

No. 31015/97/2017-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 Biological E Limited against price fixation of their formulations “Japanese Encephalitis Vaccine-with Dosage form and strength-(1)” 4 mcg to 6 mcg and (2) upto 3 mcg” vide NPPA order No. S.O. 3722(E) dated 23.11.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application, dated 19.12.2017
2) NPPA notification under review S.O. No. 3722(E) dated 23.11.2017
3) Record Note of discussions held in the personal hearing on 09.01.2018.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Biological E.Limited (hereinafter called the petitioner) against notification S.O. No. 3722(E) dated 23.11.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of their formulations Japanese Encephalitis Vaccine-with Dosage form and strength-(1) 4 mcg to 6 mcg and (2) upto 3 mcg.

2. The petitioner has contended as under:

- I. They manufacture Japanese inactivated vaccine (human) into independent dosage pack formats meant for different age groups.
 - a. JEEV 3mcg (for 1 to 3 years age group)-0.5 ml vial & 0.5 ml Prefilled syringe.
 - b. JEEV 6mcg (for 3 years and above age group)-0.5 ml vial & 0.5 ml Prefilled syringe.

NPPA has displayed draft version of proposed price calculation sheet for notified ceiling prices for **Japanese Encephalitis vaccine** on NPPA’s website on 26.10.2017.

Company pointed out that Japanese inactivated vaccine (human) is manufactured by two companies in India, M/s Biological E Ltd. (BEL & M/s Bharat Biotech International Ltd. (BBIL). Company noticed that there are significant errors in the calculation of ceiling price as detailed below:

- i) NPPA had considered wrong PTR. Regarding the price considered under PTR for **Japanese Encephalitis vaccine** (4 mcg to 6 mcg pack), Company observed that NPPA has considered PTR for the products wrongly and the operating prices in the market for brands of two companies (BEL & BBIL) are different from the price considered.
- ii) Company further observed that the same unique number has been used for both dosage forms of 3 mcg and 4 to 6 mcg.

Company also stated that in spite of their clear information and data supported by August, 2015 invoice copies, product level of both the companies, NPPA has ignored the same and mechanically adopted the same figure.

Company is of the opinion that ceiling prices notified for **Japanese Encephalitis vaccine 4 mcg to 6 mcg** and **Japanese Encephalitis vaccine** for 3 mcg in accordance with the methodology prescribed for determination for ceiling prices of schedule formulation under Drug (price control) order 2013.

Company reiterated that their entire data concerning both the above pack is available with the NPPA in IPDMS form and hence NPPA may be directed to re-determine the ceiling price for both the above packs and dosages separately in accordance with the provisions of Drugs (Prices Control) order 2013 and set aside the ceiling price notified under SO No. 3722(E)/23.11.2017

3. **Comments of NPPA:**

- I. The ceiling price of **Japanese Encephalitis vaccine with dosage form and strength –(1) 4 mcg to 6 mcg and** was notified as Rs. 632.95 per pack and Rs.482.22 per pack was notified for **Japanese Encephalitis vaccine with dosage form and strength** upto 3 mcg.
- II. The company has stated that correct methodology was not followed in arriving at the ceiling price of **Japanese Encephalitis vaccine with dosage form and strength –(1) 4 mcg to 6 mcg and (2) upto 3 mcg**. 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 they manufacture Japanese inactivated vaccine (human) into independent dosage pack formats meant for different age groups.</p> <p>c. JEEV 3mcg (for 1 to 3 years age group)-0.5 ml vial & 0.5 ml Prefilled syringe.</p> <p>d. JEEV 6mcg (for 3 years and above age group)-0.5 ml vial & 0.5 ml Prefilled syringe.</p> <p>NPPA has displayed draft version of proposed price calculation sheet for notified ceiling prices for Japanese Encephalitis vaccine on NPPA's website on 26.10.2017.</p> <p>Company pointed out that Japanese inactivated vaccine (human) is manufactured by two companies in India, M/s Biological E Ltd. (BEL & M/s Bharat Biotech International Ltd. (BBIL). Company noticed that there are significant errors in</p>	<p>NPPA notified ceiling price Rs. 632.95 per pack for Japanese Encephalitis vaccine 4 mcg to 6 mcg and Rs. 482.22 per pack for Japanese Encephalitis vaccine upto 3 mcg, considering the data provided by Pharma trac for the period of August, 2015 and data furnished by the companies.</p> <p>The draft working sheet was uploaded on 11.05.2017 in NPPA website within 10 clear working days and the company made a representation about its differentiation into two categories but did not say anything about PTR/MAT value. Accordingly the same was put up before the committee of experts (C.O.E.) under para 11 (3 &4) of DPCO, 2013 and based on recommendations of C.O.E. the ceiling price was fixed into two categories. Hence, there is no merit</p>

