

No.31015/5/2012-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 Drugs (Prices Control) Order, 1995 (DPCO, 1995) against fixation of the prices in respect of 5 (five) different imported formulations of Injection Insulin Lispro (Humalog) vide S.O. No. 1635(E) dated July 19, 2012 issued by NPPA.

Whereas Government of India, vide price fixation orders S.O. No. 1635(E) dated July 19, 2012 fixed the prices for different imported Insulin formulations.

And whereas aggrieved by the above mentioned notification M/s Eli Lilly & Co. (India) Pvt. Ltd. (hereinafter referred to as Petitioners) had represented to the reviewing authority vide review application dated 30.7.2012 against fixation of prices of five different formulations of Injection Insulin Lispro (Humalog), viz. Serial No.4, 5, 6, 12 and 13 of the Table given in the Order dated 19.7.2012. The Deputy Secretary in the Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals gave personal hearing to the Petitioners on 21.8.2012. The Petitioners were represented by S/Shri Vineet Gupta, Director. The NPPA was represented by Smt. Manmohan Kaur, Deputy Director and Shri S.K Bhatt, Deputy Director. During the hearing Shri V.K. Tyagi, DIA, Department of Pharmaceuticals was also present as a technical expert.

2. While examining the said review application the Department observed and recommended that as per Para 1(b)(vi) of the Guideline No.1/99 NPPA has amended the words “shall not exceed 50%” to “35%”. The term “shall not exceed 50%” as contained in the provision to para 7 of DPCO, 1995 can be anything between 0% to 50%, depending upon the specific circumstances of the case. This is amendment of the substantive provision of DPCO, 95 by changing a variable to fixed percentage based on the availability of the local substitute, which could be one of the factors and not the only factor. NPPA has limited the scope of the DPCO which is beyond the powers of NPPA. Proviso to para 7 of DPCO, 1995 provides that landed cost shall form the basis for fixing prices of imported formulations with a margin to cover selling and distribution expenses including interest and importers’ profit which “shall not exceed 50% “ of the landed cost. It was noted that this proviso does not relate the margin to whether an indigenous substitute exists or not. Linking indigenous substitutes to the margin has changed the substantive provision of DPCO and cannot be done without amendment of the DPCO.

The said guidelines No.1/99 have been further amended in 121st Authority meeting held on 22.7.2011 thereby giving NPPA powers to suitably reduce the 35% MAPE (should be margin) to bring the price at parity with the existing price to ensure fair

and reasonable price to consumer public. This was done without going into the fact that there was a huge variation in the then existing prices already approved by NPPA. This clearly shows that NPPA did not bother to ensure parity among various importers. They had sufficient powers to suo moto fix the prices with a variable margin and bring all the importers at par. No guidelines can justify its discretionary powers which cause wide disparity among equal players. The guidelines could have been justified if the words "parity with other importers" have been used instead of words "parity with existing price". The Department, therefore, proposed for quashing the said Guidelines viz. Para 1(b)(vi) of the Guideline No.1/99 and amendment to the said guidelines issued on 22.7.2012.

NPPA had already issued ceiling prices for other insulin formulations under para 9 of the DPCO, 1995. The company had filed a review petition, which was heard and the Order of the Hon'ble Minister has already been passed directing NPPA to revisit the decision under reference by considering all relevant information and applicable norms. Reviewing the notified prices under para 8 is meaningless at this stage. The same orders as already passed by the Hon'ble Minister will be applicable in this cases also. A copy of the relevant order No.31015/17/2012-PI.I dated 15.01.2013 is enclosed.

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

- I. Approved as proposed.
- II. NPPA be directed to issue guidelines with prior approval of the DoP.

Issued on this date 20th February, 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) Pvt. 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.

No.31015/17/2012-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 Drugs (Prices Control) Order, 1995 (DPCO, 1995) against the price fixation orders SO No. 2734 (E) and 2735 (E) both dated 16.11.2012 issued by NPPA fixing Ceiling Prices for Human Insulin Injections.

