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

National Pharmaceutical Pricing Authority

Subject: Minutes of the 69th meeting of the Multidisciplinary Committee of Experts held on 03.07.2025 at 2:30 PM.

69th meeting of the Multidisciplinary Committee of Experts was held on 03.07.2025 at 2:30 PM 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, Associate Professor, NIPER Raebareli, through Video Conferencing
3. Prof. Y. K. Gupta, Principal Scientific Advisor (Projects), THSTI-DBT, GoI & Ex-HoD, Pharmacology & Dean (Academics), AIIMS, New Delhi – Co-opted member,
4. Dr. Jai Prakash, Indian Pharmacopoeia Commission – Co-opted member

The following special invitees were also attended the meeting with respect to Agenda item No. 1:

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
3. Dr. Sumit Arora, Professor of Orthopedics, Maulana Azad Medical College (MAMC), New Delhi
4. Dr. Akshay Srivastava, Associate Professor, Department of Medical Devices, National Institute of Pharmaceutical Education and Research (NIPER), Ahmedabad

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

1. Ms. Rashmi Tahiliani, Director (Pricing)
2. Shri Mahaveer Saini, Deputy Director (Pricing)
3. Ms. Yuvika Panwar, Assistant Director (Pricing)

Agenda Item No. 1: Request from Knee Implant Manufacturers/Importers for separate price category for Cementless Knee Implants.

Record note of discussion for private circulation.

Agenda Item No. 2: Application by M/s Intas Pharmaceuticals Private limited for exemption from the provisions of Drug Price Control Order 2013 under Para 32 (ii & iii) for the formulation "Clozapine Extended Release 12.5 mg/ 25 mg/ 50 mg/ 100 mg/200 mg capsule"

1. The matter was earlier placed in 64th meeting of MDC held on 6.12.2024, wherein the agenda was deferred and the committee directed that the matter may be pursued with DPIIT for nomination of suitable officer. Further, the representative of office of DPIIT attended the 66th meeting of MDC held on 3.3.2025 and informed that the subject application as forwarded by NPPA is at an advanced stage of examination. The Committee requested that the comments may be shared with NPPA by 15th March 2025 so that the matter may be deliberated in next meeting for early disposal.

2. Further, the matter was again placed in the 67th meeting of MDC held on 02.04.2025, however, neither any comments have been received nor the meeting was attended by representative of DPIIT. Accordingly, the Committee deferred the agenda and directed to pursue the matter with DPIIT for early inputs in the matter.

3. Representative of O/o DPIIT attended the meeting and provided their written inputs on the subject matter. It has been also informed that *"the granted claim is significantly distinct from the claim submitted by the applicant to NPPA. Similarly, considerable differences are observed between the complete specification and dependent granted claims 2-4. Therefore, it is observed that the applicant has submitted a different complete specification and claim set to the NPPA on 30th October 2024, which is significantly distinct from the granted complete specification and claims"*. Representative of O/o DPIIT also suggested to get the inputs/clarification of the applicant company in this regard.

4. Accordingly, the Committee after deliberations directed to get the inputs/clarification of the applicant company in view of inputs of the DPIIT before final taking the final decision in the matter.

Agenda Item No. 3: 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).

1. The matter was earlier placed in 64th meeting of MDC held on 6.12.2024, wherein the agenda was deferred and the committee directed that the matter may be pursued with DPIIT for nomination of suitable officer. Further, the representative of office of DPIIT attended the 66th meeting of MDC held on 3.3.2025 and informed that the subject application as forwarded by NPPA is at an advanced stage of examination. The Committee requested that the comments may be shared with NPPA by 15th March 2025 so that the matter may be deliberated in next meeting for early disposal.

2. Further, the matter was again placed in the 67th meeting of MDC held on 02.04.2025, however, neither any comments have been received nor the meeting was attended by representative of DPIIT. Accordingly, the Committee deferred the agenda and directed to pursue the matter with DPIIT for early inputs in the matter.