the calculation of ceiling price as detailed below:

iii) NPPA had considered wrong PTR. Regarding the price considered under PTR for **Japanese Encephalitis vaccine** (4 mcg to 6 mcg pack), Company observed that NPPA has considered PTR for the products wrongly and the operating prices in the market for brands of two companies (BEL & BBIL) are different from the price considered.

iv) Company further observed that the same unique number has been used for both dosage forms of 3 mcg and 4 to 6 mcg.

Company also stated that inspite of their clear information and data supported by August, 2015 invoice copies, product level of both the companies, NPPA has ignore the same and mechanically adopted the same figure.

Company is of the opinion that ceiling prices notified for **Japanese Encephalitis vaccine** 4 mcg to 6 mcg and **Japanese Encephalitis vaccine** for 3 mcg in accordance with the mythology prescribed for determination for ceiling prices of schedule formulation under Drug (price control) order 2013.

Company reiterated that their entire data concerning both the above pack is available with the NPPA in IPDMS form and hence NPPA may be directed to re-determine the ceiling price for both the above packs and dosages separately in accordance with the provisions of Drugs (Prices Control) order 2013 and set aside the ceiling price notified under SO No. 3722(E)/23.11.2017

in the contention of the company with respect to PTR/MAT value.

The petitioner have not given any evidence of PTR of other company i.e. Bharat Biotech International Ltd. in their representation dated 06.11.2017. The petitioner have also not given any PTR of his own products. Pharmatrac has confirmed the price of Rs. 350/- taken in calculation is correct and claim of petitioner for product JENVEC is not correct.

Issues raised by the company have no merits as ceiling prices for the formulations under reference has been fixed in accordance with the provision of DPCO 2013.

III. Company has not challenged S.O. No. 3722(E) dated 23.11.2017 in High Court.

4. During the personal hearing, the representatives of the petitioner company submitted that the PTR taken into account by NPPA for determining ceiling price of Japanese Encephalitis Vaccine of 6mcg at Rs.750.00 per pack is incorrect and erroneous. The company enclosed its Invoice dated 23rd Jul 2015 along with their objection letter dated 3rd November 2017 acknowledged by NPPA on 6th November 2017. Company again enclosed the copy of invoice dated 23rd Jul 2015 for reference

and considering. Company stated that, the actual PTR of their product of 6mcg is Rs.753.04 per pack. The company further submitted that it has independent pack size of Japanese Encephalitis 3mcg for the age category of 1 to 3 years (Paediatric dose). It has further submitted that the ceiling price for 3mcg pack shall be determined independently as per Para 11(3) of DPCO 2013. The ceiling price can't be determined on proportionate basis as the cost don't move in linear progression for Parenteral (Injectable).

The company also submitted that it has objected the calculation sheet displayed on the NPPA website on 26th October 2017 within the time vide its letter dated 3rd November 2017 and the same was acknowledged by NPPA on 6th November 2017.

