

National Pharmaceutical Pricing Authority

Subject: Minutes of the 70th meeting of the Multidisciplinary Committee of Experts held on 05.08.2025 at 3:00 PM.

70th meeting of the Multidisciplinary Committee of Experts was held on 05.08.2025 at 3:00 PM under the convenorship of Shri Sanjay Kumar, Advisor (Cost). The following members attended the meeting:

1. Shri Ranga Chandrashekar, Joint Drugs Controller, CDSCO, through Video Conferencing
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. 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
5. Dr. Jai Prakash, Indian Pharmacopoeia Commission – Co-opted member,
6. Dr. Pooja Gupta, Professor, Department of Pharmacology, AIIMS-New Delhi through video conferencing

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: Retail price fixation of each film coated tablets contains: Amlodipine Besylate IP eq. to Amlodipine 2.5 mg and Bisoprolol Fumarate IP 2.5 mg for M/s Exemed Pharmaceuticals (Manufacturer) and M/s Torrent Pharmaceuticals Ltd. (Marketer) under DPCO, 2013 (File No. 4777)

1. The committee deliberated on the application of the company and recommended the retail price for each film coated tablets contains: Amlodipine Besylate IP eq. to Amlodipine 2.5 mg and Bisoprolol Fumarate IP 2.5 mg as below:

S. No.	Particulars	Source/ Method	Amount (Rs.)
(a)	Amlodipine 2.5 mg	Ceiling Price as applicable six months prior to month in which application is received i.e. November 2024 [SO. 1547(E) dated 26.3.2024]	1.79
(b)	Bisoprolol 2.5 mg	Retail price as on 6 months prior to application date i.e. MAT & PTR for November 2024	5.96
(c)	Total		7.75
(d)	Less 20% of the lower of (a) and (b)		0.36
(e)	Worked out Retail Price (a)+(b)+(c)-(d)		7.39
(f)	Claimed Retail price		9.85
(g)	Recommended retail price per tablet (lower of worked out (e) and claimed price (f))		7.39

Agenda Item No. 2: Retail price fixation of each film coated tablets contains: Amlodipine Besylate IP eq. to Amlodipine 2.5 mg Bisoprolol Fumarate IP 5 mg for M/s Exemed Pharmaceuticals (Manufacturer) and M/s Torrent Pharmaceuticals Ltd. (Marketer) under DPCO, 2013 (File No. 4778)

1. The committee deliberated on the application of the company and recommended the retail price for each film coated tablets contains: Amlodipine Besylate IP eq. to Amlodipine 2.5 mg and Bisoprolol Fumarate IP 5 mg as below:

S. No.	Particulars	Source/ Method	Amount (Rs.)
(a)	Amlodipine 2.5 mg	Ceiling Price as applicable six months prior to month in which application is received i.e. November 2024 [SO. 1547(E) dated 26.3.2024]	1.79
(b)	Bisoprolol 5 mg	Retail price as on 6 months prior to application date i.e. MAT & PTR for November 2024	8.04
(c)	Total		9.83
(d)	Less 20% of the lower of (a) and (b)		0.36
(e)	Worked out Retail Price (a)+(b)+(c)-(d)		9.47
(f)	Claimed Retail price		11.85
(g)	Recommended retail price per tablet (lower of worked out (e) and claimed price (f))		9.47

Agenda Item No. 3: 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 on 10.03.2025 for extension of separate ceiling prices fixed for the following I.V. fluids in Euro Head Packaging:

Sr. No.	Name of Product	Pack Size	Claimed MRP including GST (Per Pack)	Claimed MRP excluding GST (Per Pack)	Ceiling Price w.e.f. 01.04.2024 (Per Pack)
1.	Sodium Chloride Inj 0.9% w/v	100ml	44.00	39.29	42.06
2.	Sodium Chloride Inj 0.9% w/v	250ml	65.00	58.04	62.10
3.	Sodium Chloride Inj 0.9% w/v	500ml	90.00	80.36	87.94
4.	Compound Sodium Lactate Injection	500ml	70.00	62.50	50.99
5.	Compound Sodium Lactate Injection	250ml	55.00	49.11	64.96
6.	Dextrose Injection IP 5% w/v	500ml	90.00	80.36	82.27
7.	Dextrose 5% + Sodium Chloride 0.9% Inj.	500ml	90.00	80.36	85.52