3. 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 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 DPIIT also suggested to get the inputs/clarification of the applicant company in this regard.

4. Accordingly, the Committee after deliberations directed to get the inputs/clarification of the applicant company in view of inputs of the DPIIT before final taking the final decision in the matter.

Agenda Item No. 4: 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".

1. The Committee noted that M/s Biodeal Pharmaceuticals Limited has applied for exemption from the provisions of DPCO under Para 32 (iii) for their product "Midazolam nasal spray 1.25% w/v", claiming that applied formulation is developed in-house through indigenous research and development involving new drug delivery system.

2. The Committee also noted that the Midazolam Nasal Spray 1.25mg/actuation is a scheduled formulation under NLEM 2022 mentioned at Sections 1.3.3 & 5.1.7 of Schedule I of DPCO, 2013. The current ceiling price w.e.f. 01.04.2025 is Rs. 220.59 per ML, notified vide S.O. 1489(E) dated 27.03.2025, after revision as per WPI.

3. The Committee recalled that in the 68th meeting held on 03.06.2025 it had directed the applicant to appear before committee for demonstration. Accordingly, the representative of the company demonstrated the product along with following submissions:

- The product has been approved by DCGI as new drug for new indication i.e. Seizure clusters, acute repetitive seizure.
- The approved pack is for 1.2ml pack size and each actuation contains 1.25mg of the drug. The pack contains 12 actuations, out of which initial 4 sprays needs to be primed in the air, 4 sprays remain in the bottle undelivered. The artwork of the cartoon also claimed delivery of 4 actuation
- Applicant submitted that there is no comparator product in the market having same label claim i.e., 4 metered doses
- The company has also stated that Midazolam spray 1.25% w/v was never approved by DCG(I) earlier for sales and distribution in the country of India and Midazolam nasal spray is not available in the market.

4. The Committee informed the applicant that Midazolam spray 1.25% w/v is an essential drug under NLEM 2022 and hence has been approved by DCGI. Therefore, the contention that Midazolam spray 1.25% w/v was never approved by DCG(I) earlier for sales and distribution seems incorrect. It was noted that the applicant has applied for exemption under Para 32(iii) of the DPCO, 2013, which read as *"a manufacturer producing a new drug involving a new delivery system developed through indigenous Research and Development for a period of five years from the date of its market approval in India".*

5. The Committee noted that applicant has submitted the new drug approval of CDSCO/DCGI for the applied formulation and documents related to indigenous research & development facility accredited by the Department of Scientific and Industrial Research (DSIR) under Ministry of Science & Technology. The Committee inquired as how the applicant's product is a new delivery system as other sprays are also there in the market for this formulation. Accordingly, the Committee directed that the applicant to provide the documents in support of their claim w.r.t. new delivery system.

Agenda Item No. 5: Application for grant of separate price/special price for Omeprazole Delayed release orally disintegrating tablet 20 mg "OMEZ ODT" under the provision of Para 11 (3) or Para 32(3) DPCO 2013 by M/s Dr. Reddy's Laboratories Limited.

1. The Committee noted that applicant on 06.11.2024 applied for grant of separate price/special price of Rs. 17.90 per tablet without GST for Omeprazole Delayed release orally disintegrating tablet 20 mg "OMEZ ODT" under the provision of Para 11 (3) of DPCO 2013. The current applicable ceiling price of Omeprazole Tablet 20mg is Rs. 4.42 per tablet (S.O. No. 1489E dated 27.03.2025).

2. The matter was deliberated in 64th meeting of MDC held on 06.12.2024, wherein the Committee deliberated upon the matter in detail including the technical justifications provided by the applicant company and opined that there is no incremental specified therapeutic rationale of Omeprazole Orally Disintegrating tablet over the Omeprazole Enteric Coated Tablets. Accordingly, the Committee recommended to reject the application. However, the applicant on 24.12.2024 represented and requested to grant an opportunity for making a personal representation to NPPA or in person deliberation in front of upcoming Multi-Disciplinary Committee in the month of Jan 2025.

