

F. No. 12(7)/2021/DP/NPPA/Div.II/ Vol-VI

National Pharmaceutical Pricing Authority

Subject: Minutes of the 76th meeting of the Multidisciplinary Committee of Experts held on 08.04.2026 at 11:30 AM.

76th meeting of the Multidisciplinary Committee of Experts was held on 08.04.2026 at 11:30 AM under the convenorship of Shri Sanjay Kumar, Advisor (Cost). The following members attended the meeting:

1. Shri Ranga Chandrashekar, Joint Drugs Controller, CDSCO
2. Dr. Rakesh Kr. Singh, Professor & Dean, NIPER Raebareli, through Video Conferencing,
3. Dr. J. J. Cherian, Scientist-E (Med), ICMR, through Video Conferencing,
4. Dr. Balu V Gopal, Scientist C, HTAIn, D/o Health Research,
5. Prof. Y. K. Gupta, Principal Scientific Advisor (Projects), THSTI-DBT, GoI & Ex-HoD, Pharmacology & Dean (Academics), AIIMS, New Delhi – Co-opted member, through Video Conferencing
6. Dr. Shashi Bhushan, Senior Scientific Officer, Indian Pharmacopoeia Commission – Co-opted member,
7. Shri Sukhdeep Singh, Deputy Controller of Patent & Design, through Video Conferencing
(for Agenda 4)

The following special invitees were also attended the meeting with respect to Agenda item No. 7:

1. Dr. Davinder Singh, Director Professor, Sports Injury Centre, VMMC & Safdarjung Hospital, Delhi
2. Dr. Bhavuk Garg, Professor of Orthopedics, All India Institute of Medical Sciences (AIIMS), New Delhi

The following officers of NPPA attended and presented the cases before the Committee:

1. Ms. Rashmi Tahiliani, Director (Pricing)
2. Ms. Priyanka Sachdeva, Joint Director (Pricing)
3. Shri Mahaveer Saini, Joint Director (Pricing)- Additional charge
4. Ms. Yuvika Panwar, Deputy Director (Pricing) - Additional charge
5. Shri Bhiva Ram Yadav, Assistant Director (Pricing)

Agenda Item No. 1: Application for price approval - Special Safe Port Feature Products (1000 ml pack size) under Extension of separate ceiling price under para 11(3) of DPCO, 2013 by M/s Sachin Parenteral Pvt. Ltd. (Manufacturer & Marketer).

1. The Committee noted that M/s Sachin Parenteral Pvt. Ltd. applied for separate ceiling prices under 11(3) of the DPCO, 2013 on 13.11.2025 (complete application received on 21.11.2025) for IV fluids in Non-glass Euro Head / Safe-Port Bottle having special features viz. (i) Self-collapsible, self-sealable container, (ii) Non-air-vent system - prevents contamination, (iii) Prevents microbial entry during manufacturing/ infusion admixing, for the following formulations:

Sr. No.	Name of Product	Pack Size
1.	Dextrose Injection IP 5% w/v	1000ml
2.	Sodium Chloride Injection IP 0.9% w/v	1000ml
3.	Dextrose Injection IP 5% w/v + Sodium Chloride Injection IP 0.9% w/v	1000ml
4.	Compound Sodium Lactate Injection IP	1000ml

2. The Committee noted that the matter was deliberated in 74th meeting held on 18.12.2025, wherein the Committee directed that the authorized person of the company who is well-versed with the documents and claims submitted may be asked to appear before the Committee in next meeting to present their case and demonstrate the product for special features claimed in the application. Accordingly, the matter was placed in 75th MDC meeting held on 11.02.2026. However, no representative from the company appeared for the demonstration in the meeting and the matter was deferred.

3. The matter was deliberated in 76th meeting wherein the representative of company demonstrated their product. The Committee observed discrepancies in the test report submitted by the company. Based on products demonstrated by the applicant, the Committee also observed that the date of manufacturing, which is prior to the date of application, and MRP is printed on pack. Accordingly, the Committee directed the company to explain the discrepancies in the test report and to clarify as to whether the product has already been launched in the market.

