

No. 31015/46/2018-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

.....

A- Wing, Shastri Bhawan,
New Delhi 110 001

Order

1. This is an order on a review application, dated 05.12.2018, filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Biological E Limited (hereinafter called the applicant) against notification S.O. No. 5727(E), dated 13.11.2018 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Tetanus Toxoid Vaccine.

2. The applicant has contended as under:-

2.1 Vide order dated 08.06.2018, the Department of Pharmaceuticals (DoP) directed NPPA 'to fix the ceiling prices of Tetanus Toxoid Vaccine (Injection) de novo, separately for 0.5ml ampoules and 5 ml vials by considering the market price of May 2012 and September 2013 of those companies having market share of more than 1% of the moving annual turnover. In order to facilitate the process of the data collection and to arrive at a correct ceiling price, the applicant made voluntary submission on 26.06.2018, wherein the applicant provided market data of May 2012 and September 2013 for 0.5ml ampoules and 5.0ml vials. According to data, the PTR for 0.5 ml ampoules was Rs 8.85 and for 5.0 ml vials was Rs 20.08. The PTR was not considered by NPPA based on the data submitted by the applicant. In the calculation sheet published by NPPA on 13.11.2018, the base PTR of the applicant considered by NPPA for Tetanus Toxoid 0.5ml ampoules is Rs 7.72 and 5.0ml vials is Rs 16.63 which is not correct. Since the PTR data relied upon by the NPPA is incorrect, the subsequent calculation of ceiling price becomes erroneous and is liable to be set aside. The applicant requested to consider the data provided by it and requested DOP to direct the NPPA to share a draft calculation sheet prior to notification being issued as per OM No. 31015/44/2016-PI.1 dated 11.07.2016.

2.2 The applicant company also stated that NPPA does not have the power to fix the ceiling price of Tetanus Toxoid Vaccine. As per para 4 of DPCO, the NPPA only has the power to fix the ceiling price of scheduled formulations of specified strength and dosages as specified under the First Schedule. As no strength or dosage is fixed for Tetanus Toxoid vaccine, the NPPA does not have the jurisdiction to fix the ceiling price of the same. The applicant also quoted the judgment dated 10.7.2015 in the case of Reckitt Benckiser vs. Union of India & Ors., W.P.(C)7705 of 2013, where the Court held that as the strength or dosage of condoms had not been specified in the First Schedule, the NPPA would not fix the ceiling price of the same.

2.3 The applicant objected to the methodology adopted by NPPA and stated that the averaging of the invoiced packs along with the free packs is not supported by the

DPCO, which states that actual Price to Retailer (PTR) ought to be considered and not the average based on taking 'zero' as the PTR for free packs. The applicant also stated that NPPA has only considered one random invoice out of the almost 1500 invoice summaries submitted by the applicant for the month of May, 2012 with respect to the 0.5ml ampoules. NPPA has not even considered the PTR of highest count.

3. Comments of NPPA:

3.1 To implement the direction given in review order No.31015/27/2017-Pricing, dated 08.06.2018, the ceiling price of 0.5ml ampoules was fixed at Rs 9.95 and for 5.0ml vials at Rs 21.43 by considering the data submitted by M/s Serum Institute of India Limited and M/s Biological E Limited. M/s Biological E limited had submitted that they invoiced 16000 vials, where the company charged for 14540 vials at Rs 8.50 and 1460 vials are given at free of cost. Considering this, the average PTR is 7.72 per vials. ($14540 \times 8.5 / 16000 = 7.72$ per vial). Hence, there is no error in the PTR, considered by NPPA for the company.

3.2 In response to point raised by the applicant company about NPPA not having the power to fix the ceiling price of Tetanus Toxoid Vaccine, the ceiling price of the formulation was fixed considering para 4 of DPCO and the policy adopted by the Authority. Moreover, the judgment dated 10.7.2015 in the case of Reckitt Benckiser vs. Union of India & Ors., W.P.(C)7705 of 2013, quoted by the applicant, is already in appeal.

4. Examination:

4.1 The applicant filed its review application mainly on the following grounds :

(a) NPPA does not have the power to fix the ceiling price of Tetanus Toxoid Vaccine:

(b) NPPA has not taken relevant data into consideration:

4.2 As regards point (a) above, NPPA fixed the ceiling price of Tetanus Toxoid Vaccine, as the formulation is a scheduled formulation and is included in revised schedule (NLEM, 2015) at section 22.3.1.8 of DPCO. As regards the judgment dated 10.7.2015 in the case of Reckitt Benckiser vs. Union of India & Ors., W.P.(C)7705 of 2013, (where the Court held that as the strength or dosage of condoms had not been specified in the First Schedule) is concerned, as stated by NPPA, the said judgment is already in appeal. Moreover M/s Biological E Limited and M/s Serum Institute of India requested NPPA to fix/revise the ceiling price of Tetanus Toxoid Vaccine.

4.3 Regarding ground (b) of the applicant, NPPA fixed the ceiling price of Tetanus Toxoid 0.5ml ampoules at Rs 9.95 and for 5.0ml vials at Rs 21.43 by considering the data submitted by M/s Serum Institute of India Limited and M/s Biological E Limited. As regards the grievance of the company about not considering their relevant data, NPPA stated that the company had submitted that they invoiced 16000 ampoules, where the company charged for 14540 ampoules at Rs 8.50 and 1460 ampoules are given at free of cost. Considering this, the average PTR is Rs 7.72 per ampoule. ($14540 \times 8.5 / 16000 = 7.72$ per ampoule). Similarly, company furnished the data showing PTR of Rs 18.32 for 5ml pack where the company charged for 454 vials and 46 vials were given free.

Accordingly, the PTR of 5ml pack at Rs 16.63 is derived as follows : Rs 18.32 X {454/(454+46)} = Rs 16.63.

4.4 NPPA however did not upload the draft working sheet for clear 10 working days as per the department's standing instructions and the applicant company was not given any opportunity to object to the methodology used by NPPA before NPPA issued the ceiling price notification. NPPA should have complied with the government's standing instructions on this issue.

5. Decision:

NPPA is hereby directed to refix the ceiling price of Tetanus Toxoid Vaccine de novo, on merit, separately for 0.5 ml ampoules and 5ml vials, within a period of thirty days of the issue of this order. The draft working sheet would be shared with concerned companies and the companies would be given at least 10 working days to submit their objection, if any, on the draft working sheets.

Issued on this date, the 19th day of March, 2019.

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

Copy 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
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. Joint Secretary (Pharma), Deptt. of Pharmaceuticals, New Delhi.
7. T.D., NIC for uploading the order on Department's Website