3. Accordingly, the matter was placed in the 65th meeting held on 23.01.2025 wherein the applicant gave detailed presentation on the matter. The committee deliberated upon the matter and directed the applicant to submit the study/supporting documents showing the usefulness of the subject formulation and other additional document in support of their claim. The applicant vide email dated 24.01.2025 submitted their response based on the deliberations of the MDC.

4. In 66th meeting of the MDC held on 03.03.2025, the Committee deliberated upon the submission of the company dated 24.01.2025 and re-examined the applicability of Para 11(3) to the application. The Committee observed that the provision of the Para 11(3) of the DPCO, 2013 read as below:

> *(3) 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.*

5. After detailed deliberations, the Committee opined that Para 11(3) may be invoked in case of injections or inhalation or any other medicine for which dosage form or strength or both are not specified in the Schedule-I. The applied formulation is tin tablet form and the dosage & strength of the same is mentioned in the Schedule-I. Therefore, the current application does not fall in the purview of Para 11(3). Hence, the committee recommended to reject the application.

Agenda Item No. 6: Application to fix a separate Ceiling Price under Paragraph 11(3) of DPCO-2013, of a Scheduled formulation of Amoxicillin 200 mg + Clavulanic acid 28.5 mg Suspension in a Dual Chamber Pack with Novel Technology, being introduced in India for the first time. -Seeking additional Price for Dual Chamber Pack over and above Existing Ceiling Price by M/s Sun Pharmaceuticals Industries Limited.

1. The Committee noted that applicant on 29.09.2023 applied for a separate ceiling price under para 11(3) of DPCO, 2013 for scheduled formulation of Amoxicillin 200 mg + Clavulanic acid 28.5 mg Suspension in a Dual Chamber Pack claiming the same to be with Novel Technology first time in India.

2. The Committee recalled that the matter was earlier deliberated in 56th, 57th and 59th meeting of MDC held on 20.12.2023, 27.02.2024 and 08.05.2024 respectively, wherein the Committee did not find the case fit for separate ceiling price under Para 11(3) and recommended to reject the application. The recommendation of the MDC approved by the Authority in its 124th meeting held on 07.06.2024.

3. However, the applicant filed representation with DoP on 20.11.2024 for re-examination of the matter. Accordingly, DoP vide letter dated 2.12.2024 forwarded the representation to NPPA requesting for re-examination.

4. Accordingly, the matter was placed in the 65th meeting of MDC held on 23.01.2025, wherein the Committee observed that the applicant has stated that the Para 11(3) insists for 'Therapeutic Rationale' and not the 'therapeutic advantage' as observed by the MDC in its 59th meeting. The applicant mentioned that Dual chamber pack is a cutting edge novel device developed through incremental innovation to benefit patients. It represents a significant advancement over existing market options, offering an innovative delivery mechanism, ease of use, suitability of pediatric patients helping in reducing reconstitution error or improve compliance, with 'Unique packaging' ensuring 'Dosage Compliance' as stipulated in Para 11(3) of DPCO, 2013.

5. The Committee deliberated upon the representation of the applicant and directed that the company may submit the additional supporting documents, if any, in justification of their claim and appear before the committee in next meeting to present the case. The applicant vide letter dated 17.02.2025 submitted their response.

6. In the 66th meeting of the MDC held on 03.03.2025, the representatives of the company made a detailed presentation in support of their claim. The Committee deliberated upon the submission of the company dated 17.02.2025 and re-examined the applicability of Para 11(3) to the application. The Committee observed that the provision of the Para 11(3) of the DPCO, 2013 read as below:

> *(3) 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.*

7. After detailed deliberations, the Committee opined that Para 11(3) may be invoked in case of injections or inhalation or any other medicine for which dosage form or strength or both are not specified in the Schedule-I. The applied formulation is an oral suspension and the dosage & strength of the same is mentioned in the Schedule-I. Therefore, the current application does not fall in the purview of Para 11(3). Hence, the committee recommended to reject the application.