Agenda Item No. 2: Application for extension of separate ceiling prices under Para 11(3) of the DPCO, 2013 for IV fluids in Euro Head/ Euro Head Dual Port with packaging in non-glass with special feature by M/s Silica Healthcare Pvt. Ltd

1. The Committee noted that M/s Silica Healthcare Pvt. Ltd. applied for extension of separate ceiling prices under Para 11(3) of the DPCO, 2013 vide email dated 14.12.2025 (complete application on 13.01.2026) for their IV fluids packaged in Euro Head/ Euro Head Dual Port bottles, which incorporate special features viz. (i) self-collapsibility and self-sealability, (ii) Can be administered without use of Air Vent, (iii) having no chance of contamination during manufacture / infusion / admixing level, for the following formulations:

S. No.	Name of Product	Pack size	Notification
1	Dextrose Injection IP (5% w/v) - Euro Head	500 ml	1485(E) dated 27.03.2025
2	Dextrose Injection IP (5% w/v) - Euro Head Dual Port	500 ml	
3	Sodium Chloride (0.9% w/v) & Dextrose (5% w/v) Injection IP - Euro Head	500 ml	
4	Sodium Chloride (0.9% w/v) & Dextrose (5% w/v) Injection IP - Euro Head Dual Port	500 ml	
5	Sodium Chloride Injection IP (0.9% w/v) - Euro Head	500 ml	
6	Sodium Chloride Injection IP (0.9% w/v) - Euro Head Dual Port	500 ml	
7	Sodium Chloride Injection IP (0.9% w/v) - Euro Head	100 ml	
8	Sodium Chloride Injection IP (0.9% w/v)- Euro Head Dual Port	100 ml	

2. The Committee noted that the matter was deliberated in 75th MDC meeting held on 11.02.2026, wherein the Committee directed that the authorized person of the company who is

well-versed with the documents and claims submitted may be asked to appear before the Committee in next meeting to present their case and demonstrate the product for special features claimed in the application.

3. The matter was deliberated in 76th meeting wherein the representative of company demonstrated their product. The representative of the company further requested to extend the present applicable separate ceiling prices as notified vide S.O. 1583 (E) dated 25.03.2026. The Committee examined the documents relating to flow rate analysis, certificate of analysis for plastic used in manufacturing of the plastic containers for the applied formulations. The Committee noted that the product bears the features of self-sealability, self-collapsibility and has a dual port to prevent the contamination. Accordingly, the Committee recommended the present applicable separate ceiling price for the following formulations:

Sr. No.	Name of Product	Pack size	Ceiling price ex. GST	Notification
1	Dextrose Injection IP (5% w/v) - Euro Head	500 ml	84.24 / Pack	1583(E) dated 25.03.2026
2	Dextrose Injection IP (5% w/v) - Euro Head Dual Port	500 ml		
3	Sodium Chloride (0.9% w/v) & Dextrose (5% w/v) Injection IP - Euro Head	500 ml	87.58/ Pack	
4	Sodium Chloride (0.9% w/v) & Dextrose (5% w/v) Injection IP - Euro Head Dual Port	500 ml		
5	Sodium Chloride Injection IP (0.9% w/v) - Euro Head	500 ml	90.05 / Pack	
6	Sodium Chloride Injection IP (0.9% w/v) - Euro Head Dual Port	500 ml		
7	Sodium Chloride Injection IP (0.9% w/v) - Euro Head	100 ml	43.07 / Pack	
8	Sodium Chloride Injection IP (0.9% w/v)- Euro Head Dual Port	100 ml		

Agenda Item No. 3: Application for approval of separate ceiling price/ retail price under Para 11(3) of the DPCO, 2013 for 'Glycopyrronium 25 mcg + Formoterol Fumarate 20 mcg + Budesonide 500 mcg Smartules' by M/s Glenmark Pharmaceutical Ltd.

1. The Committee noted that M/s Glenmark Pharmaceuticals Ltd. vide letter dated 22.01.2026 has applied under Paragraph 11(3) of the Drug Price Control Order, 2013 seeking fixation of a separate ceiling price / retail price for 'Glycopyrronium 25 mcg + Formoterol Fumarate 20 mcg + Budesonide 500 mcg Smartules'.