Whereas Government of India, vide price fixation orders SO No. 2734 (E) and 2735 (E) both dated 16.11.2012 fixed the Ceiling Prices for Human Insulin Injections.

And whereas aggrieved by the above mentioned notifications and as per the directions passed by the Hon'ble High Court of Punjab and Haryana at Chandigarh vide Order dated 6.12.2012 in respect of Civil Writ Petition No.24163/2012 (M/s Eli Lilly & Co. (I) Pvt. Ltd. vs. Union of India & Anr.) M/s Eli Lilly & Co. (I) Pvt. Ltd. (hereinafter referred to as Petitioners) had represented to the reviewing authority 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 31.12.2012. The Petitioners were represented by S/Shri Vineet Gupta, Director (Corporate Affairs), Dr. Gaurav Arya, Associate Director (Public Health and Policy). Smt. Manmohan Kaur, Deputy Director, Shri Suneel Chopra, Consultant represented on behalf of NPPA during the hearing

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 ceiling 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 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.

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,
New Delhi-110001

Copy to:
M/s Eli Lilly & co. (I) Pvt. Limited, Plot No.92, Sector-32, Gurgaon-122001, Haryana.

No.31015/10/2012-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 Drugs (Prices Control) Order, 1995 (DPCO, 1995) against fixation of the prices in respect of 6 (six) different imported formulations of Monocomponent Human Insulin Lispro (Humalog) vide S.O. No. 1737(E) dated 26th July, 2011 issued by NPPA.

Whereas Government of India, vide price fixation orders No. S.O.1737(E) dated 26th July, 2011 fixed the prices for different imported Insulin formulations.

And whereas aggrieved by the above mentioned notification M/s Eli Lilly & Co. (India) Pvt. Ltd. (hereinafter referred to as Petitioners) had represented to the reviewing authority vide review application dated 08.8.2011 against fixation of prices of six different formulations of Monocomponent Human Insulin - Lispro (Humalog), viz. Serial No.1 to 6 of the Table given in the Order dated 26.7.2011. The concerned Director in the Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals gave personal hearing to the Petitioners on 13.9.2011. The Petitioners were represented by S/Shri Anurag Khera, Director(Corporate Affairs). The NPPA was represented by Shri S.K Bhatt, Deputy Director and Shri Manish Goswami Deputy Director.

2. While examining the said review application the Department observed and recommended that as per Para 1(b)(vi) of the Guideline No.1/99 NPPA has amended the words “shall not exceed 50%” to “35%”. The term “shall not exceed 50%” as contained in the provision to para 7 of DPCO, 1995 can be anything between 0% to 50%, depending upon the specific circumstances of the case. This is amendment of the substantive provision of DPCO, 95 by changing a variable to fixed percentage based on the availability of the local substitute, which could be one of the factors and not the only factor. NPPA has limited the scope of the DPCO which is beyond the powers of NPPA. Proviso to para 7 of DPCO, 1995 provides that landed cost shall form the basis for fixing prices of imported formulations with a margin to cover selling and distribution expenses including interest and importers’ profit which “shall not exceed 50% “ of the landed cost. It was noted that this proviso does not relate the margin to whether an indigenous substitute exists or not. Linking indigenous substitutes to the margin has changed the substantive provision of DPCO and cannot be done without amendment of the DPCO.

The said guidelines No.1/99 have been further amended in 121st Authority meeting held on 22.7.2011 thereby giving NPPA powers to suitably reduce the 35% MAPE (should be margin) to bring the price at parity with the existing price to ensure fair and reasonable price to consumer public. This was done without going into the fact that there was a huge variation in the then existing prices already approved by NPPA. This clearly shows that

NPPA did not bother to ensure parity among various importers. They had sufficient powers to suo moto fix the prices with a variable margin and bring all the importers at par. No guidelines can justify its discretionary powers which cause wide disparity among equal players. The guidelines could have been justified if the words "parity with other importers" have been used instead of words "parity with existing price". The Department, therefore, proposed for quashing the said Guidelines viz. Para 1(b)(vi) of the Guideline No.1/99 and amendment to the said guidelines issued on 22.7.2012.

