

No.31015/11/2019-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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A Wing, Shastri Bhawan,
New Delhi-110 001.

Order

1. This is an order disposing of a review application dated 26.04.2019, filed by M/s Cadila Healthcare Limited (hereinafter called the applicant) under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against notification S.O. No.1485(E), dated 29.03.2019 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) in respect of Note (b) and Note (c) of the said notification.

2. The company is aggrieved by inclusion of Note (b) and Note (c) to the ceiling prices notified vide SO 1485(E), dated 29.03.2019. The company stated that the prerogative and the responsibility of fixing and revising the Ceiling Price of Scheduled Formulations rests with the NPPA. The company further stated that there is no such pricing principle envisaged in the NPPP 2012 where the responsibility of seeking a Ceiling Price lies with a manufacturer. Accordingly, there are no provisions of seeking a Ceiling Price for a manufacturer in any of the provisions of the DPCO. There is also no prescribed form in Schedule II of the DPCO where in a manufacturer or a marketer is allowed or permitted to apply for fixation or revision of a Ceiling Price.

3. The company in its review application also mentioned about note (k) of the same notification S.O. 1485(E) dated 29.3.19, which reads "the manufacturers not complying with the ceiling price and notes specified herein above shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Prices Control) Order, 2013 read with the Essential Commodities Act, 1995". The company stated that this note (k) makes it all the more important not to allow the NPPA to include DPCO plus notes like Note (b) and Note (c). Any matter of dispute in future would lead to probable misuse of Note (b) and Note (c) through Note (k).

4. The company in its additional submissions submitted that the inclusion of said Notes are not as per the DPCO. Note (b) and Note (c) are back door entries and should be deleted till necessary amendments are carried out in the DPCO / NPPP 2012 to allow the manufacturers to apply in a prescribed form to apply for ceiling price approval of any scheduled formulation/scheduled pack of any scheduled formulation.

5. The NPPA, in its response to the issues raised by the company, stated that the ceiling prices of scheduled formulations are generally fixed on unit basis resulting in price regulations of all pack sizes of scheduled formulations. In certain instances, based on representations received from companies, NPPA fixes the ceiling prices of scheduled formulations on pack size basis under para 11(3) of the DPCO. In view of

this, Note (b) was inserted to enable the NPPA to fix ceiling price of scheduled formulations in respect of the pack size for which the same was not fixed, since all pack sizes are under price regulation.

6. The NPPA further stated that the ceiling prices of scheduled formulations are fixed under the DPCO based on market data furnished by AIOCD-Pharmatrac. In certain instances, it was observed by the NPPA that the market data of certain formulations is not available in Pharmatrac. The NPPA also stated that as per Explanation I to amended schedule I of DPCO, the ceiling prices of certain dosage forms other than that mentioned in the schedule are also required to be fixed. Accordingly, the NPPA inserted Note (c) so as to enable it to get the data for fixing the ceiling prices of the scheduled formulations.

7. The review application has been filed against the NPPA's price notification SO 1485(E), dated 29.03.2019. The said notification was issued by the NPPA under para 16 of the DPCO revising the ceiling prices of all the scheduled formulations based on wholesale price index for the calendar year 2018. Under para 16 of the DPCO, there is a provision to revise the ceiling prices of scheduled formulations as per the annual wholesale price index (WPI) for preceding calendar year on or before 1st April of every year and notify the same on the 1st day of April every year.

8. As per provisions under para 31 of the DPCO, any person aggrieved by any notification issued or order made under paragraphs 4, 5 and 6 of this Order, may apply to Government for a review of the notification. The paras 4, 5 and 6 are for fixation of ceiling/retail prices of scheduled formulations. The price notification SO 1485(E), dated 29.03.2019 is not meant for fixation of ceiling/retail price of any scheduled formulation under para 4, 5 and 6 of the DPCO, but to revise the ceiling prices of all the scheduled formulations giving impact of WPI under para 16 of the DPCO. Moreover, the issue raised by the applicant is against insertion of certain footnotes in the notification and is not related to price fixation of any formulation. Therefore, the review against the insertion of certain footnotes in the notification is not sustainable and deserves to be rejected. The review application is accordingly rejected.

Issued on this, the 26th day of November, 2019.

(M.K. Bhardwaj)
Deputy Secretary
For and on behalf of the President of India

Copy to :-

1. M/s Cadila Healthcare Limited, Zydus Tower, Satellite Cross Roads Road, Ahmedabad-380 015.
2. The Member Secretary, National Pharmaceutical Pricing Authority, YMCA Cultural Centre Building, New Delhi-110001.
3. PS to Hon'ble Minister(C&F), Shastri Bhawan, New Delhi for information.
4. PS to MoS(C&F), Shastri Bhawan, New Delhi for information.
5. PSO to Secretary(Pharma), Shastri Bhawan, New Delhi for information.
6. Joint Secretary(Pharma), Shastri Bhawan, New Delhi for information.
7. T.D., NIC for uploading the order on Department's Website.