2. The Committee was apprised that earlier the applicant had filed Form I for the subject formulation dated 07.11.2025 & 11.11.2025. However, as the data was not reflected in the Pharmarack data, the matter was deliberated in 73rd MDC meeting held on 25.11.2025, wherein the Committee recommended a price of Rs.49/- per ml (excluding GST) against the claimed price of Rs.70/- per ml. The minutes of the said meeting was uploaded on NPPA's web-site and the company did not represent against the same. Accordingly, the retail price as recommended by the Committee was approved by the Authority and notified vide S.O. No. 5975(E) dated 24.12.2025.

3. The Committee noted that now, M/s Glenmark Pharmaceuticals Ltd has applied under Para 11(3) stating that the drug and its administration mechanism is unique and is a result of innovation on multiple fronts. The applicant provided therapeutic rationale and clinical justification like only triple therapy treatment in nebulised form, avoids inhaler misuse due to ease of administration and highly effective treatment and also the technical / manufacturing rationale. It was informed to the Committee that the company has launched the formulation at the within the notified Retail Price since form V has been filed by the company.

4. The Committee deliberated upon the matter and decided that the authorized person of the company who is well-versed with the documents and claims submitted may be asked to appear before the Committee in next meeting to present their case and demonstrate the product for special features claimed in the application.

Agenda Item No. 4: Application from M/s Biological E Limited for exemption under Para 32 (i, ii & iii) of the DPCO, 2013 for the formulation Pneumococcal Polysaccharide Conjugate Vaccine (PNEUBEVAX 14) - reg.

1. The matter was earlier placed in 64th meeting held on 6.12.2024, 66th meeting held on 3.3.2025, 67th meeting of MDC held on 02.04.2025 and in 69th meeting held on 3.07.2025. Officer nominated by DPIIT attended the meeting and provided their written inputs on the subject matter. It has been also informed that in claim 1 submitted to the patent office, strength of each serotype is not mentioned. However, the strengths are mentioned in claim 6 submitted to the patent office. In written inputs, O/o CGPDTM (DPIIT) has highlighted that strength of each serotype is different in granted claim 6 and composition mentioned in application filed to NPPA. The applicant mentioned the strength in application filed to NPPA as per DCGI approval. O/o CGPDTM has also informed that “it is observed that the composition as specified in Row 4 of Form-1 dated 21/04/2023 and the claims granted by Indian Patent Office in this matter are almost equivalent when the granted claim 1 is read with claim 6.”. Representative of O/o CGPDTM also suggested to get the inputs/clarification of the applicant company in this regard for further examination of the claim. Accordingly, the Committee after deliberations directed to get the inputs/clarification of the applicant company in view of inputs of the O/o CGPDTM before final taking the final decision in the matter.

2. Accordingly, inputs were sought from the company. The company replied vide email dated 23.07.2025 and requested to refer to the claim 1, claim 6 and also the claim 3 as filed to the O/o CGPDTM. The inputs received from company were sent to O/o CGPDTM for comments on 01.08.2025. The O/o CGPDTM vide email dated 02.01.2026 provided the inputs stating that based on the comparisons of claim 3 and 6 granted by patent office, it is observed that the composition as specified in Row 4 of Form-1 dated 21.04.2023 and the claims granted by Indian Patent Office in this matter are almost equivalent when the granted claim 1 is read with claim 3 and 6.

3. In view of the above, the matter was deliberated in 75th MDC meeting held on 11.02.2026 wherein the representative from O/o CGPDTM stated that majorly the formulation is covered under the claims for which patent has been granted. However, some clarifications/ discussions are required from company. Accordingly, the Committee deliberated upon the matter and decided to invite the company in the next MDC meeting.

4. Accordingly, the matter was deliberated in 76th MDC meeting wherein the representative from the company was also present. The representative from O/o CGPDTM sought the

clarification from the company regarding the composition of the formulation as mentioned in DCGI approval and the claims as approved by the Patent office. The company was asked to clarify regarding the content of Absorbed onto Aluminium phosphate mentioned in strength as “ ≤ 75 mg” in the DCGI approval and “0.2 to 1 mg” mentioned in claim 5 submitted by the company.

5. The Committee deliberated the matter and directed the Company to submit written submissions regarding queries raised in the meeting.

