To,

M/s Macleods Pharmaceuticals Limited
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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