

No. 31015/72/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

A Wing, Shastri Bhawan,
New Delhi 110 001

Subject: Review application of M/s Kedrion Biopharma India Pvt. Limited against price fixation of “Anti-D Immunoglobulin, Intravenous Immunoglobulin, Anti-tetanus Immunoglobulin, Coagulation Factor VIII” vide NPPA order No. S.O. 2058(E), 2059(E) and 2060(E), dated 30.6.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 20.07.2017
2) NPPA notification under review S.O. No. 2058(E), 2059(E) and 2060(E), dated 30.6.2017
3) Record Note of discussions held in the personal hearing held in the matter on 21.11.2017.

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 Pvt. Limited (hereinafter called the petitioner) against notification S.O. No. 2058(E), 2059(E) and 2060(E), dated 30.6.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Anti-D Immunoglobulin, Intravenous Immunoglobulin, Anti-tetanus Immunoglobulin, Coagulation Factor VIII.

2. The petitioner has contended as under:

I. Company holds the requisite import license and registration as agent for Anti D Immunoglobulin, Coagulation Factor VIII -250 IU, Coagulation Factor VIII - 500 IU, IVIG (5 gm), RhoGAM (Anti D), Tetanus Immunoglobulin - 250 IU, Tetanus Immunoglobulin - 500 IU. The import license no. as well as the registration no. for the aforementioned products are as follows:

SR. NO	PRODUCT	IMPORT LIC NO	REGISTRATION NO
1.	ImmunoRho- Anti D immunoglobulin	BP-55-149	BP-55
2.	Coagulation factor VIII (Emoclot) 500 IU, 1000 IU	Bp-20-178	BP-71
3.	RhoGAM	BP-55-149	BP-11
4.	Tetanus Gamma 250, 500 IU	BP-55-149	BP-55

II. On 30th June, 2017, through S.O. No.2058(E), 2059(E) and 2060(E), the National Pharmaceutical Pricing Authority (NPPA) issued a notification pursuant to the DPCO, 2013, in exercise of the powers conferred by paragraphs 4, 6, 10, 11, 14, 16, 17 and 18 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated 30th

May, 2013 and S.O. 701(E) dated 10th March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers, and in supersession of the Order of the Government of India in the Ministry of Chemicals and Fertilizers (National Pharmaceutical Pricing Authority) No. S.O. 644(E), dated 2nd March, 2016, and SO 1040(E) dated 1st April 2017 in so far as it relates to formulation packs mentioned, except in respect of things done or omitted to be done before such supersession, and re-fixed the price after excluding excise duty levied prior to GST regime, being subsumed in the GST consequent to its implementation with effect from 1.7.2017 by applying the factor of 0.95905 on existing ceiling price, wherever applicable.

III. The price for Anti-D Immunoglobulin was fixed at Rs.2373.76 previously, however, in view of the abovementioned notification and SO No. 2060(E), price for the same has been reduced and re-fixed at Rs. 2321.45, pursuant to the powers of the NPPA under paragraph 4, 11 and 14 of DPCO, 2013. Similarly, for Coagulation Factor VIII (250 I.U.) - Koate - DVI from 3323.60/- to Rs.3,250.35/-, IVIG (5 Gms.) - Gammaked to Rs. 13,425.009, for Tetanus Immunoglobulin (250 I.U.) from Rs.1014.86/- to Rs. 992.49/- , for Tetanus Immunoglobulin (500 I.U.) to Rs.1654.41/-.

IV. Company submitted that the practical effect of re-calculating the average price of price-ceiling products, after they have been 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. The Applicant stated that the 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 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.

VII. The Applicant through this review seeks an oral hearing in this matter, which may be held at the earliest in the interest of justice as any further delay would have adverse implications on the operations of the Applicant.

VIII. The Applicant reserves the right to bring on record further data and other documents pertaining to the abovementioned subject matter at the time of the hearing or as soon as the same are collected or made available to the Applicant.

IX. In view of above company prayed as under:

a. Allow the Applicant to make oral hearings in support of this Application

b. Call for the record of the NPPA with regard to the impugned order and the data relied upon by the NPPA, in order to consider the facts and circumstances of the case.

c. Issue appropriate modification of the impugned order S.O. 2060(E) dated 30th June, 2017, 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.

