

F.No.31015/7/2021-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

A Wing, Shastri Bhawan,
New Delhi-110 001

Order

This is an order disposing of a review application dated 17th September 2021 filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Abbott Healthcare Private Limited (hereinafter called the Applicant) against NPPA's notification S.O. No. 3400 (E) dated 19.08.2021 in respect of "Nervup Forte Plus- Alpha Lipoic Acid USP 100mg + Vitamin D3 IP 1000 IU + Pyridoxine Hydrochloride IP 3mg + Methylcobalamin 1500 mcg + Folic Acid IP 1.5mg Tablet"

2. Background

2.1 NPPA vide notification S.O. No. 3400(E) dated 19.08.2021 fixed the retail price in respect of "Nervup Forte Plus- Alpha Lipoic Acid USP 100mg + Vitamin D3 IP 1000 IU + Pyridoxine Hydrochloride IP 3mg + Methylcobalamin 1500 mcg + Folic Acid IP 1.5mg Tablet" for M/s Abott Healthcare Private Limited at Rs. 10.97 per tablet excluding GST.

2.2 NPPA's comments on the review application were obtained. Subsequent to review hearing, the applicant was given opportunity to submit additional documents, if any. The comments of NPPA on Pharmatrac Data for the month of November, 2020 submitted subsequently by the applicant were also obtained.

3. Gist of submissions by the Applicant

3.1 The Applicant had submitted their Form I Application dated 23.05.2021 in prescribed format with NPPA under Para 5 & 15 of the DPCO, 2013 with all relevant details as well as via email on 22.06.2021.

3.2 In its Authority Meeting held on 29th July 2021, NPPA fixed the retail price for the Formulation based on recommendations of the Multi-Disciplinary Committee (MDC) of Experts, wherein average of Form V price of two companies was used to derive the retail price of Rs. 10.97 + GST per tablet.

3.3 The data from Pharmatrac of January 2021 showcases 15 brands with the same composition contributing to more than 1% market share. Thus, the retail price derived from averaging the same would be approximate around Rs. 14.24 + GST per tablet.

4. Comments by NPPA:

4.1 The application from the company was received on 22nd June 2021 and as per Para 9(4) of DPCO, 2013, data of November 2020 was looked into. However, the data of above mentioned formulation was not available in Pharmatrac database for the month of November 2020. Accordingly, the matter was placed before MDC of Experts in line with Para 5(2) (i) of DPCO 2013, which state that:

"the price to retailer of a new drug, not available in domestic market, shall be fixed by the Government on the principles of "Pharmacoeconomics" of the new drug, on the recommendation of a Standing Committee of Experts formed under paragraph 15."

4.2 The MDC of experts in its 34th meeting held on 26th July, 2021, based on average of PTR of formulations of M/s Zydus Healthcare Limited and Cadila Pharmaceuticals Ltd. and after adding 16% retailer margin thereto, fixed the retail price of formulation of the applicant at Rs. 10.97 per tablet excluding GST.

4.3 NPPA's Authority in its 91st meeting held on 29th July 2021 approved the retail price based on the recommendations of MDC of experts.

5. Examination:

5.1 Subsequent to, review hearing, the Applicant has submitted the data of the subject formulation from Pharmatrac for the period of November 2020 indicating *inter alia* that prices of 4 formulations were available therein. On seeking clarification from NPPA, it has been informed that only one Stock Keeping Unit (SKU) with Item code 227402 is similar to that provided by the applicant whereas other data stated to be provided by Pharmatrac to the Applicant is different from the data as provided by Pharmatrac to NPPA in respect to the subject formulation.

5.2 Pharmatrac is source from where the information / data about the prices of drugs is obtained and used presently by NPPA as reference. On cross-checking the data subsequently obtained/ furnished by the Applicant, NPPA has admitted that the data about formulation of at least one manufacturer was available for the relevant month.

5.3 Para-5 (1) of DPCO, 2013 prescribes that retail price of a new drug for existing manufacturers of scheduled formulations available in domestic market shall be calculated as per Para 4(1), which is basically average Price to Retailer (PTR) of all brands of the same strength and dosage with at least one per cent market share and adding 16% retailer margin thereto.

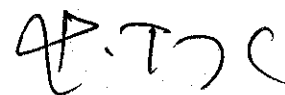
5.4 Para 5(2) of DPCO, 2013 prescribes that retail price of a new drug not available in domestic market shall be fixed by the Government on the principles of "Pharmacoeconomics" of the new drug, on the recommendation of a Standing Committee of Experts.

5.5 It is further noted that DPCO by way of Para 6 has provisions for calculation of ceiling price in case there is no reduction in price in absence of competition, but no such mechanism exists in case of retail price fixation. As such, in case of data of even one manufacturer will imply fixation of retail price as per provisions of Para 5(1) of DPCO, 2013.

6. Decision:

The review application dated 17th September 2021, is accordingly remanded back to NPPA to re-consider the same strictly as per provisions of DPCO, 2013.

Issued on this, the 21st day of October, 2022.



(Rajneesh Tingal)

Joint Secretary

[For and on behalf of the President of India]

Copy to:

1. M/s Abott Health Care Private Limited, 3, Corporate Park, Sion, Trombey Road, Mumbai-400071, India.
2. Chairman, National Pharmaceutical Pricing Authority, YMCA Cultural Centre Building, New Delhi-110001.

Copy (for information) to:

1. PS to Hon'ble Minister(C&F), New Delhi
2. PSO to Secretary(Pharma), New Delhi
3. Technical Director, NIC for uploading the order on Department's Website.
4. Joint Director (Pricing), Department of Pharmaceuticals