No.31015/05/2020-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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A Wing, Shastri Bhawan,
New Delhi-110 001.

Order

1. This is an order disposing of a review application dated 15.04.2020, filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Bharat Serums and Vaccines Limited (hereinafter called the applicant) against notification S.O. No. 1241(E), dated 03.04.2020 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Human Normal Immunoglobulin 16.5%.

2. The main contentions of the applicant are as given below:

2.1 Company mentioned that the NPPA, in exercise of the powers conferred by paragraphs 4, 6, 10, 11, 14, 16, 17 and 18 of the Drugs (Prices Control) Order 2013, has fixed and notified the ceiling price of formulation Human Normal Immunoglobulin (Solution for infusion 16.5%) at Rs. 379.83 per ml vide S.O. 1241(E) dated 3.4.2020 which was uploaded on the website of the NPPA on 6.4.2020.

2.2 Company submitted that "Display of Draft Version of Proposed Price Calculation Sheet for proposed ceiling price" was uploaded on the website of NPPA on 19th March, 2020 in respect of formulation "Human Normal Immunoglobulin 16.5%" while the Authority approved its ceiling price in its meeting on 31.3.2020. Normally and also as per past practice followed by the NPPA, a period of 10 working days is given for calling of the comments if any from the manufacturers. However, our company's comments were not awaited before approving the price.

2.3 Company further submitted that the NPPA has erred in fixing the ceiling price of formulation "Human Normal Immunoglobulin 16.5%" as the price has been fixed under Para 6 of the DPCO 2013 by applying reduction as per Monopoly condition and also not taking the correct data.

2.4 Since the price fixation of "Human Normal Immunoglobulin 16.5%" is not strictly in consonance with the provisions of the DPCO, 2013, being aggrieved by such price fixation/ notification vide S.O. 1241(E) dated 3.4.2020, Company filed this review application under Para 31 of the DPCO within the

prescribed limit of 30 days of date of publication of the notification (though uploaded on 6.4.2020) in respect of above mentioned formulation on the following grounds:-

(i) The Computation of Ceiling Price has been done on the basis of data prevailing in Aug 2015. This is not correct and is against the provisions of the DPCO, 2013.

(ii) Para 9 of the DPCO 2013 stipulates that the market based data for fixing the ceiling price of a scheduled formulation due to a revision in the first schedule shall be the data available for the month ending immediately before six month of notification of revision in the first schedule. Accordingly, the data for the month of August 2019 should have only been considered by the NPPA in calculation of the ceiling price.

(iii) Company has been submitting data to the NPPA in the prescribed Forms III and V since July 2016 on regular basis. This data should have been considered by the NPPA and the ceiling price should have been computed based on this data by giving annual WPI increase for the year 2019 w.e.f. 1st April, 2020.

(iv) It is observed that revised ceiling price has been arrived at by applying GST factor of 0.95905. The formulation "Human Normal immunoglobulin 16.5%" is excisable with "NIL" rate of excise duty. Accordingly, the multiplication factor should have been considered as '1' instead of factor of 0.9590. Hence the Ceiling Price as arrived in the computation sheet needs to be revised post GST.

(v) It is further seen that the ceiling price has been calculated under Para 6 of the DPCO, 2013 by applying reduction as per Monopoly condition. Company mentioned that there are other manufacturers also of this formulation and they are not the only manufacturer. As such calculation under Para 6 does not seem to be correct. Company has been making efforts to get the details of other manufacturers of this formulation from all sources viz Pharmatrac etc. Considering the current situation of COVID-19 epidemic, they have not been able to get the same immediately and it may take some more time.

2.5 In view of the position stated above, company submitted that there is no justification for price fixation of "Human Normal Immunoglobulin 16.5%" in the manner as adopted by the NPPA and thus this ceiling price notification needs to be withdrawn immediately and the NPPA may be directed to reconsider the price notification and revise it in accordance with the provisions of Para 4 & Para 9 respectively.

2.6 The applicant confirmed that as required under Para 31 they have implemented the ceiling price notified under S.O. 1241(E) dated 3.4.2020 before filing the Review Application. Company has uploaded the relevant Form V in this regard on IPDMS Portal of NPPA. Company has also issued necessary circular to all their distributors to bring the revised price to the knowledge of all retailers under their regions.

3. **Comments of the NPPA:-**

3.1 The NPPA stated that the notification for ceiling price fixation of "Human Normal Immunoglobulin 16.5%" was issued on 03.04.2020 after uploading the draft working sheet for 10 working days on NPPA's website (uploaded on 19.03.2020) and hence the contention of the company regarding the uploading of draft working sheet, is not tenable.

3.2 The NPPA has been consistently following the data for the month of August, 2015 while fixing the ceiling price of scheduled formulations. However, to arrive at the present ceiling price, the Wholesale Price Index (WPI) for the relevant years is allowed. Further, based on amended para 9(1) of the DPCO, 2013, the ceiling price has been calculated based on the data available in Pharmatrac. Hence, the contention of the company regarding the data issue is not tenable.

