

No. 31015/19/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

B Wing, Janpath Bhavan,
New Delhi 110 001

Subject: Review application of M/s Kedrion Biopharma India Private Ltd. against price fixation of “Coagulation Factor VIII-250 IU Injection” vide NPPA order No. S.O. 1405(E) dated 12/04/2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 13.04.2016
2) NPPA notification under review S.O. No.1405(E) dated 12.04.2016
3) Record Note of discussions held in the personal hearing held in the matter on 20.6.2016.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Kedrion Biopharma India Private Ltd. (hereinafter called the petitioner) against notification S.O. No.1405(E) dated 12.04.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Coagulation Factor VIII-250 IU Injection.

2. The petitioner has contended as under:

- i. On 5th November, 2013, through S.O. No. 3345, the National Pharmaceutical Pricing Authority (NPPA) issued a notification pursuant to the DPCO, 2013, whereby the price for Factor VIII Concentrate Injection was fixed at Rs. 6080.43 pursuant to the powers of the NPPA under paragraph 4, 11 and 14 of DPCO, 2013.
- ii. On 2nd March 2016, through S.O. No. 644(E) the year to year price of Factor VIII under the DPCO, 2013, as prescribed in paragraph 16 was adjusted to Rs 6531.57 w.e.f. from 1st April 2016. As per the NPPA, the Whole Sale Price Index was -2.7105% for the preceding twelve months.
- iii. On 12th April, in contravention of the scheme of DPCO, 2013, and its prior orders, the NPPA issued a fresh Order S.O. No. 1405(E) dated 12th April, 2016, whereby the price for Factor VIII was markedly changed to Rs.3323.60 per pack, a sharp and exorbitant reduction of 49.11%. A price calculation also dated 12th April, 2016, stated that the reason for the price calculation was the prices ostensibly of Factotel – VIII 250 IU Injection 10ML by Intas Pharmaceuticals Ltd. and HemorelA 250 IU Injection 1 by Reliance Life Science, allegedly from Aug 2015. On 22nd April, 2016, the NPPA issued an office memorandum seeking price to retailer (PTR) and Moving Annual Turnover (MAT), for 94 formulations, including Factor VIII.

- iv. Practical effect of re-calculating the average price of price-ceiling products, three years after the company have subjected to price ceiling, would render the calculation contrary to the principle of “Pharma Economics” as enumerated under Para 2(w) of the DPCO, 2013.
- v. NPPA does not have the authority to calculate prices for formulation already certified and determination of pre ceiling prices under Paras 4 and 5, afresh except for the changes in the pricing as stipulated under rule 16 of the DPCO. The powers of NPPA are limited to Para 16, or correction of the price calculation for the period taken. DPCO, 2013 has no enabling clause which allows any change in the pricing except for Paragraph 16. That the DPCO, 2013 in fact does not allow for any amendment or review of pricing based on any change, such as a new custom duties or a change of raw materials.
- vi. The Pharma Trac data used, for calculation is not available in the public domain, and is internal. Hence the veracity and the authenticity of the said cannot be relied upon. In this respect, it is pertinent that after the impugned notification, NPPA itself has sought to inquire about pricing and market data. Pursuant to Rule 9 of DPCO, 2013, the NPPA had to base its calculations on the data available with IMS Health, and there has been no notification amending DPCO, 2013, to use Pharma Trac. Neither has this data been validated in the market. Reasonableness and administrative consistence with natural justice requires that before fixing prices, representations of the concerned pharmaceutical companies should be solicited and considered by the NPPA, not after. The data should be validated, not halved before information sought.
- vii. The NPPA’s reliance on one market research is erroneous. Such powers cannot be delegated under Sec 3 of the Essential Commodities Act, 1955 (10 of 1955). The data and its sources have not been disclosed also neither the rationale behind shifting IMS, whose prior data was been used to another private data collection agency.
- viii. Pricing without data is arbitrary. The details of the data submitted by Pharma Trac cannot be expected to be independent and unbiased. The NPPA has not taken a holistic approach in this instance.
- ix. Price fixation For Factor VIII injection should be reviewed as in the case for Human Insulin Injection domestically and internationally as well. **The impugned notification is erroneous** and *de hors* sanction and regulatory power. A price fixing decision must be an exercise that is both within the powers delegated to the authority under s.3. NPPA has no powers to amend the DPCO, 2013, which may only be amended by the delegating authority, after due consultation. Further, price fixing must withstand the test of reasonableness. A price fixing decision must stand the test of scrutiny of reasonableness. The impugned notification does not, given the incorrect data, issued from the wrong agency and without validation, an appeal for which has been made post hoc.