The Company also submitted that the Japanese Encephalitis vaccines made by two companies in the market are completely different in Therapeutic terms like Dosage, Virus strain etc. and therefore cannot be clubbed together to derive the ceiling prices in the 4 to 6mcg segment.

Company requested to direct NPPA to take into account correct PTRs and re-determine ceiling prices separately for 6mcg and 3mcg of Japanese Encephalitis.

4.2 NPPA representative, in addition to the comments already submitted on this review hearing, further submitted that the ceiling price of the formulation Japanese Encephalitis injection was fixed based on the recommendation of the Committee of Experts under para 11(3&4) of DPCO, 2013. Further, with respect to PTR issue, the same was not considered by the Authority while fixing the ceiling price since the company has not submitted the requisite information/ documents as per the extant OM within 10 clear working days after the proposed draft working sheet was uploaded in NPPA's website.

5. Examination:

In the instant case, the company's contention is that NPPA had considered wrong PTR. Regarding the price considered under PTR for **Japanese Encephalitis vaccine** (4 mcg to 6 mcg pack), Company observed that NPPA has considered PTR for the products wrongly and the operating prices in the market for brands of two companies (BEL & BBIL) are different from the price considered. Company submitted that inspite of their clear information and data supported by August 2015 invoice copies, product labels of both the Companies, NPPA has ignored the same and mechanically adopted the same figures which are entirely erroneous and grossly mistaken.

Company in its representation to NPPA dated 3.11.2017 stated that the PTR of JENVAC 0.5ml PFS of Bharat Biotech International Limited is Rs.931.15/pfs. On going through the representation, it is noticed that no documentary proof about actual PTR/MAT value of M/s Bharat Biotech International Limited has been submitted by the company. Company only enclosed the Invoice of its own company, which states the PTR of Rs.753.04 per pack. On going through the calculation sheet, it is seen that NPPA considered the PTR of the Biological E.Limited as Rs.750/-. The difference in both the PTRs is insignificant, considering the price of the subject formulation. As regards the claim of PTR of M/s Bharat Biotech International Limited, NPPA stated that Pharmatrac has confirmed the price of Rs.350/- and the price taken in the calculation is correct and claim of petitioner for product JENVEC is not correct. **Even on the date of hearing, i.e. on 9.1.2018, the company did not submit any documentary proof about actual PTR of Bharat Biotech International Ltd.** NPPA fixed the ceiling prices

of subject formulations based on the data furnished by Pharmatrac for the month of August, 2015.

The representation submitted by the company was referred to Committee of Experts under para 11(3&4) of DPCO 2013. On the basis of recommendations of the committee of experts, the ceiling price was fixed into two categories.

As regards the observation of the company, about the same unique number being used for both dosage forms of 3 mcg and 4 to 6 mcg., has got no relevance, as in Schedule I of DPCO, 2013, the unique number is 22.3.1.5 for Japanese encephalitis vaccine. The different prices of dosage forms, i.e. (i) upto 3 mcg and (ii) 4 to 6 mcg, have been fixed based on the recommendation of Committee of Experts for the same formulation, having unique number 22.3.1.5 in Schedule I of DPCO, 2013.

In view of the above, the ceiling prices of the subject formulations have been fixed as per provisions of DPCO, 2013 and there is no merit in the review petition of the company and may be rejected.

6. **Government Decision:**

“The ceiling prices of Japanese Encephalitis Vaccine-with Dosage form and strength - (1) 4 mcg to 6 mcg and (2) upto 3 mcg have been fixed on the basis of recommendations of the Committee of Experts. There is no merit in the contention of the company with respect to PTR/MAT value as the petitioner company has not submitted any documentary proof in support of actual PTR of other company i.e. Bharat Biotech International Ltd. Therefore, the review application of the company stands rejected.”

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

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

To

1. **M/s. Biological E Limited,
Plot No. 623-H, Road NO. 35,
Jubilee Hills,
Hyderabad-500033, Telangana.**
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**