

No.31015/75/2023-Pricing (E-24296)
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 100 mg Tablet. The Applicant is engaged, inter alia, in manufacturing ‘Solonex 100 mg Tablet 10’s containing Isoniazid 100 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 ceiling price of the above drug and hence may be directed to revise the same on the following grounds:

3.1 As per Para 16 of DPCO, the manufacturers reserve the right to increase the MRP of the Scheduled formulations by WPI once in a year, and the provisions of Para 4 and Para 18 do not alienate the said right. Thus, an increase in the PTR in April, 2022 should also be reflected in the calculation of ceiling prices of the Scheduled formulation. A 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 the 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.

3.2 Para 6 of DPCO, 2013 is 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 the price of medicine based on the same molecule with different dosages or strength or different therapeutic category will be applied only if there is no reduction in price.

3.3 As per the draft working sheet of NPPA, the maximum permissible PTR for the formulation “Solonex 100 mg Tablet 10’s” is higher than the actual PTR of the company by 0.11 paise i.e. 16.9%. Thus, a calculation of the ceiling price under Para 4 of DPCO, 2013 would lead to a reduction in ceiling price of 16.9%.

3.4 The Company had revised the price of Solonex 100 mg Tablet 10’s based on the WPI increase as per Para 16 of DPCO. The ceiling price calculation of Isoniazid 100 mg should have included the revised PTR for Solonex 100 mg Tablet 10’s at Rs. 6.00 and not Rs. 5.44.

3.5 Considering the average PTR at Rs. 0.54 per tablet and not the level of maximum permissible PTR i.e. Rs. 0.65 is akin to the 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:

4.1 DPCO provides the methodology of ceiling price fixation based on:

Para 4(1): Simple average of brands having market share equal to 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 are applicable, the reduction as per Para 6(1) 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.

4.5 As for revision in PTR, the company filed Form-II on 29.04.2022 and Form-V on 14.04.2022 i.e. within the time limit as prescribed under DPCO, 2013. However, the applicant had not filed representation to NPPA within 10 working days of uploading the draft worksheet on its website, i.e. 11.05.2023. Hence, the revision in price was not considered.

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. Both these conditions are germane to this case. Hence, application of reduction as per provisions of Para 6 of DPCO is in order.

5.2. The Applicant had filed Form-II and Form-V within the timeline permissible under DPCO 2013, indicating revised price based on permissible increase as per the notified WPI. NPPA accepted that the revised price was not included in the calculation of the ceiling price. NPPA contended that the Company also did not represent against the draft worksheet of price fixed and uploaded on the website of NPPA within 10 working days. However, the mere

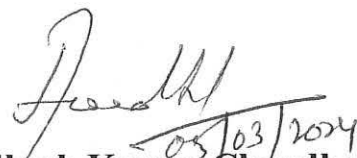
failure to represent within ten days to NPPA, despite the fulfilment of all other conditions / provisions i.e. filing of requisite forms within the timelines as prescribed under DPCO 2013, may not deprive the Applicant of the legitimate fixation of the price of the drug manufactured by them.

6. Decision:

6.1 The fixation of the price of 'Solonex 100 mg Tablet 10's containing Isoniazid 100 mg' under Para 6 of the DPCO by NPPA suffers from no infirmity and hence is upheld.

6.2 However, the contention of the Applicant regarding incorrect fixation of price due to not using the revised price of 'Solonex 100 mg Tablet 10's containing Isoniazid 100 mg' is accepted. Accordingly, the case is referred back to NPPA for recalculation of the price of the subject formulation as per the extant provisions of DPCO 2013.

Issued on this, the 5th 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