Agenda Item No. 7: Application for separate ceiling price for "special feature" scheduled product under para 11(3) by M/s Gufic Biosciences Limited Meropenem injection in DCB (Dual Chamber Bags).

1. The Committee noted that M/s Gufic Biosciences Limited applied under para 11(3) for 'Special Feature rate' for packing of scheduled the formulation Meropenem in DCB (Dual Chamber Bags) under 'New Drug Delivery System' their vide letter dated 10.06.2025 as detailed below:

SI. No.	Product Name	Composition	Proposed Ceiling Price	Existing Ceiling Price	Proposed % increase
1	Merofic DCB 500 MG Injection	Meropenem Sterile 500 MG	Rs.1000	Rs.735.60	35.94 %
2	Merofic DCB 1 GM Injection	Meropenem Sterile 1 GM	Rs.1300	Rs.969.32	34.11 %

2. It was noted that the company claimed following special features for its Dual Chamber Bag (DCB):

i. The DCB keeps components separate until use, allowing quick and sterile reconstitution directly in the IV bag.
ii. Reduces drug preparation time from 6–7 minutes to just 20 seconds, streamlining ICU and hospital workflows.
iii. Minimizes manual handling, reducing the risk of cross-contamination, needle stick injuries, and dosing errors—especially critical during high pressure situations like pandemics.
iv. Eliminates the need for additional packaging materials (vials, syringes, needles), lowering medical waste and transport/storage costs.
v. Ensures correct dosing with integrated design and simplifies administration for healthcare workers.
vi. Meropenem is used to treat serious, life-threatening infections such as bacterial meningitis and complicated intra-abdominal or skin infections.
vii. Rapid and accurate administration is vital to patient outcomes, particularly in critical care settings.

3. The Committee deliberated upon the application of the company and directed that the applicant 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. 8: Application for approval of separate ceiling price for formulations in EURO Head packaging by M/s BML Parenteral Drugs

1. The Committee noted that M/s BML Parenteral Drugs applied for extension of separate ceiling prices fixed for the following I.V. fluids in Euro Head Packaging vide their email dated 12.03.2025:

Sr. No.	Name of Product	Pack Size	MRP including GST Claimed
1.	Sodium Chloride Injection 0.9% w/v	100ml	44.00
2.	Sodium Chloride Injection 0.9% w/v	250ml	65.00
3.	Sodium Chloride Injection 0.9% w/v	500ml	90.00
4.	Compound Sodium Lactate Injection	500ml	70.00
5.	Compound Sodium Lactate Injection	250ml	55.00
6.	Dextrose Injection IP 5% w/v	500ml	90.00
7.	Dextrose 5% + Sodium Chloride 0.9% Injection	500ml	90.00

2. The Committee noted that the complete documents were submitted by the company vide letter dated 8.05.2025 and 28.06.2025. The Committee deliberated upon the application of the company and directed that the applicant 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. 9: Application for extension of ceiling price of I.V. Fluids with Packaging in non glass with special feature by M/s Pharma Impex Laboratories Pvt. Ltd.

1. The Committee noted that M/s Pharma Impex Laboratories Pvt. Ltd. applied for extension of ceiling price of following I.V. with packaging in non glass with special feature for the following formulations vide its letters dated 7.11.2024 and 10.1.2025:

Sr. No.	Name of Product	Pack Size	Notification No. as mentioned in application
1.	Sodium Chloride Injection 0.9% w/v	100ml, 500 ml & 1000 ml	1552(E) Dated 26.03.2024
2.	Dextrose (Glucose) Injection 25% (w/v)	100ml	2289(E) Dated 14.06.2024
3.	Metronidazole Injection (0.5% w/v)/500mg/100ml	100ml	1555(E) Dated 26.03.2024
4.	Ciprofloxacin Injection 200 mg per 100 ml	100ml	2286(E) Dated 14.06.2024
5.	Glucose (Dextrose) 5% + Sodium Chloride 0.9% Injection	500 ml & 1000 ml	1552(E) Dated 26.03.2024
6.	Glucose Injection 5% (w/v)	500 ml & 1000 ml	1552(E) Dated 26.03.2024
7.	Mannitol Injection 20%	100ml	1556(E) Dated 26.03.2024
8.	Ringer Lactate Injection	500 ml & 1000 ml	1553(E) Dated 26.03.2024