The petitioner requested to Issue appropriate modification of the impugned order S.O. 1405(E) dated 12th April, 2016, after consideration of the appropriate data on average prices to the retailer in relation to the different drugs considered for calculating

the ceiling prices of the DPCO,2013, in terms of Rule 4 as well as Rule 11 of the DPCO, 2013, as amended.

Comments of NPPA:

- (i) Coagulation Factor VIII was included in NLEM, 2011 as well as in NLEM, 2015 the ceiling price for this pack was first time fixed as Rs. 6080.43 for each pack Vide S.O. 3345 (E) dated 05.11.2013 and the same was revised to Rs. 6464.71, 6713.54 & 6531.57 Vide S.O. 1156 (E) dated 28.4.2014, 619 (E) dated 26.2.2015, 644 (E) dated 2.3.2016 on account of WPI impact (Based on data submitted by IMS Health).
- (ii) DOP has amended substituting NLEM 2011, by NLEM 2015 and therefore the price for this formulation was again revised to Rs. 3323.60 Vide S.O. 1405 (E) dated 12.4.2016 based on the data submitted by Pharma Trac as per existing practice.
- (iii) NPPA has also issued OM No. 19(714)/2016/Div.II/NPPA, dated 20.5.2016 regarding prefixing of ceiling price. Company may approach to NPPA in case aggrieved by NPPA price fixation.
- (iv) Company's request to fix the price of this pack in line with the insulin based formulations **cannot be considered as there no provision for same under DPCO. 2013.** However, Company may approach for the same.

4. During the personal hearing on 20.6.2016, the company representative stated that:

- i. On 2nd March 2016, through S.O. No. 644(E) the year to year price of Factor VIII under the DPCO, 2013, as prescribed in paragraph 16 was adjusted to Rs 6531.57 w.e.f. from 1st April 2016. As per the NPPA, the Whole Sale Price Index was -2.7105% for the preceding twelve months.
- ii. On 12th April, in contravention of the scheme of DPCO, 2013, and its prior orders, the NPPA issued a fresh Order S.O. No. 1405(E) dated 12th April, 2016, whereby the price for Factor VIII was markedly changed to Rs.3323.60 per pack, a sharp and exorbitant reduction of 49.11%. A price calculation also dated 12th April, 2016, stated that the reason for the price calculation was the prices ostensibly of Factotel – VIII 250 IU Injection 10ML by Intas Pharmaceuticals Ltd. and HemoreIA 250 IU Injection 1 by Reliance Life Science, allegedly from Aug 2015. On 22nd April, 2016, the NPPA issued an office memorandum seeking price to retailer (PTR) and Moving Annual Turnover (MAT), for 94 formulations, including Factor VIII.
- iii. On 22nd April, 2016 the NPPA issued an OM seeking price to retailer (PTR) and Moving Annual Turnover (MAT) for 94 formulations, including Factor VIII. A true copy of the OM dated 22nd April, 2016 is enclosed.
- iv. The Pharma Trac data used, for calculation is not available in the public domain, and is internal. Hence the veracity and the authenticity of the said cannot be relied upon. In this respect, it is pertinent that after the impugned notification, NPPA itself has sought to inquire about pricing and market data. Pursuant to Rule 9 of DPCO, 2013, the NPPA had to base its calculations on the data available with IMS Health, and there has been no notification amending DPCO, 2013, to use Pharma Trac. Neither has this data been validated in the market. Reasonableness and administrative consistence with natural justice requires that

before fixing prices, representations of the concerned pharmaceutical companies should be solicited and considered by the NPPA, not after. The data should be validated, not halved before information sought.

- v. The NPPA's reliance on one market research is erroneous. Such powers cannot be delegated under Sec 3 of the Essential Commodities Act, 1955 (10 of 1955). The data and its sources have not been disclosed also neither the rationale behind shifting IMS, whose prior data was been used to another private data collection agency.
- vi. Pricing without data is arbitrary. The details of the data submitted by Pharma Trac cannot be expected to be independent and unbiased. The NPPA has not taken a holistic approach in this instance.
- vii. Further they requested that price fixation For Factor VIII injection should be reviewed as in the case for Human Insulin Injection domestically and internationally as well. **The impugned notification is erroneous** and *de hors* sanction and regulatory power. A price fixing decision must be an exercise that is both within the powers delegated to the authority under s.3. NPPA has no powers to amend the DPCO, 2013, which may only be amended by the delegating authority, after due consultation. Further, price fixing must withstand the test of reasonableness. A price fixing decision must stand the test of scrutiny of reasonableness. The impugned notification does not, given the incorrect data, issued from the wrong agency and without validation, an appeal for which has been made post hoc.

The company Representative mentioned that the Government must know the process or direct the collection agency to follow the stringent process to which includes all the relevant data including but not limited to those products and scheduled formulations that are necessarily only made available through institutional sales. It causes disparity in the market without using market data that is restricted and the manufacturers are thus affected by such arbitrators data analysis that leads to differential pricing which results in initial removal of company market bearers.

