

No.31015/15/2012-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 Sanofi India Ltd. under DPCO, 1995 against the price fixation orders SO No. 2735 (E) dated 16.11.2012 issued by NPPA fixing Ceiling Prices for Human Insulin Injections.

Whereas Government of India, vide price fixation orders No. S.O.2735 (E) dated 16.11.2012 fixed the Ceiling Prices for Human Insulin Injections.

And whereas aggrieved by the above mentioned notification M/s Eli Lilly & Co. (I) Pvt. Ltd. (hereinafter referred to as Petitioners) had represented to the reviewing authority against the said price fixation order. Personal hearing was granted to the Petitioners by the Department of Pharmaceuticals on 26.12.2012. The Petitioners were represented by S/Shri M.K. Narayanaswamy, Senior Director (Acct. & Tax.) and Mrs. Yasmin Cama, Senior Director (Legal). On behalf of NPPA Smt. Manmohan Kaur, Deputy Director was present during the hearing. Shri V.K. Tyagi, Deputy Industrial Adviser, Department of Pharmaceuticals was also present as a technical expert.

2. After examination, the Department submitted the case to the competent authority with the recommendation as under:

“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, if the company feels aggrieved they may file a revision application in Form IV 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, 95 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/importers 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.”

3. Based on the observations made in the similar review applications earlier the reviewing authority has passed the following order:

“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."

Issued on this date 25nd March, 2013.

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

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

M/s. Sanofi India Limited
D-2, 4th Floor, Southern Park,
Saket District Centre, Saket,
New Delhi-110017

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.