2. The Committee noted that there were deficiencies in the documents submitted by the applicant and the same were rectified vide letter dated 21.04.2025 and 10.06.2025. The committee deliberated upon the application of the company and directed that the applicant 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. 10: Application for approval of separate ceiling prices under Para 11(3) of the DPCO, 2013 for IV fluid in Euro Head /LDPE Bottles with special features by M/s Hindustan Polyfab

1. The Committee noted that M/s Hindustan Polyfab applied for separate ceiling prices under Para 11(3) of the DPCO, 2013 vide their letter dated 30.6.2025. The company mentioned that their Euro Head/LDPE bottles are designed with to ensure the safety and well-being of patients. The self-collapsibility feature allows for easy administration of the fluid, while the self -sealability ensured that there is no leakage or spillage during the process. Furthermore, the absence of an air vent eliminates the possibility of contamination, making their product a safer and more reliable choice of healthcare providers. These bottles are unbreakable and lightweight. The applicant filed the application for the following IV Fluids:

Sr. No.	Name of Product	Pack Size	MRP including GST Claimed
1.	Sodium Chloride Injection 0.9% w/v	100ml	47.92
2.	Sodium Chloride Injection 0.9% w/v	500ml	100.21
3.	Dextrose Injection IP 5% w/v	500ml	93.74
4.	Dextrose 5% + Sodium Chloride 0.9% Injection	500ml	97.45
5.	Dextrose Injection IP 25% w/v	100ml	26.88
6.	Compound Sodium Lactate Injection	500ml	74.02
7.	Ciprofloxacin Injection 200mg/100ml	100ml	25.76
8.	Metronidazole Injection 500mg/100ml	100ml	28.00
9.	Dextrose Injection IP 10% w/v	500ml	41.25

2. The Committee deliberated upon the application of the company and directed that the applicant 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. 11: Retail price fixation of each extended-release film coated tablets contains: Clarithromycin IP 1000 mg for M/s Abbott Healthcare Pvt. Ltd. (Manufacturer & Marketer) under DPCO, 2013 (F.No. 4709).

1. The Committee noted that data for the Clarithromycin IP 1000 mg ER tablets is not available in the Pharmarack database of May, 2025. It was noted that the company had claimed a price of Rs.13 per tablet (excluding tax).

2. It was also noted that Clarithromycin tablet 500mg is a scheduled formulations and the ceiling price applicable on 6 months prior to date of application i.e. November 2024 is 39.84 per tablet (S.O.1547(E) dated 26.03.2024).

3. The Committee observed the retail price data for the Clarithromycin IP 1000 mg ER tablets using the formula recommended in the Pronab Sen Committee report comes to Rs.71.71 per tablet (excluding taxes) as calculated below:

Derived retail price as per recommendation of Pronab Sen committee:
P(s) = P*[1+a.{(s-s*)/s*}]
Where: P(s) =Price ceiling of the strength s
P* = price ceiling for reference strength s*
s = strength in terms of API content
s* = reference strength
a= 0.8 for tablet / capsule and 0.7 for injectables.

= 39.84[1+0.80{(1000-500)/500}] = Rs. 71.71 (excluding GST) per tablet

4. Accordingly, the committee deliberated upon the matter and recommended the price for Clarithromycin IP 1000mg at Rs.13 per tablet (excluding tax) being lower of claimed or worked price.

The meeting ended with a vote of thanks to all.

MAHAVEER SAINI
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(Mahaveer Saini)
Dy. Director (Pricing)

Copy to:
All members of the Committee.