3. **Comments of NPPA:**

I. Ceiling price ceiling price for **Anti-D Immunoglobulin**, was notified as Rs. 2321.45 vide S.O. 2060 (E) dated 30.06.2017. Ceiling price Rs. 137.27/ml was fixed for **Human Normal Immunoglobulin** vide S.O. 787 (E) dated 10.03.2017, and the same was revised to Rs. 134.25/ml vide S.O. 2058 (E) dated 30.06.2017. Similarly, ceiling price **Rs.992.49** was fixed for **Antitetanus Human Immunoglobulin 250 IU/500IU**, and **Rs.1654.51** vide S.O. 2060 (E) dated 30.06.2017. And the same was again revised to Rs. 139.98/ml vide S.O. 2400 (E) dated 28.07.2017. Ceiling price **Rs.3389.14** was fixed for **Coagulation Factor VIII-250 IU**, and Rs.8316.70 for **Coagulation Factor VIII-500 IU** vide S.O. 2400 (E) dated 28.07.2017.

II. The company has stated that correct methodology was not followed in arriving at the ceiling price of **Anti-D Immunoglobulin, Human Normal Immunoglobulin (Intravenous Immunoglobulin), Antitetanus Immunoglobulin, Coagulation Factor VIII**. The points raised by the company are not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013. Details are as follows:-

Company's Grievances	NPPA's comments
<p>Company stated that NPPA vide S.O. 2058 (E), 2059 (E), 2060 (E) dated 30.06.2017 reduced the price of formulation as detailed below:</p> <p><u>Anti-D Immunoglobulin:</u> Rs.2321.45/pack vide S.O. 2060 (E) dated 30.06.2017.</p> <p><u>Coagulation Factor VIII 250IU:</u> Rs. 3250.35/pack vide S.O. 2058 (E) dated 30.06.2017.</p> <p><u>Human Normal Immunoglobulin:</u> Rs.134.25/ml and 13425.00/100ml vide S.O. 2058 (E) dated 30.06.2017.</p> <p><u>Anti-Tetanus Immunoglobulin (250 IU)</u> Rs. 992.49/pack vide S.O. 2060(E) dated 30.06.2017.</p> <p><u>Anti-Tetanus Immunoglobulin (500 IU)</u></p>	<p>NPPA did not re-calculate the ceiling price and only excluded the excise components from the earlier notified ceiling price and re-notified the ceiling price (exclusive G.S.T.) for scheduled formulations.</p> <p>The same was again revised to Rs.3389.14 vide S.O. 2400(E) dated 28.07.2017.</p> <p>The same was revised to Rs.139.98/ml (13998.00/100 ml) vide S.O. 2400(E) dated 28.07.2017.</p>

<p>Rs. 1654.51/pack vide S.O. 2060(E) dated 30.06.2017.</p> <p>Company has stated that re-calculation of ceiling price is contrary to the principle of "Pharma-Economics" as enumerated under para 2(w) of DPCO, 2013.</p> <p>Company re-iterated that NPPA does not have the authority to calculate the prices for calculation already certified and pre-determination of ceiling price under Para 4&5, afresh except for changing in the prices as stipulated under Rule 16 of DPCO. The powers of NPPA are limited to Para 16. In fact, DPCO, 2013 does not allow any amendment or review of pricing based on any change such as a new custom duty or a change of raw-material.</p>	<p>Para 2(W) of DPCO, 2013 is applicable for retail price fixation of new drug, not for ceiling price fixation. Therefore, issue raised by company has no merit.</p>
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III. Company has not challenged any notification in respect of **Anti-D Immunoglobulin, Human Normal Immunoglobulin (Intravenous Immunoglobulin), Antitetanus Immunoglobulin, Coagulation Factor VIII-250 IU and 500 IU.**

4. During the personal hearing, the petitioner company made following further submissions –

1. On 30.06.2017, through S.O. No.2058(E) and 2060(E), the National Pharmaceutical Pricing Authority (NPPA) issued a notification pursuant to the DPCO, 2013, in exercise of the powers conferred by paragraphs 4,6,10,11,14,16,17 and 18 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated 30.05.2013, and S.O. 701(E) dated 10.03.2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers, and in suppression of the Order of the Government of India in the Ministry of Chemicals and Fertilizers (NPPA) No. S.O. 644(E) dated 2.03.2016 and SO 1040(E) dated 1.04.2017 in so far as it relates to formulation packs mentioned, except in respect of things done or omitted to be done before such suppression, and re-fixed the price after excluding excise duty levied prior to GST regime, being subsumed in the GST consequent to its implementation with effect from 1/7/2017 by applying the factor of 0.95905 on existing ceiling price, wherever applicable.
2. The price for Anti-D Immunoglobulin was fixed at Rs.2373.76 previously, however, in view of the abovementioned notification and SO No. 2060(E), price for the same has been reduced and re-fixed at Rs.2321.45, pursuant to the powers of the NPPA under paragraph 4, 11 and 14 of DPCO, 2013. Similarly, for Coagulation Factor VII(250 I.U)- Koate- DVI from 3323.60/- to Rs. 3,250.35, IVIG (5 Gms.)- Gammaked to Rs. 13,425.009, for Tetanus Immunoglobulin (250 I.U.) from Rs. 1014.86/- to Rs. 992.49, for Tetanus Immunoglobulin (500 I.U.) to Rs. 1654.41.