NPPA had already issued ceiling prices for other insulin formulations under para 9 of the DPCO, 1995. The company had filed a review petition, which was heard and the Order of the Hon'ble Minister has already been passed directing NPPA to revisit the decision under reference by considering all relevant information and applicable norms. Reviewing the notified prices under para 8 is meaningless at this stage. The same orders as already passed by the Hon'ble Minister will be applicable in these cases also. A copy of the relevant order No.31015/17/2012-PI.I dated 15.01.2013 is enclosed.

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

- I. Approved as proposed.
- II. NPPA be directed to issue guidelines with prior approval of the DoP.

Issued on this date 20th February, 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) Pvt. 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.

No.31015/17/2012-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 Drugs (Prices Control) Order, 1995 (DPCO, 1995) against the price fixation orders SO No. 2734 (E) and 2735 (E) both dated 16.11.2012 issued by NPPA fixing Ceiling Prices for Human Insulin Injections.

Whereas Government of India, vide price fixation orders SO No. 2734 (E) and 2735 (E) both dated 16.11.2012 fixed the Ceiling Prices for Human Insulin Injections.

And whereas aggrieved by the above mentioned notifications and as per the directions passed by the Hon'ble High Court of Punjab and Haryana at Chandigarh vide Order dated 6.12.2012 in respect of Civil Writ Petition No.24163/2012 (M/s Eli Lilly & Co. (I) Pvt. Ltd. vs. Union of India & Anr.) M/s Eli Lilly & Co. (I) Pvt. Ltd. (hereinafter referred to as Petitioners) had represented to the reviewing authority 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 31.12.2012. The Petitioners were represented by S/Shri Vineet Gupta, Director (Corporate Affairs), Dr. Gaurav Arya, Associate Director (Public Health and Policy). Smt. Manmohan Kaur, Deputy Director, Shri Suneel Chopra, Consultant represented on behalf of NPPA during the hearing

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 ceiling 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 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."

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,
New Delhi-110001

Copy to:
M/s Eli Lilly & co. (I) Pvt. Limited, Plot No.92, Sector-32, Gurgaon-122001, Haryana.

No.31015/1/12-PI-I
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals

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

ORDER

Subject: Review application under para 22 of the DPCO, 1995 of M/s Eli Lilly against price fixation order No. S.O.789(E) dated 10.4.12 in respect of four forms of Injection Insulin Lispro (Humalog) at serial nos. 3,4,11, and 12 of the price order.

Whereas Government of India, vide price fixation orders No. S.O.789(E) dated 10.4.12 fixed the prices for different imported Insulin formulations.

And whereas aggrieved by the above mentioned notification M/s Eli Lilly & Co. (India) Pvt. Ltd. (hereinafter referred to as Petitioners) had represented to the reviewing authority vide review application dated 23.4.2012 against fixation of prices of four different formulations of Injection Insulin Lispro (Humalog), viz. Serial No.3, 4, 11 and 12 of the Table given in the Order dated 10.4.2012. The Deputy Secretary in the Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals gave personal hearing to the Petitioners on 7.5.2012. The Petitioners were represented by S/Shri Melt Van Der Spuy, CMD, Vineet Gupta, Director, S. Kamat, Director, and Manish Verma, CRP. The NPPA was represented by Shri S.K Bhatt, Deputy Director, Manish Goswami, Deputy Director and Shri Sunil Chopra, Consultant. During the hearing Shri V.K. Tyagi, DIA, Department of Pharmaceuticals was also present as a technical expert.