3.3 The contention of the company regarding the applicability of GST factor of '1' instead of '0.95905' which was considered in the calculation needs to be cross checked from the documents submitted from the company.

3.4 From the Pharmatrac database, it was observed that only one company was manufacturing/ marketing the formulation. Accordingly, the monopoly condition, as applicable under para 6 of the DPCO, 2013, has been considered in the calculation of ceiling price. Hence, the contention of the company is not tenable.

4. **Examination:**

4.1 The applicant has made the following main contentions: -

a. *The NPPA did not follow the past practice of uploading the draft working giving clear 10 working for calling of the comments if any from the manufacturers. The company's comments were not awaited before approving the price;*
b. *The computation of ceiling price has been done on the basis of data prevailing in Aug 2015. Para 9 of the DPCO 2013 stipulates that the market-based data for fixing the ceiling price of a scheduled formulation due to a revision in the first schedule shall be the data available for the*

month ending immediately before six months of notification of revision in the first schedule. Accordingly, the data for the month of August 2019 should have only been considered by the NPPA in calculation of the ceiling price by giving annual WPI increase for the year 2019 w.e.f. 1st April, 2020.

c. *The formulation "Human Normal immunoglobulin 16.5%" is excisable with "NIL" rate of excise duty. Accordingly, the multiplication factor should have been considered as '1' instead of factor of 0.9590.*

d. *The ceiling price has been calculated under Para 6 of the DPCO, 2013 by applying reduction as per monopoly condition. There are other manufacturers also of this formulation and they are not the only manufacturer. As such calculation under Para 6 does not seem to be correct.*

4.2 As regards contention at point (a), the NPPA uploaded the draft working sheet on 19.03.2020 whereas the ceiling price was notified on 03.04.2020. Hence, sufficient time was given to the manufacturers for raising objections, if any, before notifying the ceiling price. Hence, the contention of the company is not tenable.

4.3 Regarding the contention of the company at point (b) that the data for the month of August 2019 should have been considered by the NPPA in calculation of the ceiling price, the formulation Human Normal Immunoglobulin 16.5% was included in the revised scheduled (NLEM 2015) of the DPCO and is listed at Section 22.2.6. The provision in para 9(5) of the DPCO about reference data is as under: -

"The market-based data for fixing the ceiling price of a scheduled formulation due to a revision in the first schedule shall be the data available for the month ending immediately before six months of notification of revision in the first schedule."

The formulation was included in the revised scheduled vide SO 701(E), dated 10.3.2016. The ceiling price of the formulation was fixed for the first time after inclusion of the revised schedule. Therefore, for fixing the ceiling price, the NPPA has rightly considered the data of August, 2015 available with pharmatrac (and given impact of WPI for the subsequent years), as was done for all other scheduled formulations in the revised schedule. Hence, the contention of the company that the NPPA should have considered August, 2019 data is not acceptable.

4.4 As regards the issue of applicability of GST factor on excisable products, raised in point (c) above, the company has submitted supporting documents in support of its claim. The NPPA has also admitted in its comments furnished in

response to the company's review applicable that calculation needs to be cross checked from the documents submitted from the company.

4.5 In point (d) above, the company raised the issue that applying reduction as per monopoly condition seems to be not correct as there are other manufacturers also of this formulation and they are not the only manufacturer. The NPPA considered the Pharmatrac data of August, 2015 as per provision in para 9(5) of the DPCO. As per the Pharmatrac database, only one company was manufacturing/ marketing the formulation at that time, hence the monopoly reduction was applied as per provision contained in para 6 of the DPCO. Hence, the applicability of reduction as per monopoly condition is in order.

4.6 The points raised by the company in its review application, except the point of applicability of GST factor on excisable products, are not tenable. Hence, the NPPA needs to verify the applicability of GST factor by cross checking the documents furnished by the company and revise the ceiling price of the formulation, if necessitated on the basis of verification, on merit.

5. **Decision:**

The NPPA is hereby directed to verify the applicability of GST factor by cross checking the documents furnished by the company and revise the ceiling price of the formulation, if necessitated on the basis of verification, on merit.

Issued on this, the 14th day of December, 2020.

(Navdeep Rinwa)
Joint Secretary
For and on behalf of the President of India

Copy to: -

1. M/s Bharat Serums and Vaccines Limited, 17th Floor, Hoechst House, Nariman Point, Mumbai-400021.
2. The Chairperson, National Pharmaceutical Pricing Authority, YMCA Cultural Centre Building, New Delhi-110001.
3. PS to Hon'ble Minister(C&F), Shastri Bhawan, New Delhi for information.
4. PS to MoS(C&F), Shastri Bhawan, New Delhi for information.
5. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
6. T.D., NIC for uploading the order on Department's Website.