2. The Committee noted that the matter was deliberated in 69th meeting held on 03.07.2025, wherein the Committee decided to call the applicant in the next meeting to present their case and demonstrate their product. Accordingly, the applicant company appeared before the committee and demonstrated its products. The committee noted that the product bears the features of self-sealability, self-collapsibility and has a Euro head to prevent the contamination. The representative of the Company also informed that the application was filed in March 2025 and at that time the ceiling price applicable

for these formulations was notified in March 2024. The applicant claimed prices lesser than the separate ceiling prices notified at that time. Now, these prices have been revised based on WPI in March 2025, which are effective from 01.04.2025. The applicant requested to extend the separate ceiling prices for the applied formulations as applicable w.e.f. 01.04.2025.

3. Accordingly, 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 and recommended the separate ceiling price for the following formulations:

Sr. No.	Name of Product	Pack Size	Notification No.	Ceiling price (Rs.)
1.	Sodium Chloride Inj 0.9% w/v	100ml	1485(E) Dated 27.03.2025	42.79/pack
2.	Sodium Chloride Inj 0.9% w/v	250ml	1485(E) Dated 27.03.2025	63.18/pack
3.	Sodium Chloride Inj 0.9% w/v	500ml	1485(E) Dated 27.03.2025	89.47/pack
4.	Ringer Lactate Inj.	250ml	1474(E) Dated 27.03.2025	51.88/pack
5.	Ringer Lactate Inj.	500ml	1474(E) Dated 27.03.2025	66.09/pack
6.	Glucose Injection 5% (w/v)	500ml	1485(E) Dated 27.03.2025	83.70/pack
7.	Glucose (Dextrose) 5% + Sodium Chloride 0.9% Inj.	500ml	1485(E) Dated 27.03.2025	87.01/pack

Agenda Item No. 4: 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 on 30.06.2025 for separate ceiling prices under Para 11(3) of the DPCO, 2013 stating that their Euro Head/LDPE bottles are designed with the utmost care 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 Inj 0.9% w/v	100ml	47.92
2.	Sodium Chloride Inj 0.9% w/v	500ml	100.21
3.	Dextrose Injection IP 5% w/v	500ml	93.74
4.	Dextrose 5% + Sodium Chloride 0.9% Inj.	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 noted that the matter was deliberated in 69th meeting held on 03.07.2025, wherein the Committee decided to call the applicant in the next meeting to present their case and demonstrate their product. Accordingly, the applicant company appeared before the committee and demonstrated its products. The committee noted that the product bears the features as claimed self-sealability, self-collapsibility and has a Euro head to prevent the contamination. The applicant also requested to withdraw the application for two formulations listed at S.No. 5 and 9 of above tablet i.e., Dextrose Injection IP 25% w/v in 100ml and Dextrose Injection IP 10% w/v in 500ml.

3. Accordingly, the Committee examined the documents relating to flow rate analysis, certificate of analysis and undertaking for plastic used in manufacturing of the plastic containers as per IP for the remaining 7 formulations and recommended the separate ceiling price for the following formulations:

Sr. No.	Name of Product	Pack Size	Applicable ceiling price w.e.f. 01.04.2025 (S.O. No. & Date)	Claimed MRP/pack including GST	Claimed MRP/pack excluding GST	Recommended Price (Per Pack)
1.	Sodium Chloride Inj 0.9% w/v	100ml	42.79/pack (1485(E) dt.27.03.2025)	47.92	42.79	42.79
2.	Sodium Chloride Inj 0.9% w/v	500ml	89.47/pack (1485(E) dt.27.03.2025)	100.21	89.47	89.47
3.	Dextrose Injection IP 5% w/v	500ml	83.70/pack (1485(E) dt.27.03.2025)	93.74	83.70	83.70
4.	Dextrose 5% + Sodium Chloride 0.9% Inj.	500ml	87.01/pack (1485(E) dt.27.03.2025)	97.45	87.01	87.01
5.	Compound Sodium Lactate Injection	500ml	66.09/pack (1474(E) dt.27.03.2025)	74.02	66.09	66.09
6.	Ciprofloxacin Injection 200mg/100ml	100ml	0.23/ml (1486(E) dt.27.03.2025)	25.76	23.00	23.00
7.	Metronidazole Injection 500mg/100ml	100ml	0.25/ml (1486(E) dt.27.03.2025)	28.00	25.00	25.00

Agenda Item No. 5: Application for extension of ceiling price of L.V. Fluids with Packaging in non-glass with special feature in line with 1552(E), 1553(E), 1555(E), 1556(E) dated 26.03.2024, S.O. No. 2286(E) dated 14.06.2024 & S.O. No. 2289(E) dated 14.06.2024 by M/s Pharma Impex Laboratories Pvt. Ltd.