2. While examining the said review application the Department observed and recommended that as per Para 1(b)(vi) of the Guideline No.1/99 NPPA has amended the words “shall not exceed 50%” to “35%”. The term “shall not exceed 50%” as contained in the provision to para 7 of DPCO, 1995 can be anything between 0% to 50%, depending upon the specific circumstances of the case. This is amendment of the substantive provision of DPCO, 95 by changing a variable to fixed percentage based on the availability of the local substitute, which could be one of the factors and not the only factor. NPPA has limited the scope of the DPCO which is beyond the powers of NPPA. Proviso to para 7 of DPCO, 1995 provides that landed cost shall form the basis for fixing prices of imported formulations with a margin to cover selling and distribution expenses including interest and importers’ profit which “shall not exceed 50% “ of the landed cost. It was noted that this proviso does not relate the margin to whether an indigenous substitute exists or not. Linking indigenous substitutes to the margin has changed the substantive provision of DPCO and cannot be done without amendment of the DPCO.

The said guidelines No.1/99 have been further amended in 121st Authority meeting held on 22.7.2011 thereby giving NPPA powers to suitably reduce the 35% MAPE (should be margin) to bring the price at parity with the existing price to ensure fair and reasonable price to consumer public. This was done without going into the fact that

there was a huge variation in the then existing prices already approved by NPPA. This clearly shows that NPPA did not bother to ensure parity among various importers. They had sufficient powers to suo moto fix the prices with a variable margin and bring all the importers at par. No guidelines can justify its discretionary powers which cause wide disparity among equal players. The guidelines could have been justified if the words "parity with other importers" have been used instead of words "parity with existing price". The Department, therefore, proposed for quashing the said Guidelines viz. Para 1(b)(vi) of the Guideline No.1/99 and amendment to the said guidelines issued on 22.7.2012.

NPPA had already issued ceiling prices for other insulin formulations under para 9 of the DPCO, 1995. The company had filed a review petition, which was heard and the Order of the Hon'ble Minister has already been passed directing NPPA to revisit the decision under reference by considering all relevant information and applicable norms. Reviewing the notified prices under para 8 is meaningless at this stage. The same orders as already passed by the Hon'ble Minister will be applicable in this cases also. A copy of the relevant order No.31015/17/2012-Pl.I dated 15.01.2013 is enclosed.

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

- I. Approved as proposed.
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Issued on this date 20th February, 2013.

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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,
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2. M/s Eli Lilly & Co. (I) Pvt. Limited,
Plot No.92, Sector-32,
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Haryana.

Copy to :

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2. Sr. PPS to Secretary (Pharma), Shastri Bhawan, New Delhi for information.

No.31015/17/2012-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 Drugs (Prices Control) Order, 1995 (DPCO, 1995) against the price fixation orders SO No. 2734 (E) and 2735 (E) both dated 16.11.2012 issued by NPPA fixing Ceiling Prices for Human Insulin Injections.

Whereas Government of India, vide price fixation orders SO No. 2734 (E) and 2735 (E) both dated 16.11.2012 fixed the Ceiling Prices for Human Insulin Injections.

And whereas aggrieved by the above mentioned notifications and as per the directions passed by the Hon'ble High Court of Punjab and Haryana at Chandigarh vide Order dated 6.12.2012 in respect of Civil Writ Petition No.24163/2012 (M/s Eli Lilly & Co. (I) Pvt. Ltd. vs. Union of India & Anr.) M/s Eli Lilly & Co. (I) Pvt. Ltd. (hereinafter referred to as Petitioners) had represented to the reviewing authority 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 31.12.2012. The Petitioners were represented by S/Shri Vineet Gupta, Director (Corporate Affairs), Dr. Gaurav Arya, Associate Director (Public Health and Policy). Smt. Manmohan Kaur, Deputy Director, Shri Suneel Chopra, Consultant represented on behalf of NPPA during the hearing

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 ceiling 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 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.

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,
New Delhi-110001

Copy to:
M/s Eli Lilly & co. (I) Pvt. Limited, Plot No.92, Sector-32, Gurgaon-122001, Haryana.