

No. 31015/48/2014-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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

REVIEW O R D E R UNDER PARA.31 OF DPCO, 2013

Subject: Review application of M/s Bayer Zydus Pharma Limited against fixation of ceiling prices of Sodium Meglumine Diatrizoate Injection 60% and 76% vide NPPA notification No. S.O.2092(E) dated 20.8.2014 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013).

Ref. 1) Applicant Review application No.nil dated 10.9.2014.
2) NPPA impugned notification under review No. S.O.2092(E) dated 20.8.2014.
3) Record Note of discussions of the personal hearing held on 23.9.2014.

Whereas National Pharmaceutical Pricing Authority (NPPA), Government of India, vide price fixation Order S.O.2092(E) dated 20.8.2014 fixed ceiling price of Sodium Meglumine Diatrizoate Injection 60% and 76% under Drugs (Prices Control) Order, 2013 (DPCO, 2013).

2. And whereas aggrieved by the above notification, M/s Bayer Zydus Pharma Limited (hereinafter referred to as the Petitioner) submitted review application dated 10.9.2014 under para.31 of DPCO, 2013 for the review of NPPA Price fixation Order No. S.O.2092(E) dated 20.8.2014 fixing Ceiling price of Sodium Meglumine Diatrizoate Injection 60% and 76% under para.4 of DPCO, 2013 included in Schedule-I of DPCO, 2013.

3. And whereas a personal hearing in the said review matter was accorded to the Petitioner by the Department on 23.9.2014. The Petitioner was represented by Shri K. Parmeshwar, Business Unit Head and Shri R.M. Pandit, Sales Manger. On behalf of the National Pharmaceutical Pricing Authority (NPPA) Shri Naresh Arya, Dy. Director attended the hearing.

4. The grievance of the Petitioner raised in their review application dated 10.9.2014 were sent to NPPA and the comments of NPPA thereon were given to the Petitioner through the record note of discussions of the personal hearing held on 23.9.2014. Record note of discussions is made integral part of the review order. After considering the comments of NPPA the Petitioner 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:** Petitioner's representative mentioned that there are 3 major players having more than 1% market share i.e. M/s J.B. Chemicals, Unijules Life Sciences and Bayer Zydus Pharma. Therefore, the method of fixation of price of the formulation i.e. "monopoly" should not have been applied by NPPA.

NPPA: NPPA representative mentioned that as per available information M/s Arco Lifesciences was the only manufacturer of this formulation and thus the prices have been fixed as a “monopoly” situation under para 6 of DPCO 2013. NPPA had placed a request on the website requesting all the manufacturers of this formulation and different pharma associations to provide the data in respect of the said formulation. However, no response was received from other manufacturers except M/s Arco Lifesciences. In the absence of information prices have been fixed on the information provided by M/s Arco Lifesciences.

Department’s comments: In the instant formulation NPPA did not get any information from IMS Health. A request was accordingly placed on the website requesting concerned manufacturers/marketing companies to provide PTR and MAT value. A copy of the O.M. was also sent to Pharma Associations. As per NPPA no company had provided the requisite information except M/s Arco Lifesciences, based on which the said formulation was considered to be a ‘monopoly’ formulation and the prices were fixed under para 6 of DPCO 2013.

It is observed that IMS Health had not provided any information to NPPA. Since IMS had provided the information to the Petitioner about the availability of two brands of the instant formulation, NPPA needs to take up the issue with IMS Health for not providing the information to NPPA.

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

“The four players M/s J.B. Chemicals, Unijules Life Sciences, Bayer Zydus Pharma and Arco Lifesciences may be requested to provide the data to NPPA within a fixed time and NPPA should review the notification dt. 20.8.2014 by revalidating the data as mandated under para 9(1) of DPCO, 2013.”

Issued on this date 5th November, 2014.

(Roshan Lal)
Under Secretary to the Govt. of India
For and on behalf of the President of India

To

1. The Member Secretary,
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