

**No. 31015/70/2017-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 Serum Institute of India Pvt. Limited against price fixation of their formulation "DPT Vaccine 0.5ml." vide NPPA order No. S.O. 1688(E), dated 24.05.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref: 1) Review application dated 20.06.2017
2) NPPA notification under review S.O. No.1688(E), dated 24.05.2017
3) Record Note of discussions held in the personal hearing on 10.10.2017.**

1. This is a review petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Serum Institute of India Pvt. Limited (hereinafter called the petitioner) against notification S.O. No.1688(E), dated 24.05.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of their formulations DPT Vaccine 0.5ml.

2. The petitioner has contended as under:

(i) The ceiling price fixation and the computation is not as per the provision of DPCO, 2013 for the following reasons:-

a. While arriving at ceiling price of DPT 0.5ml the PTR and MAT details of all type of formulations i.e. Single and Multi dose formulation have been taken together.

In the computation sheet for Ceiling price of DPT 0.5ml Vaccine, PTR and MAT of DPT Injection 5ml which is a multi-dose formulation is taken together with PTR & MAT of 0.5ml vaccines.

b. The price of Single dose and Multi dose vaccine do not move in linear progression as purported to have taken in price working.

c. **Similarly in the computation sheet PTR & MAT details taken of one manufacturer Biological E Ltd appears to be incorrect & they are no longer supplying DPT 0.5ml vaccines.** Therefore there is a need to recalculate the ceiling price working under Para 18 (ii) & (iii) of DPCO 2013- revision of ceiling price on the basis of moving annual turnover (MAT).

(ii) Para 11(3) was inserted in the DPCO 2013 vide S.O. 1192(E) dated 22.03.2016, and states:

Notwithstanding anything contained in sub-paragraph (1) and (2), in the case of injections or inhalation or any other medicine for which dosage form or strength or both are not specified in the Schedule-I of the Drugs (Prices Control) Order, 2013, the Government may fix and notify separate ceiling price or retail price for such formulations with specified therapeutic rationale, considering the type of packaging or pack size or dosage compliance or content in the pack namely liquid, gaseous or any other form, in the unit dosage as the case may be, conforming to Indian Pharmacopeia or other standards as specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules made thereunder for the same formulation.

(iii) Subsequently, a Committee of Experts was formed by Department of Pharmaceuticals as per the provisions of Para 11(4) of the DPCO to address the issue regarding single and multidose usage based on therapeutic rationale. As per the Minutes of the 3rd Meeting of the Committee held on 28.12.2016. the Committee had recommended for fixation of separate prices under Para 11(3&4) of DPCO 2013 for single and multi-dose formulations.

(iv) Company had already brought to the notice of NPPA stating the issues vide their letter dated 03/03/2017 in reply to the NPPA's draft version of the proposed calculation sheets for revised/ notified ceiling price/ retail of DPT Vaccine 0.5ml formulation vide office memorandum no.8(35)/2016/DP/NPPA-Div.-II dated 27th Feb 2017.

(v) In view of above, company requested this Department to once again review the Ceiling price working of DPT Vaccine 0.5ml taking into consideration of the above facts & issue a revised price notification accordingly.

3. Comments of NPPA:

I. Ceiling price of DPT Vaccine 0.5ml was notified as Rs. 12.85/ (0.5ml) vide S.O. 1688(E) dated 20.06.2017 as per para 4, 6, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.

II. The company has stated that correct methodology was not followed in arriving at the ceiling price of **DPT Vaccine 0.5ml**. 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:-

Sl. No.	Company's Grievances	NPPA's comments
1.	Company has stated that NPPA has clubbed the PTR and MAT value of single and multi-dose formulation while arriving at ceiling price of DPT 0.5ml.	NPPA had fixed the ceiling price of DPT Vaccine 0.5ml vide S.O. 1688(E) dated 20.06.2017 based on the data provided by pharma-trac for the month of August, 2015.
2.	Company has also pointed out that the price of Single dose and Multi-dose vaccine do not move in linear progression.	The matter was raised in the 4 th (continued) meeting of committee of experts under para 11(3&4) of DPCO, 2013 held on 02.05.2017.

		The committee recommended separate ceiling price fixation for packs may not be considered.
3.	In the opinion of company, NPPA has not considered the correct PTR and MAT value of the formulation of Biological E. Ltd. Biological E. Ltd is not supplying DPT 0.5ml Vaccine and requested to recalculate the ceiling price in the light of Para 18(i) and (ii) of DPCO, 2013.	Company did not raise this issue during representation against draft upload of work sheet in NPPA's website.
4.	Company has also requested separate price for different pack in the light of para 11(3) of DPCO, 2013 and based on the recommendation of 3 rd meeting of committee of experts held on 28.12.2016.	Company's request for separate price for different pack in light of para 11(3) of DPCO, 2013 cannot be considered as per the recommendation of 4 th meeting of committee of experts held on 02.05.2017.
5.	Company stated that they made a representation against draft version of proposed calculation sheet and requested to revise the ceiling price of DPT vaccine 0.5ml.	The representation of company was examined by NPPA and ceiling price of Rs.12.85 was fixed by the Authority in its 45 th meeting held on 24.05.2017.

III. Company has not challenged S.O. No. 1688(E) dated 24.05.2017 in any Court.

4. During the personal hearing, the representatives of the company did not make any further submission.

5. **Examination:**

NPPA notified the ceiling price of **DPT Vaccine 0.5ml** vide SO 1688(E), dated 24.05.2013. Company contended to fix separate ceiling price for Single dose (0.5ml) and Multi-dose (5 ml) vaccine. On going through the submission made by NPPA, it is observed that NPPA had raised the matter in the 4th (continued) meeting of Committee of Experts under para 11(3&4) of DPCO, 2013 held on 02.05.2017 and the Committee recommended that separate ceiling price fixation for packs may not be considered. As the Expert Committee's recommendation has already been obtained and it has been recommended by the Committee not to fix separate ceiling price based on pack size, the request of company for separate ceiling price based on pack size cannot be agreed to. In view of this, the review application of the petitioner company may be rejected.

6. **Government Decision:**

"The Committee of Experts has recommended not to fix separate ceiling price of DPT Vaccine based on pack size. Therefore, the request of petitioner company for separate ceiling price of Single dose and Multi-dose DPT Vaccine cannot be agreed to, and the review application stands rejected."

Issued on this date of 16th day of January, 2018.

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

To

- 1. M/s. Serum Institute of India Pvt. Limited,
212/2, Hadapsar,
Pune-411028.**
- 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**