1. The Committee noted that M/s Pharma Impex Laboratories Pvt. Ltd. vide email dated 07.11.2024 & 10.1.2025 applied for extension of ceiling price of following I.V. with packaging in non-glass with special feature for the following formulations:

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

2. It is also pertinent to mention that, with respect to the documents submitted by the applicant, clarifications were sought vide letter dated 07.03.2025. The applicant submitted a response on 21.04.2025. Subsequently, due to deficiencies in the submitted documents, further clarifications were requested through a letter dated 26.05.2025, to which the applicant responded on 10.06.2025. Accordingly, the matter was deliberated in 69th meeting held on 05.07.2025, wherein the Committee decided to call the applicant in the next meeting to present their case and demonstrate their product. Accordingly, the applicant company appeared before the committee and demonstrated its products. The Committee noted that the product bears the features as claimed i.e., no chances of contamination during manufacture/ infusion/admixing level, self-sealability, self-collapsibility and not having air-vent. The Committee examined the documents relating to flow rate analysis, certificate of analysis for plastic used in manufacturing of the plastic containers and undertaking for the plastic used as per IP.

3. The Committee also noted that application was received in 2024 and at that the ceiling prices for these formulations were applicable based on WPI notification issued effective from April 2024. However, the present applicable ceiling price of the applied formulations having special features to the eligible applicant companies have been revised w.e.f. 01.04.2025. Accordingly, the Committee recommended the separate ceiling prices as below:

Sr. No.	Name of Product	Pack Size	Notification No. as mentioned in application	Ceiling price applicable as on date (Rs.)
1.	Sodium Chloride Inj 0.9% w/v	100ml	1485(E) Dated 27.03.2025	42.79/pack
2.	Sodium Chloride Inj 0.9% w/v	500ml	1485(E) Dated 27.03.2025	89.47/pack
3.	Sodium Chloride Inj 0.9% w/v	1000ml	1485(E) Dated 27.03.2025	100.22/pack
4.	Dextrose (Glucose) Injection, 25%(w/v)	100ml pack	1486(E) Dated 27.03.2025	0.24/ml

Sr. No.	Name of Product	Pack Size	Notification No. as mentioned in application	Ceiling price applicable as on date (Rs.)
5.	Metronidazole Inj. (0.5% w/v)/500mg/100ml	100ml	1486(E) Dated 27.03.2025	0.25/ml
6.	Ciprofloxacin Inj. 200 mg. per 100 ml	100ml	1486(E) Dated 27.03.2025	0.23/ml
7.	Glucose (Dextrose) 5% + Sodium Chloride 0.9% Inj.	500ml	1485(E) Dated 27.03.2025	87.01/pack
8.	Glucose (Dextrose) 5% + Sodium Chloride 0.9% Inj.	1000ml	1485(E) Dated 27.03.2025	101.68/pack
9.	Glucose Injection 5% (w/v)	500ml	1485(E) Dated 27.03.2025	83.70/pack
10.	Glucose Injection 5% (w/v)	1000ml	1485(E) Dated 27.03.2025	96.77/pack
11.	Mannitol Inj. 20%	100ml	1486(E) Dated 27.03.2025	0.41/ml
12.	Ringer Lactate Inj.	500ml	1474(E) Dated 27.03.2025	66.09/pack
13.	Ringer Lactate Inj.	1000ml	1474(E) Dated 27.03.2025	116.20/pack

Agenda Item No. 6: 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 for ‘Special Feature rate’ of scheduled product ‘Meropenem injection’ in DCB (Dual Chamber Bags) under para 11(3) of DPCO, 2013 as detailed below:

Sl. 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. The Committee also recalled that separate ceiling price i.e., 15% increase over the existing ceiling prices was recommended by the MDC in its 52nd meeting held on 11.07.2023 for another formulation i.e., Tazofic Injection formulations (2.25 gm and 4.5 gm) containing Piperacillin and Tazobactam in dual-chamber packaging for the applicant. This recommendation was accepted by the Authority in its 116th meeting held on 06.09.2023. Accordingly, separate ceiling prices were notified in this respect for the applicant.

