

No. 31015/23/2015-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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B Wing, Janpath Bhavan, New Delhi-110001

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 retail price of “CHLOROQUINE PHOSPHATE INJECTION (40mg/ml- 64.5mg eq to 40mg CHLOROQUINE) AND METRONIDAZOLE 200 mg & METRONIDAZOLE 400 mg TABLETS” vide NPPA notification S.O. No. 834(E) dated 25/3/2015 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013).

Ref. 1) Applicant's Review application dated 16.4.2015
2) NPPA notification under review S.O. No. 834(E) dated 25/3/2015
3) Record Note of discussions in the personal hearing held on 13.5.2015 in the matter

Whereas National Pharmaceutical Pricing Authority (NPPA), Government of India, vide price fixation Order S.O. No. 834(E) dated 25/3/2015 fixed/revised ceiling price of “CHLOROQUINE PHOSPHATE INJECTION (40mg/ml- 64.5mg eq to 40mg CHLOROQUINE) AND METRONIDAZOLE 200 mg & METRONIDAZOLE 400 mg TABLETS” under DPCO, 2013.

2. And whereas aggrieved by the above notification, M/s Abbott Healthcare Pvt. Ltd. (hereinafter referred to as the Petitioner) submitted review application dated 16.4.2015 under para 31 of DPCO, 2013 for the review of NPPA Price fixation Order S.O.No. 834(E) dated 25/3/2015 fixing retail price of “CHLOROQUINE PHOSPHATE INJECTION (40mg/ml- 64.5mg eq to 40mg CHLOROQUINE) AND METRONIDAZOLE 200 mg & METRONIDAZOLE 400 mg TABLETS”, under DPCO, 2013.

3. The grievance of the Petitioner raised in their review applications dated 16.4.2015 was sent to NPPA and the comments of NPPA received thereon, were given to the Petitioner through the record note of discussions held in the hearing on 13.5.2015. Record notes of discussions are made integral part of the review order. After considering the comments of NPPA, the Petitioner has raised the following points, on which comments were given by NPPA representative during the hearing and Department's comments on the issue is recorded subsequently against each point:-

Petitioner: The petitioner representative mentioned that the prices of CHLOROQUINE PHOSPHATE INJECTION (40mg/ml- 64.5mg eq to 40mg CHLOROQUINE) AND METRONIDAZOLE 200 mg & METRONIDAZOLE 400 mg TABLETS” have been fixed by NPPA vide SO No. 834(E) dt. 25.3.2015. The petitioner representative further mentioned that the price of these formulations which are common formulations under DPCO 1995 and DPCO 2013 were fixed under DPCO 1995 on 20th December 2013. As per provisions of para 9(6) the reference data for the formulations which are part of the DPCO 1995 shall be as per the provisions of para 10 of DPCO 2013. Para 10(1) deals with common formulations the prices of which were fixed upto May, 2012 and para 10(2) pertains to common formulations prices of which were fixed after May 2012. As per provision of para 10(2) immediately after completion of one year the manufacturers were permitted to revise the prices as per annual WPI for the previous calendar year and on 1st April of succeeding financial year as per the formula in sub para 1 of para 4 of DPCO 2013. The petitioner representative mentioned that their case falls under para 10(2) of DPCO 2013 and immediately on completion of one year i.e. 21.12.2014 they had availed WPI as per the provision of para 10(2). Further as per provisions of same para 10(2) they were eligible on first April of the succeeding financial year i.e. 1.4.2015 on which they were eligible for another WPI increase.

4. The petitioner representative mentioned that this increase on 21.12.2014 has not been accounted for by NPPA while fixing the price on 1.4.2015.

5. 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.

6. NPPA representative stated that NPPA in its 21st 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.

7. It is further stated that the data as provided by the companies for September 2014 was considered and WPI @ 3.849% was also allowed for the calendar year 2014. DPCO 2013 does not permit two WPI in one year.

8. Petitioner : The petitioner representative mentioned that para 10(2) clearly states that the petitioner is entitled for two increases one immediately after the 12 months i.e. on 21.12.2014 and again on 1.4.2015.

9. The petitioner representative further mentioned that para 16(1) & (2) is related to a situation of annual price increase which will fall due on 1st April to the extent of WPI. In the subject case which is covered under para 10(2), the petitioner was entitled to a price increase of 6.32% in December, 2014 (i.e. immediately after one year of notification issued under DPCO 1995 and further 3.849% on 1st April, 2015 as per para 16(1) and 16(2).

10. It is further added by petitioner that the ceiling price notified by NPPA for Chloroquine phosphate Injection (40mg/ml-64.5mg eq to 40mg chloroquine) was based on a per ml average and includes various packs of differing sizes (2 ml, 5 ml, 30 ml, in the same basket). This being an injection, packaging cost plays an important role in the total cost of the product. While API and excipient cost goes up in linear proportion, the packaging cost does not go up in linear proportion. Hence per cost in a 30 ml multi dose vial will always be lesser than that of a 2 ml vial. Hence taking an average for determining per ml cost and ceiling price is not correct.

11. It is stated by petitioner that Para 11 of DPCO,13 clearly states, "Ceiling price or retail price of a pack – (1) the average price to retailer calculated as per the provisions in paragraphs 4, 5 and 6 shall be on the dosage basis, (per tablet, per capsule or injection in volume as listed in first schedule) and the ceiling price or retail of a pack shall be reached by multiplying the same with the number or quantity in the pack as the case may be." The calculations applied by the NPPA are not in keeping with Para 11.

12. NPPA comments: 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. Thus, as per provisions of the DPCO 2013, increase can be taken only once a year and the petitioner's view that two increases within 4 months can be taken is incorrect.

13. As regards issue of averaging is considered, it is stated that the prices have been worked out on 'market based data' under DPCO 2013 where there is no cost consideration as in the erstwhile DPCO 1995 which was cost based. The prices were worked out based on the para 4 of DPCO 2013. Further, regarding averaging, it is stated that this practice of working out ceiling price on per ml basis is being followed consistently in all the concerned cases in line with provisions of paragraph 11 of DPCO, 2013.

Department comments:

14. 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."

15. 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, fixed and notified under the provisions of Drugs (Prices Control) Order, 1995 upto 31st May, 2012, shall remain effective for further one year i.e. upto 30th Mat 2013 and the manufacturers may revise the prices of such scheduled as per the annual wholesale price index for the previous calendar year announced by Department of Industrial Promotion and Policy and thereafter the formula as in sub-paragraph (1) of paragraph 4 of this Order shall be applied for fixing the ceiling prices of such formulations."

16. 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.

17. 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 was in December 2014 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.

18. DPCO 2013 provides in para 4(1) to include all brands and generic versions irrespective of their size or volume. Under para 11(1) the prices of the pack has to be calculated by multiplying the ceiling price with the volume. The petitioner has no merit in this point.

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

“NPPA is 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 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 Healthcare Pvt. Ltd.
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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. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
3. Technical Director, NIC with the request to upload the review order on the Department's website