

No. 31015/30/2015-PLI
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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B Wing, 3rd Floor, Janpath Bhavan, New Delhi

ORDER BY REVIEWING AUTHORITY UNDER PARA.31 OF DPCO, 2013

Subject: Review application of M/s. Abbott India Ltd. against fixation/revision of ceiling prices of “Ibuprofen 200 mg and 400 mg tablet” vide NPPA notification S.O. No. 1202(E) dt. 6.5.2015 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013).

Ref. 1) Applicant Review application dated 18.5.2015
2) NPPA notification under review S.O. No. 1202(E) dt. 6.5.2015
3) Record Note of discussions held in the personal hearing held in the matter on 18.6.2015

Whereas National Pharmaceutical Pricing Authority (NPPA), Government of India, vide price fixation Order S.O. No. 1202(E) dt. 6.5.2015 fixed/revised ceiling price of “Ibuprofen 200 mg and 400 mg 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 India Ltd. (hereinafter referred to as the Petitioner) submitted review application dated 18.5.2015 under para.31 of DPCO, 2013 for the review of NPPA Price fixation Order S.O.No. 1202(E) dt. 6.5.2015 fixing Ceiling price “Ibuprofen 200 mg and 400 mg tablet” under DPCO, 2013.

3. The grievances of the Petitioner raised in their review application dated 18.5.2015 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 18.6.2015. 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: The petitioner representative mentioned that their formulations i.e.Ibuprofen 200 mg and 400 mg were fixed on 20.12.2013 on the basis of their review application. As per the provisions of DPCO 2013 the price of the formulations which are covered under para 10 the price of their formulations were freezed for one year and, thereafter they were allowed a WPI increase on 20.12.2014 which they have availed. However while fixing the ceiling price vide notification 1202(E) dt. 6.5.2015 NPPA did not take into account the WPI taken by the petitioner on 20.12.2013. They have, therefore, requested for revising the price notification notified vide notification 1202(E) dt. 6.5.2015.

4. NPPA comments:- NPPA representative stated that para 9 of DPCO 2013 specifies the reference data and source of market based data. The reference data for new drug has been stated to be 6 months before the receipt of application for new drug. In case of first time introduced formulations under DPCO 2013 the reference data of May 2012 has been specified under DPCO 2013 which is 6 months before the date of announcement of National Pharmaceuticals Pricing Policy 2012. In case of revision in first schedule reference date

would be 6 months before the date of notification of revision of first schedule. Para 9(6) states that the reference date for the common formulations shall be as per provision of para 10 of DPCO 2013. However, reference date relevant to reference data has not been specified in para 10. In a nutshell, there must be a reference date/data to be considered for price fixation. DPCO 2013 only prescribes 6 months criteria.

5. NPPA representative stated that NPPA in its 12th Authority Meeting decided that cases where ceiling prices were fixed prior to May 2012 in DPCO 1995 would be notified in April 2014 and cases where ceiling prices were fixed after May 2012 in DPCO 1995 would be notified in April 2015. Accordingly, NPPA started notifying ceiling price under DPCO 2013 from April 2014 onwards for common formulations where ceiling prices were fixed prior to May 2012 by considering reference data of September 2013. The data of September 2013 was uniformly considered for all common formulations irrespective of actual date of fixation to have uniformity. Similarly, the reference data for common formulations where ceiling prices in DPCO 1995 were fixed after May 2012 (June,2013 / December,2013 for concerned formulations), reference data for September 2014 i.e. 6 months prior to April 2015 was considered.

6. NPPA representative mentioned that para 16 relating to revision of ceiling price of scheduled formulations is relevant in this context. As per para 16(1) of the DPCO,2013, the government shall 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. Para 16(2) states that the manufacturers may increase the MRP of scheduled formulations once in a year, in the month of April.

Department comments:

7. Para 9(6) of DPCO 2013 reads as under:-

“Notwithstanding anything contained in this order, the reference date for the formulations which are part of the Drugs (Price Control) Order,1995 shall be as per the provisions of paragraph 10 of this Order.”

8. Further para 10(2) of DPCO 2013 is also reproduced below:-

“The price of scheduled formulations, which are also specified in the First Schedules to the Drugs (Price Control) Order, 1995, fixing and notified under the provisions of Drugs (Prices Control) Order,1995 after 31st May, 2012, shall remain effective for one year from the date of notification of such prices under Drugs (Prices Control) Order, 1995 and immediately thereafter the manufacturers may revise the prices as per the annual wholesale price index for the previous calendar year announced by Department of Industrial Promotion and Policy and on the 1st April of succeeding financial year, the formula as in sub-paragraph (1) of paragraph 4 of this Order shall be applied for fixing the ceiling prices of such schedule formulations.”

9. It is seen from the provisions of DPCO 2013 mentioned above that the drugs which were under scheduled category under DPCO 1995 and are also under scheduled category under DPCO 2013 i.e. common scheduled formulations in both the DPCOs there has been a differential treatment given i.e. these formulations will remain under cooling period for one year i.e. no increase from the date of notification and immediately after one year the companies were allowed a WPI for the previous calendar year. Thereafter they will come on board with other scheduled formulations and be eligible for WPI with effect from 1st April of next year.

10. NPPA has erred in considering the data pertaining to 6 months before i.e. 30th September of the previous year by which they have ignored the WPI availed by the petitioner under para 10(2) quoted above. NPPA is also not correct in presuming that two WPI cannot be given in one year. DPCO, 2013 under para 9(6) and 10(2) contains special provision of WPI for common formulations under both DPCO 1995 and DPCO 2013 i.e. first after one year of cooling and second in the beginning of the next financial year. Moreover in the instant case the WPI availed by the petitioner in December 2014 after one year of the notification date and second on 1st April, 2015 i.e. in the next financial year. Therefore the point of two WPI in one year by NPPA has no merit.

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

“NPPA may be directed to revise the prices of the subject formulations after the petitioner had availed WPI in December 2014 as per provisions of para 9(6) and 10(2) of DPCO 2013. The petitioner will be entitled for WPI again w.e.f. 1.4.2015.”

Issued on this date of 4th September, 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 India Ltd.,
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2. The Member Secretary,
National Pharmaceutical Pricing Authority,
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Copy to :

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