

No. 31015/51/2014-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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B Wing, Janpath Bhawan, New Delhi

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

Subject: Review application of M/s. Mankind Pharma Ltd. against fixation/revision of Retail prices of Bisoprolol Fumarate 5 mg + Amlodipine 5 mg tablet vide NPPA notification S.O. No. 2104(E) dated 20/8/2014 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013).

Ref. 1) Applicant Review application dated 15.9.2014
2) NPPA notification under review S.O. No. 2104(E) dated 20/8/2014
3) Record Note of discussions held in the personal hearing held in the matter on 30.9.2014

Whereas National Pharmaceutical Pricing Authority (NPPA), Government of India, vide price fixation Order S.O. No. 2104(E) dated 20/8/2014 fixed/revised Retail price of Bisoprolol Fumarate 5 mg + Amlodipine 5 mg tablet under DPCO, 2013.

2. And whereas aggrieved by the above notification, M/s Mankind Pharma Ltd. (hereinafter referred to as the Petitioner) submitted review application dated 15.9.2014 under para.31 of DPCO, 2013 for the review of NPPA Price fixation Order S.O.No. 2104(E) dated 20/8/2014 fixing Retail price of Bisoprolol Fumarate 5 mg + Amlodipine 5 mg tablet under DPCO, 2013 as 'New Drug' under paragraphs 5.11.415 of the Order.

3. The grievance of the Petitioner raised in their review application dated 15.9.2014 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 30.9.2014. 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 on the issue are recorded subsequently against each point:

4. Petitioner: The petitioner representative mentioned that there are two manufacturers who are producing the same formulation with same combination viz. M/s Merck and M/s. USV. The data taken by NPPA before fixing their retail price pertained to only M/s USV and the data of M/s Merck was not taken into consideration. Therefore, NPPA had fixed the price under monopoly condition under para 6 of DPCO, which is not correct. The petitioner representative gave two market samples one of M/s USV and other of M/s Merck. Both the samples are attached with the record note of discussion.

5. NPPA comments: NPPA representative mentioned that after receiving representation of the company they had written to M/s Merck. As per the information provided by M/s Merck, a copy of which is attached with the record note of discussion, M/s Merck did not produce the same combination with same strength i.e. 5 mg each of Bisoprolol Fumarate + Amlodipine Besilate equivalent to Amlodipine 5mg.

Government's comments and decision:

6. It is seen the Annexure to the Record Note that M/s USV is only marketing and the manufacturer is M/s Accent Pharma. In the case of M/s Merck they are themselves manufacturing and also marketing. However, they did not give the information on a request from NPPA. It transpired during the review hearing that there is more than one manufacturer and more than one marketer. Therefore, the monopoly condition does not apply.

7. As the companies do not cooperate with the Govt. there is possibility that there are other manufacturers/marketers who are selling the same combination at a lesser market rate. NPPA may be directed to revalidate the data through all available sources and revisit their notification No. 2104(E) dt. 20.8.2014 fixing the price of Bisoprolol Fumarate 5 mg plus Amlodipine 5mg.

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

“NPPA is directed to revalidate the data in respect of the instant formulation through all available sources and revisit their notification No. 2104(E) dt. 20.8.2014 fixing the price of Bisoprolol Fumarate 5 mg plus Amlodipine 5mg tablet.”

Issued on this date 9th February, 2015.

(Anil Jain)

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

To

1. The Member Secretary,
National Pharmaceutical Pricing Authority,
YMCA Cultural Centre Building, New Delhi-110001
2. M/s. Mankind Pharma Ltd.,
236, Okhla Industrial Estate, Phase 3
New Delhi-110020

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.