मिसिल स.- 8(147)/2026/डी.पी/एनपीपीए-डीवी-II

F. No. 8(147)/2026/DP/NPPA-Div. II

कार्यवाही स. : 279/147/2026/F

Proceeding No: 279/147/2026/F

Minutes of the 279th (overall) and 147th meeting of the Authority under DPCO, 2013 held on 11.06.2026 at 12:30 PM.

The 279th meeting of the Authority (overall), which is the 147th meeting under the DPCO, 2013 was held on 11.06.2026 at 12:30 PM under the Chairmanship of Shri P. Krishnamurthy, Chairman, NPPA. The following Authority members were present during the meeting:

(i) Ms. Sai Ahlladini Panda, Member Secretary, NPPA

(ii) Shri Anand Kumar Pal, Chief Adviser (Cost), O/o Chief Adviser Cost, Department of Expenditure

(iii) Dr. Rose Mary K. Abraham, Economic Advisor, Department of Economic Affairs

Shri Ranga Chandrashekar, Joint Drug Controller, CDSCO, Ministry of Health & Family Welfare.

The following officers of NPPA attended the meeting and assisted the Authority in its deliberations:

(i) Shri Rajiv Wadhawan, Adviser (Cost)

(ii) Ms. Priyanka Sachdeva, Joint Director (Pricing)

(iii) Shri Mahaveer Saini, Joint Director (Pricing) – Additional Charge

(iv) Ms. Yuvika Panwar, Deputy Director (Pricing) – Additional Charge

(v) Shri Bhiva Ram Yadav, Assistant Director (Pricing)

At the outset, the Authority welcomed Shri Rajiv Wadhawan, who has joined as Adviser (Cost) at NPPA.

1. Agenda item no. 1 - Confirmation of minutes of 146th Meeting held on 26.05.2026.

1.1 The Authority confirmed the minutes of the meeting without any change.

2. Agenda item no. 2 – Action Taken Report (ATR) on decisions taken by NPPA in its 146th Meeting held on 26.05.2026.

2.1 Noted.

3. Agenda item no. 3 – Status of Review Orders.

3.1 Noted.

4. Agenda item no. 4 – Revision of ceiling price of 'BCG Vaccine, Measles Rubella Vaccine & Measles Vaccine', notified vide NPPA's notification S.O. No. 5497 (E) dated 19.12.2024, based on Review Order under NLEM, 2022.

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4.1 The Authority noted that Department of Pharmaceuticals (DoP) has issued Review Order no. 31015/01/2025-Pricing (E-30166) dated 07.04.2026 in respect of three scheduled formulations 'BCG vaccine, Measles vaccines and Measles Rubella vaccine' stating that, *"given the critical public health significance of these vaccines, their stable price trends, relatively low financial impact on citizens, and the fact that a single company supplies them at low prices, the case is being referred back to NPPA for reconsideration in accordance with precedence of BCG vaccine under NLEM 2015, wherein monopoly reduction was not considered".*

4.2 The Authority noted that M/s Serums Institute of India Private Limited filed a review application for the three formulations 'BCG vaccine, Measles vaccines and Measles Rubella vaccine' notified vide S.O. 5497 (E) dated 19.12.2024 contending that applying the monopoly price reduction based on the average price reduction of products within the same sub-therapeutic category is inappropriate for biologicals and vaccines, as each vaccine is a distinct product. It further referred to action previously undertaken by NPPA in 2018.

4.3 The applicant has emphasized that BCG, Measles and Measles-Rubella vaccines are distinct biological products of significant public health importance, each involving unique manufacturing processes, technologies, disease indications and market dynamics. It has been contended that these vaccines are critical and maintaining their commercial viability is essential to ensure uninterrupted supply, particularly in view of the limited number of manufacturers, high compliance costs and the strategic importance of domestic vaccine production.

4.4 In this regard, the Authority recalled that in its 56th meeting held on 23.04.2018, the Authority had decided that the ceiling price of BCG vaccine may be fixed/revised under Para 19 without applying reduction under monopolistic condition to address the genuine grievance of the applicant as well as to ensure sufficient availability of the drug in the market.