NPPA Representative stated that:

- (i) in this regard, it is stated that Coagulation Factor VIII was included in NLEM, 2011 as well as in NLEM, 2015 the ceiling price for this pack was first time fixed as Rs.6080.43 for each pack vide SO.3345(E) dated 05.1.2013 and the same was revised to Rs.6464.71,6713.53 and 6531.57 vide SO.1156(E) dated 28.4.204, 619(E) dated 26.2.2015 and 2.3.2016 on account of WPI impact (Based on data submitted by IMS Health).
- (ii) DOP has amended substituting NLEM 2011, by NLEM 2015 and therefore the price for this formulation was again revised to Rs. 3323.60 Vide S.O. 1405 (E) dated 12.4.2016 based on the data submitted by Pharma Trac as per existing practice.
- (iii) NPPA has also issued OM No. 19(714)/2016/Div.II/NPPA, dated 20.5.2016 regarding prefixing of ceiling price. Company may approach to NPPA in case aggrieved by NPPA price fixation.

- (iv) Company request to fix the price of this pack in line with the insulin based formulations **cannot be considered as there no provision for same under DPCO. 2013** however Company may approach for the same.

The company representative further stated that there is no jurisdiction of powers for NPPA to revise the prices in the manner in which it has been so revised.

5. **Examination:**

The review petition is filed against S.O. No. 1405(E) dated 12.4.2016 for the fixation/revision of the ceiling prices under DPCO, 2013 due to amendment in scheduled-I replacing NLEM-2015 in place of NLEM-2011 on 10th March, 2016 using power under Para 17 & 18 of DPCO, 2013. It is observed that the ceiling price of Coagulation Factor VIII 250 IU Injection is first time fixed on 5.11.2013 after announcement of the DPCO, 2013. After that the ceiling price is revised upward two times on 28.4.2014 & 26.2.2015 due to change/increase of WPI as Para 16 of DPCO, 2013 and ceiling price revised downward one time on 2.3.2016 due to reduction in WPI. The base PTR price for this product and for all revision prices is old one, i.e. May, 2012 and the ceiling price was revised per pack not per ML but due to amendment in Schedule-I, the revision in the ceiling price is based on considering the new PTR for the product (Aug, 2015).

The petitioner stated that the ceiling price for the product fixed in November,2013, cannot be revised or changed on PTR basis but price can be changed/revised under Para 16 on account of change in WPI, as already done by NPPA during last three revisions. Petitioner also stated that NPPA has no power to revise the ceiling price using power given Para 17 & 18 of DPCO, 2013 since the said product was already listed in both the NLEMs, viz. NLEM-2011 & NLEM-2015. As there is no effect on this product due to amendment of scheduled-I of DPCO, 2013, therefore, ceiling price fixed vide S.O. No. 1405(E) dated 12.4.2016 is null and void and requested the reviewing authority to re-store the ceiling price for this product as notified vide S.O. No. 644(E) dated 2.3.2016.

NPPA stated that they have fixed the price as per DPCO, 2013 provisions and revised the ceiling price after the amendment of scheduled-I of DPCO, 2013, but on the examining the work sheet for the product, it is noted that NPPA had considered the PTR of two companies for August, 2015 and not considered the PTR of M/s Kedrion Biopharma (I) Pvt. Ltd.

In this regard, it is seen that para 18(1) of DPCO 2013 provides as under:-

“as and when the National List of Essential Medicines is revised by the Ministry of Health and Family Welfare or five years from the date of fixing the ceiling price under this Order whichever is earlier;”

In the instant case, the formulation, i.e. Coagulation Factor-VIII – 250 IU of M/s Kedrion Biopharma (I) Pvt. Ltd. was included in revised Schedule I of DPCO 2013, based on revision of NLEM 2015. As such, NPPA is mandated to revise the ceiling price of the aforesaid formulation.

6. **Government Decision:**

NPPA is directed to take into account on merit any relevant data furnished by the petitioner and refix the ceiling price of Coagulation Factor VIII-250 IU Injection.

In view of the above, the review application is disposed off.

Issued on this date, the 14th day of September, 2016.

(M.K. Bhardwaj)
Deputy Secretary
For and on behalf of the President of India

To

1. **M/s. Kedrion Biopharma India Private Ltd.**
House No.R265C, Ground Floor,
Greater Kailash, Part-I,
NEW DELHI-110 048.
2. **The Member Secretary,**
National Pharmaceutical Pricing Authority,
YMCA Cultural Centre Building, New Delhi-110001

Copy to :

1. **PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.**
2. **PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.**
3. **T.D., NIC for uploading the order on Department's Website**