No.31015/76/2023-Pricing (E-25172)
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS
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Room No. 340-B, A Wing, Shastri Bhawan,
New Delhi-110 001.

Order

M/s Neon Laboratories Limited (hereinafter called the "Applicant") filed a Review Application dated 24.04.2023 under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against price fixation order issued vide S.O. No. 1577 (E) dated 31.03.2023 by the National Pharmaceutical Pricing Authority (NPPA). Vide its aforesaid Order, NPPA, inter alia, fixed the ceiling price of Methylprednisolone injection 40 mg/ml.

2. On the aforesaid plaint, reference was invited by the Department of Pharmaceuticals from NPPA. Both the parties entered appearance on 06.11.2023 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 NPPA while fixing the ceiling price of Methylprednisolone injection 40mg/ml considered applicants two brands i.e. "Neodrol 40mg injection 1ml" and "Premaxo 40mg/ml". "Neodrol 40mg injection 1ml" contains Methylprednisolone Sodium Succinate and "Premaxo 40mg/ml contains Methylprednisolone Acetate.

3.2 The Sr. No. 18.1.4 and 27.3 of Schedule-I of DPCO 2013 includes "Methylprednisolone" and specifically the strength of 40mg/ml injection. It is pertinent to note that Methylprednisolone Acetate 40mg/ml injection is not explicitly included in the Schedule-I of DPCO 2013 and hence, must be construed as a non-scheduled formulation. Therefore, NPPA has erred by including the formulation "Premaxo 40mg/1ml" in its calculation of ceiling price for "Methylprednisolone Acetate 40mg/ml injection".

3.3 The Explanation Note 6 to the Schedule-I of DPCO as amended on 11th November, 2022 clearly states as under:

> *"Innovation in medicine must be encouraged. The formulations developed through incremental innovation or novel drug delivery systems like*

lipid/liposomal formulations etc. should be considered as included only if specified in the list against any medicine. Such different formulations should be considered differently for purposes such as procurement policy, pricing, etc".

In this context, it may be appreciated that the Methylprednisolone Sodium Succinate is administered through injection in the bloodstream and is usually prescribed for emergency treatment whereas Methylprednisolone Acetate is administered through intra-muscular or intra- articular route for long-term pain management. Thus, the two products differ with respect to the route of administration and medical indication.

3.4 The ceiling price calculation of Methylprednisolone 40mg/ml must only include injections containing Methylprednisolone 40mg/ml" and not "Methylprednisolone Acetate" having the same strength, which is in direct violation of Explanation Note 6 to Schedule-1 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 Methylprednisolone Inj. 40 mg/ml was listed in NLEM, 2015 in section 21.1.4 and continued in NLEM, 2022 in sections 27.3 and 18.1.4. There has been no change w.r.t. Dosage form(s) and strength(s).

4.2 Further, Explanation Note 2 of DPCO, 2013 states as under:

"In case, a medicine is available in more than one salt without any significant difference in potency / pharmacokinetics / pharmacodynamics / efficacy-safety profile aspects, it indicates that these salts are therapeutically similar. Therefore, all salts of such medicines with specified dosage form and strength are considered included in this schedule. In case, where the different salts of a medicine have significant difference in potency/ pharmacokinetics/ pharmacodynamics/ efficacy-safety profile, the medicine has been mentioned in this schedule with respect to its specific salt."

4.3 In the present case, Methylprednisolone Sodium Succinate and Methylprednisolone Acetate is not separately mentioned in Schedule-I of DPCO, 2013. Therefore, ceiling price fixed considering all salts as per practice and precedence.

5. Examination:

5.1 Methylprednisolone Injection 40 mg/ml has been included in both NLEM 2015 and 2022. There has been no change w.r.t. Dosage form(s) and strength(s). Methylprednisolone Sodium Succinate and Methylprednisolone Acetate is not separately mentioned in Schedule-I of DPCO, 2013.

5.2 Explanation Note 2 of the DPCO 2013 clearly mentions that medicines with more than one salt without any significant difference in potency /pharmacokinetics / pharmacodynamics / efficacy-safety profile aspects are therapeutically similar. In such cases, all salts of such medicine with specified dosage form and strength are considered included in this schedule.

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 subject formulation is upheld and the Review Application under consideration is accordingly rejected.

Issued on this, the 18th day of November, 2024.

18/11/2024

(**Awadhesh Kumar Choudhary**)
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[For and on behalf of the President of India]

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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.
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