

**No. 31015/5/2014-PI.I**  
**GOVERNMENT OF INDIA**  
**MINISTRY OF CHEMICALS & FERTILIZERS**  
**DEPARTMENT OF PHARMACEUTICALS**

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B Wing, Janpath Bhavan, New Delhi

**O R D E R BY REVIEWING AUTHORITY UNDER PARA.31 OF DPCO, 2013**

**Subject: Review application of M/s. Abbott Healthcare Pvt. Ltd. against fixation/revision of ceiling prices of Vitamin A 50000 IU tablet vide NPPA notification S.O. No. 3129(E) dated 10/12/2014 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013).**

Ref. 1) Applicant Review application dated 5.1.2015  
2) NPPA notification under review S.O. No.3129(E) dated 10/12/2014  
3) Record Note of discussions held in the personal hearing held in the matter on 27.1.2015

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Whereas National Pharmaceutical Pricing Authority (NPPA), Government of India, vide price fixation Order S.O. No. 3129(E) dated 10/12/2014 fixed/revised ceiling price of Vitamin A 50000 IU tablet under DPCO, 2013 included in section 27.08.1 in Schedule-I of the order.

2. And whereas aggrieved by the above notification, M/s Abbott Healthcare Pvt. Ltd. (hereinafter referred to as the Petitioner) submitted review application dated 5.1.2015 under para.31 of DPCO, 2013 for the review of NPPA Price fixation Order S.O.No. 3129(E) dated 10/12/2014 fixing Ceiling price of Vitamin A 50000 IU tablet under DPCO, 2013.

3. The grievance of the Petitioner raised in their review application dated 5.1.2015 were sent to NPPA and the comments of NPPA thereon were given to the Petitioner through the Record Note of discussions held in the hearing on 27.1.2015. Record Note of discussion is made integral part of the review order. After considering the comments of NPPA the Petitioner has raised the following points, on which comments given by NPPA representative during the hearing and Government's comments on the issue is recorded subsequently against each point:

Petitioner: Petitioner representative mentioned that Vitamin A capsules, ceiling price of which has been notified by NPPA vide notification SO No. 3129(E) dt. 10.12.2014 is a common formulation under DPCO 1995 and DPCO 2013. He further mentioned that USV is not the only manufacturer for 50000 IU as they are also the manufacturer of Vitamin A tablets 50000 IU and tablets/capsules are under same category against entry 27.08.1 of DPCO 2013. Their price should have been clubbed and the average price should have been applied rather than applying the monopoly condition. Further

under para 6(2) of DPCO 2013 monopoly conditions are not applied where the formulation was also covered under DPCO 1995.

NPPA comments:

NPPA representative stated that the ceiling price for Vitamin A capsules 50000 IU has been worked out by considering the data of M/s USV as per IMS data available

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with NPPA. Since M/s Abbott is manufacturing Vitamin A tablets the same might not have been reflected in the data. NPPA has notified price of Vitamin A capsules 50000 IU. As regards application of para 6(2) is concerned NPPA is of the view that cases where the specific ceiling price or NCP was given in DPCO 1995 in those cases only monopoly condition would not be applied.

Government's comments and recommendation:

4. As per section 27.08.1 of Schedule I of DPCO 2013 tablets and capsules have been taken as a single entity and clubbed together and therefore NPPA should have collected the data of both tablets and capsules and fixed the price as per the provisions of DPCO 2013. Even if there happens to be a single manufacturer, the provisions under para 6(2) of DPCO 2013 make specific exemption in respect of medicines whose prices were fixed under DPCO 1995 and also they are under scheduled category under DPCO 2013. In such cases the provision of sub para 6(1) i.e. monopoly conditions are not to be applied. NPPA's decision that cases where specific ceiling price or NCP was given in DPCO 1995 only in those cases monopoly conditions would not apply is without any basis. NPPA has, therefore, erred in applying the monopoly conditions in this case which needs to be corrected by revalidating the data of both capsules and tablets.

5. Based on the above and other documents on record, the Government has decided as under:

“NPPA may be directed to revalidate the data of both capsules and tablets and refix the ceiling price of Vitamin A tablets 50000 IU, accordingly.”

Issued on this date of 14<sup>th</sup> May, 2015.

(A.K.Sah)

Under Secretary to the Govt. of India  
For and on behalf of the President of India

To

1. M/s. Abbott Healthcare Pvt. Ltd.,  
4, Corporate park,  
Sion Trombay Road,  
Mumbai-400071

2. The Member Secretary,  
National Pharmaceutical Pricing Authority,  
YMCA Cultural Centre Building, New Delhi-110001

Copy to :

1. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.
2. Sr. PPS to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
3. T.D., NIC for uploading the order on Department's Website.