

No.51015/3/10-PI.I
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals

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

ORDER

Subject: Review application of M/s Novo Nordisk India Pvt. Ltd. under the Drugs (Prices Control) Order, 1995 (DPCO, 1995) against NPPA price fixation Notification No. S.O.1779(E) dated 21.7.2010 fixing prices of an Insulin formulation – Novomix 50 Flexpen - imported by the company.

Whereas Government of India, vide price fixation Order SO No. 1779(E) dated 21.7.2010 fixed the price of an Insulin formulations, Novomix 50 Flexpen (5x3 ml pen).

2. And whereas aggrieved by the above notification, M/s Novo Nordisk India Pvt. Ltd. (hereinafter referred to as Petitioners) had represented to the reviewing authority against the said price fixation. Personal hearing was granted to the Petitioners by the Department of Pharmaceuticals on 22.9.2010. The Petitioners were represented by S/Shri Shri Suhas Karambelkar and Rohit Gangeshwari. On behalf of NPPA Shri Jagdish Kumar, the then Deputy Director(Tech) and Smt. Man Mohan Kaur, Deputy Director(Cost), were present during the hearing.

3. After examination, the Department submitted the case to the Reviewing Authority for orders.

4. Based on the discussions in the personal hearing and documents on record the reviewing authority has passed the following order:

“Observation made by me in File No.31015/10/12-PI-I may be referred to.”

The recommendation made by the Department in File No.31015/10/12-PI-I and observation of the Reviewing Authority in that file are reproduced below:

Recommendation made by the Department

“While the ceiling price issued by the NPPA on 16.11.2012 may be maintained, which is in the public interest and also as per the spirit of DPCO, NPPA is required to follow the procedure provided under DPCO 1995. The company may be asked to provide the information in form III or form IV as the case may be within 15 days from the date of issue of the review order and NPPA may be directed to revise the ceiling price by considering the information as provided in this review order or the latest information available to them as per the provisions of DPCO, 1995 and fix the revised ceiling price within a period of 2 months as specified in the DPCO 95 for

price fixation of formulations. While fixing the revised ceiling price NPPA should keep in mind that the allowed price is not evasive and should not have the potential of forcing the major manufacturers out of business thereby creating a shortage of the product in the market. In the meanwhile the company should be directed to maintain the ceiling price.”

Observations of the Reviewing Authority

“Insulins are life saving dissimilar biological analogues derived from different sources and processes resulting in different costs. As indigenous production is not sufficient to meet country’s total requirement, the import of insulin crystals/formulations is also necessary in the public interest to avoid shortages.

As suggested by the Department and to establish the principle of natural justice, NPPA may follow the procedure under DPCO, 1995 (Para-11) and it may revisit the decision under reference by considering all relevant information and applicable norms and also keeping in view of observation of the Hon’ble Court also.”

5. NPPA is directed to take action accordingly.

Issued on this date 28th March, 2013.

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

To

1. The Member Secretary,
National Pharmaceutical Pricing Authority,
YMCA Cultural Centre Building
1, Jai Singh Road,
New Delhi-110001

2. M/s Novo Nordisk India Pvt. Ltd.,
Plot No.32, 47-50,
EPIP Area Whitefield,
Bangalore -560066

Copy to :

1. PS to Hon’ble Minister of State(Independent Charge) of the Ministry of Chemicals & Fertilizers, Shastri Bhawan, New Delhi for information.
2. Sr. PPS to Secretary (Pharma), Shastri Bhawan, New Delhi for information.