3. Company submitted that the 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, and affixation of pricing initially as per Rule 4(1) r/w Rule 5(1) of DPCO. Furthermore, it is extremely pertinent to remark that DPCO, 2013 has no enabling clause which allows any change in the pricing except for Paragraph 16. The DPCO, 2013 in fact does not allow for any amendment or review of pricing based on any change, such as new custom duties or a change of raw materials.
4. It is a well settled law that a public body invested with statutory powers such as those conferred upon the Corporation must take care not to exceed or abuse its powers. The administrative authority, which is created under a scheme, cannot act beyond the provisions of the scheme itself. It must keep within the limits of the authority committed to it. It must act in good faith, reasonably and within its purview. The exercise of power whether legislative or administrative should be set aside if there is manifest error in the exercise of such power or the exercise of the power is manifestly arbitrary. The statutory authorities are bound to exercise their power only within the four corners of the rules framed thereunder and not de hors the same.
5. The DPCO 2013, order is subject to the principles of equality and reasonableness, and an act of subordinate legislation in itself. As held in *Shri Sitaram Sagar Company Ltd & Anr. Vs. Union of India & Anr.*, (1990) 3 SCC 223, by the Hon'ble Supreme Court: *"Price fixation is in the nature of a legislative action even when it is based on objective criteria rounded on relevant material. No rule of natural justice is applicable to any such order. It is nevertheless imperative that the action of the authority should be inspired by reason. The Government cannot fix any arbitrary price. It cannot fix prices on extraneous considerations: Renusagar, (supra). Any arbitrary action, whether in the nature of a legislative or administrative or quasi-judicial exercise of power, is liable to attract the prohibition of Article 14 of the Constitution. The principle of equality enshrined in Article 14 must guide every state action, whether it be legislative, executive, or quasi-judicial."*
6. Company submitted that price fixation of drugs has been similarly held by the Hon'ble Supreme Court to be subject to judicial review for arbitrariness and reasonableness. It has further been held to require natural justice as the determination of a price is an act of quasi-judicial nature.
7. Company further submitted that the impugned notification dated 30.06.2017, 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 Section 3. Moreover, NPPA does not confer any inherent power to amend the DPCO 2013, which may only be amended by the delegating authority after due consultation. Therefore, the said action adopted by NPPA is arbitrary, without application of mind, unreasonable and against the principles of natural justice.
8. The NPPA's averments that the price has not been changed, but merely adjusted to account for imposition of GST are untenable. As per the Goods and Services Tax, 2017, GST is chargeable by the buyer, and not adjustable on the price charged by the seller. Thus, the change in the maximum price is not, as averred, to merely exclude "the excise components from the earlier notified

ceiling price and re-notified the ceiling price (exclusive G.S.T.). The NPPA has no such powers under Rule 4(1) or Rule 16 of DPCO 2013.

