

No. 31015/82/2014-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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B Wing, Janpath Bhavan, New Delhi

O R D E R BY REVIEWING AUTHORITY UNDER PARA.31 OF DPCO, 2013

Subject: Review application of M/s. Bharat Serum and Vaccines Ltd. against fixation/revision of Ceiling prices of Rabies Immunoglobulin Injection 150 IU/ml vide NPPA notification S.O. No. 3350(E) dated 5/11/2013 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013).

Ref. 1) Applicant Review application dated 15.11.2013
2) NPPA notification under review S.O. No. 3350(E) dated 5/11/2013
3) Record Note of discussions held in the personal hearing held in the matter on 27.2.2014

Whereas National Pharmaceutical Pricing Authority (NPPA), Government of India, vide price fixation Order S.O. No. 3350(E) dated 5/11/2013 fixed/revised ceiling price Rabies Immunoglobulin Injection 150 IU/ml under DPCO, 2013 included in Section 19.2 (sera and Immunoglobulin) in Schedule-I of the Order.

2. And whereas aggrieved by the above notification, M/S Bharat Serum and Vaccines Ltd. (hereinafter referred to as the Petitioner) submitted review application dated 15.11.2013 under para.31 of DPCO, 2013 for the review of NPPA Price fixation Order S.O.No.3350 (E) Dated 5.11.2013 fixing Ceiling price of Rabies Immunoglobulin Injection 150 IU/ml under DPCO, 2013.

3. The grievance of the Petitioner raised in their review application dated 15.11.2013 were sent to NPPA and the comments of NPPA thereon were given to the Petitioner through the Record Note of discussions held in the personal hearing on 27.2.2014. Record Note of discussion is made integral part of the review order. After considering the comments of NPPA, the Petitioner has raised the following points, on which comments given by NPPA representative, during the hearing and Government's comments on the issue is recorded subsequently against each point:

- i) Rabies Immunoglobulin 150 IU/ml is the formulation covered under DPCO, 2013 Schedule I (section 19.2.5) while 300 IU/ml is not covered under DPCO 2013.
- ii) While fixing the price, NPPA had included price of Abhay RIG which is 300 IU/ml. which is not as envisaged in the DPCO.
- iii) Formulation pertaining to M/s synergy Diagnostics and Kamada Ltd. have not been included in the price fixation data by NPPA.

4. The petitioner claimed that Abhay RIG is an Equine Rabies Immunoglobulin and made from Equine Plasma at recommended dosages of 40 IU per kg body weight whereas their Brand Berirab P is human Rabies Immunoglobulin and is made from human Rabies Plasma at recommended dosage of 20 IU per kg body weight. These are two different drugs with different dosage and different source. It is incorrect to compare the two drugs.

NPPA Comments

5. NPPA representative told that NPPA has fixed the price of Rs. 1255.84/ml vide S.O. 3350(E) dated 05.11.2013 on the basis of data collected from the companies i.e. M/s Bharat Serums & Vaccines Ltd. and Indian Immunological Ltd. as the IMS-Health was not having relevant information in their data base.

6. After fixation of this price, NPPA received representations from (1) M/s Synergy Diagnostics dated 13.11.2013; and (2) Reliance Life Sciences dated 18.11.2013. Both the above companies contended that the price fixed for the subject formulation is incorrect due to the comparison of two different products and two different processes of production. According to them, Rabies Immunoglobulin is manufactured from Human Plasma, by M/s Bharat Serums & Vaccines and M/s Synergy Diagnostics, while M/s Indian Immunological is manufacturing it from Equine which is having a concentration of 300 IU/ml, thus, they requested to exclude their data. However, M/s Reliance Life Sciences has not furnished any data, as they are yet to get the manufacturing license.

7. M/s Synergy Diagnostics on its own obtained a clarification dated 05.12.13 from Joint Drugs Controller (India), CDSCO West Zone, Mumbai stating that both the products having 150 IU/ml and 300 IU/ml are different and have different sources also.

8. The Authority in its 10th meeting considered the clarification issued by Joint Drug Controller West Zone and directed that the views of DCG(I) may be obtained. The matter was referred to DCG(I) vide letter dated 06.01.2014, followed by D.O. reminder dated 16.01.2014. DCG(I) vide its letter dated 30.01.2014 informed that with regard to Rabies Immunoglobulin 150IU/ml, it is produced by two different methods i.e. equine based and human plasma based. Both the products have different specification and different usage and method of process and also figure separately in the Indian Pharmacopeia (I.P.). However, it seems to NPPA that the reply is not conclusive.

Department's Comments

9. A clarification on the two strength viz 150 IU/ml and 300 IU/ml was sought by the Department from DCGI who has clarified that Rabies immunoglobulin (Human Rabies Immunoglobulin) and Rabies Antiserum are included in the Indian Pharmacopies as two separate monographs.

10. First, Rabies immunoglobulin (Human Rabies Immunoglobulin) is obtained from plasma from donors immunized against Rabies. The stated potency under the IP is not less than 150 units per ml.

11. Second, the drug Rabies Antiserum is obtained by purification of hyper immune serum or plasma of healthy horse or other suitable animals having specific activity of neutralizing the rabies virus. Rabies Antiserum contains not less than 300 units per ml. It is added by DCGI that the two products are different in nature in terms of source potency, specification etc.

It was decided to refer the issue to Standing Technical Committee (STC)

Standing Technical Committee

12. A Standing Technical Committee was constituted vide OM dated 20.12.2013 to decide the technical issues raised by various companies during the review under para 31 of DPCO, 2013. The Experts in the Committee included members from Department of Science and Technology; Central Drugs Standards Control Organisation (CDSCO); NIPER, Mohali; Department of Biotechnology; Karnataka Antibiotics and Pharmaceutical Limited (KAPL).

13. The Committee after consideration of DCGI letter dated 07.04.2014 recommended that the two formulations with strength 150 IU/ml and 300 IU/ml have different source and to be treated differently. The Committee also noted that DPCO 2013 covers only rabies immunoglobulin with strength 150 IU/ml and the formulations with strength 300 IU/ml is outside purview of DPCO.

Government's Decision:

14. Based on the recommendation of the Standing Technical Committee it is recommended that NPPA may be directed to consider the PTR of rabies immunoglobulin 150 IU/ml only, since rabies immunoglobulin 300 IU/ml is not within the purview of DPCO, 2013. The formulation of Abhay RIG with 300 IU/ml may not therefore, be taken into consideration while fixing price of rabies immunoglobulin 150 IU/ml. The company had also raised the point regarding formulation pertaining to synergy manufactured by Kamada Ltd. NPPA should consider that formulation also if it is 150 IU/ml and falls within the scope of price calculation under provisions of DPCO 2013. NPPA may also exclude the possibility of any other formulation in the market with 150 IU/ml. Since no differential pricing has been recommended by the Standing Technical Committee only one product with strength 150 IU/ml is included. The question of differential pricing and amendment of DPCO 2013 as suggested by NPPA or otherwise does not arise.

15. Based on the above and other documents on record, the Government has decided as under:

“NPPA may be directed to consider the PTR of rabies Immunoglobulin with 150 IU/ml only.”

Issued on this date 20th January, 2015.

(Anil Jain)

Under Secretary to the Govt. of India
For and on behalf of the President of India

To

1. M/s. Bharat Serum and Vaccines Ltd.,
17th Floor, Hoechst House,
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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. Sr. PPS to Secretary (Pharma), Shastri Bhawan, New Delhi for information.