4.5 The Authority deliberated upon the matter, in view of the above Review Order and the decision taken in the 56th Authority meeting, and decided that the ceiling prices of three formulations may be revised under Para 19 without applying monopoly restrictions. Accordingly, the Authority approved the revised ceiling prices inclusive of WPI revision of year 2025 and 2026 as below:

Table 1 : Revision of ceiling prices based on Review Order

S. No.	Formulation	Dosage and Strength	Unit	Present Ceiling Price notified (in Rs.)	Revised Ceiling Price (In Rs.)
1	BCG Vaccine	As licensed	Each dose (0.10 ML)	8.20	9.89
2	Measles Rubella Vaccine	As licensed	Each Vial of 0.5ml	72.90	87.93
3	Measles Vaccine	As licensed	Each Vial of 0.5ml	51.40	62.00

5. Agenda item no. 5: Revision of ceiling price of 'Anti-tetanus Immunoglobulin 250 IU & 500 IU', notified vide NPPA's notification S.O. No. 5497 (E) dated 19.12.2024, based on Review Order under NLEM, 2022.

5.1 The Authority noted that Department of Pharmaceuticals (DoP) has issued Review Order no. 31015/03/2025-Pricing (E-30195) dated 07.04.2026 in respect of two scheduled formulations 'Anti-tetanus immunoglobulin 250IU & 500IU' stating that , *"given the critical public health significance of these vaccines, their stable price trends, relatively low financial impact on citizens, and the fact that a single company supplies them at low prices, the case is being referred back to NPPA for reconsideration with precedence in case of Anti-Tetanus Immunoglobulin and BCG Vaccine under NLEM, 2015".*

5.2 The Authority noted that M/s Bharat Serums & Vaccines Limited filed a review application in respect of ceiling prices of 'Anti-tetanus Immunoglobulin 250 IU' & 'Anti-tetanus Immunoglobulin 500 IU' notified vide S.O. 5497 (E) dated 19.12.2024 stating non-viability in producing the formulations due to reduction in the ceiling price. The company also mentioned about the request made under Para 19 for price increase of the said formulations.

5.3 The applicant has emphasized that Anti-Tetanus Immunoglobulin (ATIG) is a life-saving biological product used for passive immunization against tetanus in high-risk injury cases and in individuals with inadequate or uncertain immunization status. Timely availability of ATIG is critical for preventing tetanus, a potentially fatal disease with high morbidity and mortality, and any disruption in its supply may have serious public health implications.

5.4 In this regard, the Authority recalled that in its 56th meeting held on 23.04.2018, the Authority had decided that the ceiling price of BCG vaccine may be fixed/revised under Para 19 without applying reduction under monopolistic condition to address the genuine grievance of the applicant as well as to ensure sufficient availability of the drug in the market.

5.5 The Authority also noted that the company has filed an application for upward prices revision under Para 19 of DPCO, 2013. The application of the company has already been examined by the Committee on Para 19 which has recommended both formulations for upward price revision. As the matter is placed at Agenda item no. 6, the Authority decided to consider this agenda with the next.

6. Agenda item no. 6- Applications received for upward price revision of scheduled formulations under Para 19 of DPCO, 2013.

6.1 The Authority noted that NPPA has been receiving requests for upward price revision of various drugs under para 19 of DPCO, 2013 from the manufactures citing various reasons like increase in cost of Active Pharmaceutical Ingredients (APIs); increase in the cost of production; change in exchange rate etc.; resulting in unviability in sustainable production and marketing of the drugs. Companies have also applied for discontinuation of some of the formulations on account of their unviability.

6.2 The Authority recalled that, in 2019, NPPA referred the issue to the Committee on Affordable Medicines and Health Products (CAMHP), NITI Aayog, Government of India for guidance on the modalities/ methodology to be followed. CAMHP recommended an increase of 50% in the ceiling prices and also authorized NPPA to examine additional formulations / molecules

experiencing similar issues of manufacturing unviability due to low prices and apply upward price revision on principles determined by CAMHP.

6.3 Accordingly, on previous occasions, ceiling prices were increased for 21 formulations for 12 drugs in the 71st Authority meeting held on 09.12.2019, for 9 formulations of 3 drugs in the 89th Authority meeting held on 28.06.2021 and for 11 formulations of 8 drugs in the 127th Authority meeting held on 08.10.2024.

6.4 The Authority noted that the preliminary examination of current applications under Para 19 received in NPPA was done based on the inputs/details/data available in the NPPA as well as data relating to API prices for the years FY 2021-22 to FY 2025-2026 received from the companies. The applications related to 82 formulations for which API data has been received from the companies were examined by the Committee on Para 19 in its 8th meeting held on 18.05.2026.