9. Company submitted that NPPA's representatives stated in the hearing dated 21.11.2017, that they have re-fixed the price of Anti D Immunoglobulin, Coagulation Factor VII-250 IU, Coagulation Factor VII-500 IU, IVIG (5 gm), RhoGAM (Anti D), Tetanus Immunoglobulin – 500 IU after excluding excise duty levied prior to GST regime, being subsumed in the GST consequent to its implementation with effect from 1/07/2017 by applying the factor of 0.95905 on existing ceiling price in reference to the Rule 2(y), DPCO 2013, i.e. **“price to retailer”** means the price of a drug at which it is sold to a retailer which includes duties and does not include local taxes. It is submitted that the reliance placed by NPPA on Rule 2(y), DPCO 2013 for the re-fixation of price of is untenable on the ground that price limitation does not include taxation and therefore, price ceiling cannot be reduced. Moreover, if additional or new legislation has been added to the total cost by increasing the taxation on the drug, then it does not imply that the price ceiling would be affected by the same.
10. Company also submitted that the said notification of the NPPA is barred by the rules laid down in Section 171 of the Goods and Services Tax Act, 2017. It is submitted that sub-section (2) of Section 171 of the act provides for establishment of an authority by the Central Government for an anti-profiteering clause in order to ensure that business pass on the benefit of reduced tax incidence on goods and services or both to the consumers.
11. Company submitted that as per the letter dated 10.11.2017, of Secretary, Govt. of India, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, it is stated that the Applicant is required to submit a self-certification regarding 100% IPDMS compliance in the said matter, for the review to be maintainable. It is pertinent to point out that Rule 31 of DPCO 2013, which confers the Power to hold a review does not prescribe any such mandate of the aforesaid compliance. Thus, making such a condition *sine qua non* for hearing of the appeal is *ultra vires* of the DPCO. Further, the Applicant is 100% compliant and no current notice for non-compliance has been served or is pending. Furthermore, any past notices have been complied with and remedial action has been duly taken care of.
12. Therefore, in view of the submissions made herein above, the Applicant prays the following as under:
 - a) Allow the Applicant to make oral hearings in support of this Application;
 - b) Call for the record of the NPPA with regard to the impugned order and the data relied upon by the NPPA, in order to understand the facts and circumstances of the case;
 - c) Issue Appropriate modification of the impugned order S.O. 2060(E) dated 30.06.2017, 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.

5. **Examination:**

NPPA, vide its S.O. 2058(E), SO 2059(E) and SO 2060(E), dated 30.6.2017, fixed prices of specified pharma formulations after excluding the excise duty levied prior

to GST regime by applying a factor of 0.95905 on the prevailing prices, wherever applicable. Company contended that NPPA does not have the authority to calculate the prices for formulation already certified and determination of pre-ceiling prices under Para 4&5, afresh except for changing in the prices as stipulated under Rule 16 of DPCO.

5.2 It may be mentioned here that NPPA has not re-fixed the scheduled prices of Anti D Immunoglobulin, Coagulation Factor VIII-250 IU, Coagulation Factor VIII-500 IU, IVIG (5 gm), RhoGAM (Anti D), Tetanus Immunoglobulin – 500 IU, but only re-calculated the ceiling prices of certain formulations, by excluding the excise component from the earlier notified ceiling price and re-notified the ceiling price (exclusive GST) for scheduled formulations.

5.3 Department of Revenue, Ministry of Finance vide its Gazette Notifications No.12/2012-Customs and 12/2012-Central Excise has exempted certain formulations from Central Excise and Counter Vailing Duty (CVD). However, Department of Revenue, Ministry of Finance vide its notification No.6/2016-Customs, dated 28.01.2016 has removed the exemption on certain formulations.

5.4 In view of the above notifications of Department of Revenue, Ministry of Finance, NPPA revised the prices of certain formulations after excluding excise duty levied prior to GST regime and applied the factor of 0.95905 on those formulations which were earlier exempted from excise component at the time of fixation of ceiling price, but later on excise exemption was removed by Department of Revenue, Ministry of Finance vide its notification No.6/2016-Customs, dated 28.01.2016. Therefore, revision of ceiling prices by applying factor of 0.95905 by NPPA while fixing the ceiling price of post-GST regime is in order.

5.5 It may also be mentioned here that NPPA revised the ceiling price of Coagulation Factor VIII 250IU to Rs.3250.35/pack vide SO 2058(E), dated 30.6.2017, by applying a factor of 0.95905. However, the same was again revised to Rs.3389.14/pack (upward revision) vide SO 2400(E), dated 28.07.2017 by applying a factor of 1, as excise exemption was not removed by Department of Revenue vide its notification No.6/2016-Customs, dated 28.01.2016. Similarly, in the case of Human Normal Immunoglobulin, the ceiling price revised to Rs.134.25/ml vide SO 2058(E), dated 30.6.2018, was again upwardly revised to Rs.139.98/ml, vide SO 2400(E), dated 28.7.2017.

5.6 In view of the above, the revision of ceiling prices of post-GST regime by NPPA is in order. Hence, the request of the company cannot be considered and the review application may be rejected.

6. **Government Order:**

“Applying factor of 0.95905 by NPPA while revising the ceiling prices of those formulations on which excise exemption was removed by Department of Revenue, Ministry of Finance vide its notification No.6/2016-Customs, dated 28.01.2016 for post-GST regime is in order. Hence, the request of the company cannot be considered and the review application stands rejected.”

Issued on this date, the 21st day of March, 2018.

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

To

- 1. M/s. Kedrion Biopharma India Pvt. Limited,
House No.R265C, Ground Floor,
Greater Kailash, Part-I,
New Delhi-110048.**
- 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**