

No.31015/12/2012-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 Lupin Ltd. under Drugs (Prices Control) Order, 1995 (DPCO, 1995) against the price fixation orders SO No. 2734 (E) dated 16.11.2012 issued by NPPA fixing Ceiling Prices for Human Insulin Injections manufactured indigenously.

Whereas Government of India, vide price fixation orders SO No. 2734 (E) dated 16.11.2012 fixed the Ceiling Prices for Human Insulin Injections.

And whereas aggrieved by the above mentioned notification M/s Lupin Ltd. (hereinafter referred to as Petitioners) had represented to the reviewing authority against the said price fixation order. The Deputy Secretary in the Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals gave personal hearing to the Petitioners on 18.12.2012. The Petitioners were represented by S/Shri Kuldeep R. Wakhloo, Director (Corporate Affairs), Dr. Akshaya S. Odak, Head (Regulatory Biotech) and Shri Venktaraman C.V. (G.M., Corporate Services). Shri S.K. Bhatt, Deputy Director, Shri Suneel Chopra, Consultant represented on behalf of NPPA during the hearing. Shri V.K. Tyagi, Deputy Industrial Adviser, Department of Pharmaceuticals was also present during the hearing as a Pharma 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, 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.

It is a fact that insulin requires special facilities like cold chain. NPPA has in the past allowed cold chain charges for insulin formulations. While considering the revised ceiling prices under para 9(2) NPPA should also consider this aspect and any other additional charge and issue a reasoned order allowing or disallowing such additional charges claimed by the companies."

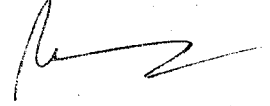
3. Based on the discussions in the personal hearing and documents on record the reviewing authority, i.e. Minister (Chemicals & Fertilizers) has passed the following order:

"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.

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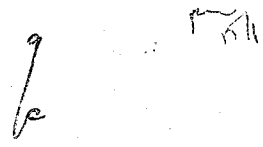
As suggested by the Department and to establish the principle of natural justice, NPPA may follow the procedure under DPCO, 1995 (Para-11) and it may revisit the decision under reference by considering all relevant information and applicable norms and also keeping in view of observation of the Hon'ble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

Issued on this date 15th January, 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,
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(by Speed Post)