6.5 The Committee examined the applications based on parameters of essentiality of the formulations, market share of the companies requesting for price revision, the period since which the formulation is under price control, concern regarding possible shortages; if any, request for discontinuation received from the companies, and trend of API prices during the last five years as reported by the companies.

6.6 The Authority noted that the Committee recommended that four formulations viz. Carboplatin 10mg/ml Injection, Cisplatin 1mg/ml Injection, Anti-Tetanus Immunoglobin 250IU Injection and Anti-Tetanus Immunoglobin 500IU Injection may be considered for an appropriate upward price revision. The remaining 78 formulations were deferred by the Committee for seeking additional information.

6.7 It was further noted that concerns regarding shortage of **Carboplatin and Cisplatin drug** have been raised on various platforms on account of increase in prices of API. A meeting was also held with the manufacturers to address the concerns and to ensure continued supply of these drugs.

6.8 The Authority noted that the formulations recommended by the Committee for upward price revision have been under repeated price control, are generally used as first line of treatment and are important to address the public health needs of the country. Further, the mandate of NPPA is to ensure availability of drugs at affordable prices. While ensuring affordability, access cannot be jeopardized and the life-saving essential drugs must remain available to the general public at all times. Therefore, unviability of these formulations should not lead to a situation, where these drugs become unavailable in the market and the public is forced to switch to expensive alternatives.

6.9 The Authority deliberated upon the matter in detail and based on principles laid down by CAMHP, current stock-out situation of critical drugs, past precedence and recommendation of the Committee, decided to invoke extraordinary powers in public interest under para 19 of DPCO, 2013 for upward price revision of the ceiling prices of following four formulations of three drugs as recommended by the Committee:

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(a) With respect to ceiling prices of Anti-tetanus Immunoglobulin 250IU and 500IU, it was noted that ceiling prices are also to be revised in line with the review order passed by DoP as deliberated in Agenda item 5 above. Accordingly, the Authority decided to increase the ceiling prices by allowing one time price increase of 50% on the prevailing ceiling price on account of the application under para 19. The Authority further noted that the said increase is being granted as a comprehensive measure already taking into account all relevant factors including market structure and supply conditions, and therefore, reconsideration of monopoly reduction or any adjustment on that account is not warranted separately in the present case.

(b) With respect to Carboplatin 10mg/ml Injection and Cisplatin 1mg/ml injection, considering the increase in the API prices, wide fluctuation in their API prices and concerns regarding shortage, the Authority decided to allow one time price increase of 50% over the prevailing ceiling prices and such revision of prices shall be reviewed after 6 months, or earlier, as warranted.

6.10 Accordingly, the details of revised ceiling prices are as under-

Table 2 : Revision in ceiling prices of scheduled formulations

S. No.	Name of the Scheduled Formulation	Dosage form & Strength	Unit	Existing Ceiling prices	Existing S.O. No. & Date		Revised ceiling prices
(1)	(2)	(3)	(4)	(5)	6(a)	6(b)	7
1.	Carboplatin	Injection 10mg/mL	1 ML	Rs. 60.49 per ml	1575 (E) Sl. No. 141	25.03.2026	Rs. 90.74 per ml
2.	Cisplatin	Injection 1mg/mL	1 ML	Rs. 7.26 per ml	1575 (E) Sl. No. 182	25.03.2026	Rs. 10.89 per ml
3.	Anti-tetanus immunoglobulin	As licensed (250IU)	1 Vial	Rs. 1274.68 per vial	1575 (E) Sl. No. 59	25.03.2026	Rs. 1912.02 per vial
4.	Anti-tetanus immunoglobulin	As licensed (500IU)	1 Vial	Rs. 1920.79 per vial	1575 (E) Sl. No. 60	25.03.2026	Rs. 2881.19 per vial

6.11 Further, the provision of Para 13(2) of DPCO, 2013 would not be applicable on the revised ceiling prices of the formulations mentioned in para 6.10 above.

The Authority also placed on record the valuable contributions rendered by Shri Sanjay Kumar, Advisor (Cost), upon his transfer from NPPA. The Committee acknowledged his dedicated service, professionalism, and commitment to the organization's objectives, and conveyed their best wishes for continued success and fulfillment in his future assignment.

The meeting ended with a vote of thanks to the Chair and all the participants in the meeting.

(Sai Ahlladini Panda)
Member Secretary