

No.31015/7/2012-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 Eli Lilly & Co. (India) Pvt. Ltd. under under Drugs (Prices Control) Order, 1995 (DPCO, 1995) against fixation of price in respect of their five (5) different forms of imported Injection Insulin Lispro (Humalog) vide notification No. S.O.2740 (E) dated 16.11.2012 issued by NPPA.

Whereas Government of India, vide price fixation order SO No. 2740 (E) dated 16.11.2012 fixed the prices of various imported insulin formulations.

And whereas aggrieved by the above mentioned notifications M/s Eli Lilly & Co. (I) Ltd. (hereinafter referred to as Petitioners) had represented to the reviewing authority vide their application dated 29.11.2012 against the said price fixation orders. The Deputy Secretary in the Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals gave personal hearing to the Petitioners on 11.12.2012. The Petitioners were represented by Shri Vineet Gupta, Director and Dr. Gaurav Arya, Associate Director. Shri S.K Bhatt, Deputy Director, Smt. Manmohan Kaur, Deputy Director and Shri Suneel Chopra, Consultant represented on behalf of NPPA during the hearing. Shri V.K Tyagi, DIA, Department of Pharmaceuticals was also present as a technical expert in the hearing.

The issues involved in the review application were examined as under:

Whether insulin analogue imported by M/s Lilly has an indigenous substitute.

In this regard the Department had sought the comments of NIPER, Mohali and their technical opinion is that automatic substitution i.e. dispensing of generic medicines in place of innovator product without knowledge of or consent of the physician works very well with the small molecules where once the structural equivalence has been established. Results of clinical trials are not normally required. This abridged approach however is generally not recommended for Protein Pharmaceuticals even in cases where the structures are similar. NIPER, Mohali, therefore, opined that clinical equivalence needs to be established.

The guidelines dated 22.7.2011 and guidelines No.1/99 dated 20.1.2000 pertain to imported formulations having domestic substitute. Considering advice of NIPER Mohali, the guidelines pertaining to substitute are not applicable in this case.

Guidelines No. 1/99 dated 20.1.2000 revising the MAPE(margin) from not exceeding 50% to 35%

Proviso to para 7 of DPCO provides for a margin not exceeding 50% of the landed cost with no distinction of availability of a local substitute. While Guidelines No. 1/99 provides for Margin (MAPE) at 35% subject to Authority's best judgment.

No guidelines can change the import of the legislation and any change which affects the basic principles of the legislation i.e. concept of local substitute or changing margin from "upto 50%" to "35%" should have been carried out through amendment of the DPCO itself. These guidelines, therefore, are beyond the powers of NPPA.

Guidelines dt. 22.7.2011

NPPA further revised the guidelines which provides that "MAPE" (margin) would continue to be 35% so long as the price remains at existing level. NPPA even deliberately did not take cognizance of their own price fixations which had a wide variation on the date of issue of this guideline.

It was observed that maintaining the existing price as per guidelines dated 22.7.2011 cannot thus be justified as they have discriminatory effect. No guidelines can be justified on any ground if they cause discrimination among various players in the market.

Therefore, it was proposed that NPPA may be directed not to implement the two guidelines, call for/consider the latest information from all the importers of insulin analog and fix the prices as per the provisions of DPCO, 1995.

2. The reviewing authority, i.e. Hon'ble Minister (Chemicals & Fertilizers) has approved the above proposal.

Issued on this date 7th 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,
New Delhi-110001
2. M/s Eli Lilly & co. (I) Limited,
Plot No.92, Sector-32,
Gurgaon-122001.
Haryana.

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.