

No. 31015/56/2014-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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. Alkem Laboratories Ltd. against fixation/revision of ceiling prices of Cefotaxime 250 mg and 500 mg injections vide NPPA notification S.O. No. 2350(E) dated 15/9/2014 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013).

Ref. 1) Applicant Review application dated 13.10.2014
2) NPPA notification under review S.O. No.2350(E) dated 15/9/2014
3) Record Note of discussions held in the personal hearing held in the matter on 31.10.2014

Whereas National Pharmaceutical Pricing Authority (NPPA), Government of India, vide price fixation Order S.O. No.2350(E) dated 15/9/2014 fixed/revised ceiling price of Cefotaxime 250 mg and 500 under DPCO, 2013, included in section 6.2.1.4 in schedule-I of the DPCO.

2. And whereas aggrieved by the above notification, M/s Alkem Laboratories Ltd. (hereinafter referred to as the Petitioner) submitted Review application dated 13.10.2014 under para.31 of DPCO, 2013 for the review of NPPA Price fixation Order S.O.No.2350 (E) Dated 15.9.2014 fixing Ceiling price of Cefotaxime 250 mg and 500 mg DPCO, 2013.

3. The grievance of the Petitioner raised in their review application dated 13.10.2014 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 31.10.2014. 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 Department's comments on the issue is recorded subsequently against each point:

- i) Petitioner: The company representative had represented against NPPA Notifications SO No. 2093 (E) dt. 20.8.2014 and SO No. 2350 (E) dt. 15.9.2014. The first application against SO No. 2093 (E) was received after 30 days as provided under para 31 of DPCO 2013 and, therefore it was not included in the reviewing hearing. However, the petitioner had stated that they could not give review application as the data sheet was not made available on the NPPA website before 17.9.2014. They had represented through a letter to NPPA and copies of pre-receipted letters are enclosed. Since the grievances in both the notifications are the same and the common decision is to be applied, all three formulations prices may be reviewed.
- ii) Petitioner representative mentioned that the PTR taken by NPPA in their calculation sheet is not correct for their company. There may be similar discrepancies in other cases also. The discrepancies noted by the company is that after the PTR of Rs. 12.35 NPPA had not taken a WPI of 7.54% due for the year 2012 to be availed by the company in 2013 under para 10 of DPCO 2013. IMS Health has not revised the data after the company had availed WPI under para 10.

The company representative mentioned that their PTR after including latex free rubber stopper is Rs. 13.55 for 250 mg and Rs. 17.60 for 500 mg.

NPPA comments for point (i) & (ii): NPPA representative mentioned that they had taken the data as provided by IMS Health. IMS had mentioned PTR of M/s Alkem as Rs.12.92 (250 mg) and Rs.16.42 (500 mg) but the same was restricted to derived PTR of Rs.12.35(250 mg) and Rs.16.29(500 mg) worked out on the basis of DPCO 1995 ceiling vide SO 1612 (E) dt. 19.7.12. In working out derived PTR the WPI of 7.54% has not been considered since availing of WPI depends on decision of the company and cannot be assumed to be availed by all the companies. PTR given by IMS is lower than the PTR claimed by the Petitioner. However NPPA used the data as per derived PTR details of which is already given in written reply.

Government's comments: The first issue raised by the Petitioner is that their PTR has not been taken correctly by NPPA i.e. after they had availed WPI for 2012 due for availing in 2013 under para 10 of DPCO 2013 relevant extracts of para 10 reproduced below:

“Para 10 (1): The prices of scheduled formulations, which are also specified in the First Schedule to the Drugs (Prices Control) Order, 1995, fixed and notified under the provisions of the said order, up to 31st May, 2012, shall remain effective for further one year i.e. up to 30th May 2013 and the manufacturers may revise the prices of such scheduled formulations as per the annual wholesale price index for the previous calendar year announced by Deptt. of Industrial Promotion and Policy and thereafter the formula under sub paragraph (1) of paragraph 4 of this Order shall be applied for fixing the ceiling prices of such formulations.”

NPPA had, however, taken the derived PTR of Rs. 12.35 and Rs.16.29 respectively for 250 mg and 500 mg based on the 1995 ceiling prices without providing WPI for the year 2012 due in 2013 as per provision of para 10 of DPCO, 2013. IMS had given different figures. The method of PTR derived by NPPA does not seem to be logical firstly on the ground that under DPCO 2013 nobody could sell above the ceiling price, but the companies could sell the formulations below ceiling price. NPPA should, therefore, have included lesser PTR in case some brands were being sold at less than the ceiling price otherwise framers of DPCO 2013 could have depended on derived PTR in all cases rather than formula under para 4(1) as mentioned above. Derived price mechanism as applied by NPPA is not as per DPCO provisions and may not be free from mistakes.

Further NPPA should have allowed WPI 2012 due in 2013 albeit only in those cases where the companies have availed it. If the companies have intentionally not availed the WPI 2012 due to marketing strategy, then it could not have been taken. NPPA should, therefore, revalidate the data as per para 9(1) of DPCO 2013.

(iii) Petitioner: Petitioner representative mentioned that under previous notification SO 1612(E) dt. 19.7.2012 the companies were allowed additional cost of 0.90 per pack towards use of bromobutyle rubber stopper. They, therefore, requested that cost of rubber stopper should also be included in the PTR and their final PTR of Rs.13.55 for 250 mg and Rs.17.60 for 500 mg.

NPPA comments: NPPA representative mentioned that issue of providing 90 paise for rubber flap was not raised by the petitioner in the review application. The ceiling price applicable to the company would be considered. Since this issue has been raised now, the allowability/ non allowability of same may be decided by the Reviewing Authority.

Government's comments: Under the previous notification under DPCO 1995 NPPA was allowing 90 paise per pack of bromobutyle rubber stopper (Latex free) in addition to the notified prices. The company was allowed to sell only the medicines as covered under DPCO 1995. It was an additional cost provided to the companies who were using the rubber stopper. Since DPCO, 1995 was cost based and DPCO 2013 is a conscious deviation from cost based to market based no additional cost can be allowed. Any company wishing to supply rubber stopper may do it as a market strategy, which cannot affect the price notified by NPPA. Therefore, the companies cannot be allowed rubber stopper price in addition to the prices notified by NPPA.

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

“NPPA may be directed to revalidate the data as empowered under para 9(1) of DPCO 2013, after the companies have availed WPI 2012 allowable in 2013 strictly as per the provisions contained in para 10 of DPCO 2013. Derived prices are not provided under DPCO 2013 and therefore cannot be applied.”

Issued on this date 23rd January, 2015.

(Anil Jain)
Under Secretary to the Govt. of India
For and on behalf of the President of India

To

1. M/s. Alkem Laboratories Ltd.
K-4, Udyog Nagar Industrial Area
Rohtak Road, Peera Garhi
New Delhi-110041
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. TD (NIC) for uploading the Order on Department's Website.