Agenda Item No. 5: Application by M/s. Biodeal Pharmaceuticals Limited for exemption from the provisions of Drug Price Control Order 2013 under Para 32 (iii) for the formulation “Midazolam nasal spray 1.25 mg” – reg.

1. The Committee noted that the application submitted by M/s Biodeal Pharmaceuticals Limited seeking exemption from the provisions of the DPCO, 2013 under Para 32(iii) for their product Midazolam Nasal Spray 1.25% w/v has been received. The Committee recalled that the matter was earlier deliberated in 68th, 69th, 70th and 71st MDC meetings held on 03.06.2025, 03.07.2025, 05.08.2025 and 16.09.2025 respectively.

2. In the 71st meeting, the Applicant Company delivered a presentation explaining the details of the formulation. Further, the Committee deliberated upon the inputs provided by the O/o DCGI, vide letter dated 01.08.2025 and 11.09.2025, stating that “*M/s Biodeal Pharmaceuticals Limited was granted New Drug Permission for the drug product - Midazolam Nasal Spray 1.25% w/v strength only, on 05.05.2025 and no other strength of Midazolam Nasal Spray has been approved by this office till date*”. It was also noted that Midazolam Nasal Spray has already been included in the National List of Essential Medicines (NLEM), 2022. Accordingly, the Committee recommended that views/inputs may be obtained from the Standing National Committee on Medicines (SNCM) and CDSCO regarding the approval and inclusion of Midazolam Nasal Spray in NLEM 2022.

3. The inputs received from SNCM vide letter dated 27.11.2025 and CDSCO vide letter dated 25.02.2026 were placed for deliberation of the Committee in 76th Meeting. Accordingly, the Committee deliberated on the matter and opined that it needs further examination to establish that the applied formulation meets the requirements of para 32 (iii) of DPCO, 2013.

Agenda Item No. 6: Retail price fixation of ‘Each ml contains: Gentamicin Sulphate IP eq. to Gentamicin Base (40000 IU) 40 mg + Methyl Paraben IP 0.18% w/v + Propyl Paraben IP 0.02% w/v’ for M/s Cotec Healthcare Pvt. Ltd (Manufacturer) & M/s TTK Healthcare Ltd (Marketer) (F. No.5035).

1. The Committee noted that NPPA has received Form I application for retail price fixation of formulation ‘Each ml contains: Gentamicin Sulphate IP eq. to Gentamicin Base (40000 IU) 40 mg + Methyl Paraben IP 0.18% w/v + Propyl Paraben IP 0.02% w/v’ in pack of **100 ml**. It was informed to the Committee that ‘Gentamicin Injection 40 mg/ml’ is mentioned in Schedule I of DPCO, 2013 under NLEM, 2022 and NPPA has fixed different ceiling prices of the subject formulation on per ml basis for pack sizes of 1.5ml, 2ml, 10ml, 20ml and 30ml. The current applicable ceiling prices for these pack are notified vide S.O. 1575(E) dated 25.03.2026. The ceiling prices for the pack of 100ml has not been fixed by NPPA. Further, the notification also mentioned that *‘In respect of formulation where pack wise ceiling price is notified, for any*

other pack size manufactured, the manufacturer shall approach NPPA under para 11(3) of DPCO, 2013 for specific price approval for its formulations’.

2. The Committee noted that the data for pack of 100ml is not reflected in the Pharmarack database, however, some companies are selling the subject formulation in pack size of 100ml. The Committee directed to seek data regarding MAT sales and PTR from the companies selling subject formulation in pack size of 100 ml for ceiling price fixation. Further, the Committee also directed to ask the applicant company to submit the manufacturing license in Form 28-D as the product is 100ml pack size.

Agenda Item No. 7: Requests from Knee Implant Manufacturers/Importers for separate price category for Uncemented Knee Implants:

Record note of discussion for private circulation.

The Committee members and the officers present in the meeting placed on record the deep appreciation for the contributions of Ms. Rashmi Tahiliani, Director (Pricing), who has been selected on Deputation as Deputy Director, AIIMS Jodhpur. The Committee acknowledged her contributions and dedication and conveyed best wishes for success in her new assignment.

The meeting ended with a vote of thanks to all.

(Priyanka Sachdeva)
Joint Director (Pricing)

Copy to:
All members of the Committee.