4. The Committee also recalled that M/s Gufic Biosciences Limited earlier applied on 19.07.2023 for separate price for Meropenem Sterile Injection 500mg and 1000mg in Dual Chamber Bags (DCB) i.e., for the products under consideration. The matter was discussed in several meetings, where the company demonstrated the benefits of DCB, including faster reconstitution, reduced dilution errors, improved stability, and minimized contamination. However, the company did not submit CDSCO

approval for the Large Volume Parenteral (LVP) version of Meropenem 1000mg. Accordingly, the Committee in its 60th MDC held on 26.06.2024 rejected the application.

5. Now the applicant company has submitted the CDSCO/DCGI approval for the LVP and presented their case before the Committee. The Committee deliberated on the submissions of the applicant and observed that M/s Gufic Biosciences Limited have special feature (i) self-collapsibility and self-sealability (ii) not having air-vent; and (iii) there is no chance of contamination during manufacture/ infusion/ admixing levels in their dual chamber bags. Accordingly, the Committee recommended the separate ceiling price for Meropenem injection 500mg and 1000mg in DCB (Dual Chamber Bags) under para 11(3) of DPCO, 2013 @ present applicable ceiling prices + 15% in line with increase considered earlier for this type of packaging, as detailed below:

SI. No.	Name of the Scheduled Formulation	Claimed Price	Existing Ceiling Price w.e.f. 01.04.2025	Separate Ceiling proposed i.e., ceiling price + 15%
1	Meropenem Powder for Injection 500 mg (as trihydrate) in Dual chamber bags	Rs. 1000	Rs. 735.60	Rs. 845.94
2	Meropenem Powder for Injection 1000 mg (as trihydrate) in Dual chamber bags	Rs. 1300	Rs. 969.32	Rs. 1114.72

Agenda Item No. 7: Application for separate pricing for paracetamol infusion as per Para 11 (3) of the Drugs Price control order (DPCO), 2013 in Non-PVC bag with special features by M/s Themis Medicare Limited.

1. M/s Themis Medicare Limited and M/s Appasamy Ocular applied for special price approval of Paracetamol 1000MG/100ML in a non-PVC bag with special features under Para 11(3) of the DPCO, 2013, on 03.12.2024. They requested a price of Rs. 850 per pack, higher than the existing Rs. 577.57 per pack for the FFS bottle, citing features like a closed system of infusion.

2. The Committee in the discussions held in the 67th and 68th meetings held on 02.04.2025 & 03.06.2025 respectively, observed that the company had already launched the formulation with special features. However, the MRP was same as product without special features (FFS bottle). The company has now sought separate price at RS. 850 per pack. The committee in the 68th meeting requested additional information, including the launch date and price of the product, as well as certified quantity data. The applicant submitted the launch details and pricing history on 02.07.2025. However, the company vide email dated 31.07.2025, withdrew the application and decided to continue marketing the product at the existing MRP. The committee accepted the withdrawal and recommended to close the matter.

Agenda Item No. 8: Application or approval of separate ceiling prices under Para 11(3) of the DPCO, 2013 for IV fluid in Euro Head / PP Bottles with special features by M/s IV Tech Healthcare

1. The Committee noted that M/s IV Tech Healthcare applied on 18.07.2025 applied for separate ceiling prices under Para 11(3) of the DPCO, 2013 stating that their IV fluids packaged in Twin port Euro Head / PP bottles, which incorporate special features enhancing their utility and performance for the following formulations:

Sr. No.	Name of Product	Pack Size	Notification	Claimed MRP excluding GST /Pack
1	Metronidazole Injection: Each 100ml contains Metronidazole 0.5gm	100ml	1486(E) dt. 27.03.25	25.00
2	Dextrose Injection IP 5% w/v : Each 100ml contains Dextrose Anhydrous IP 5gm	500ml	1485(E) dt. 27.03.25	83.70
3	Dextrose Injection IP 5% w/v : Each 100ml contains Dextrose Anhydrous IP 5gm	1000ml	1485(E) dt. 27.03.25	96.77
4	Dextrose Injection IP 5% w/v & Sodium Chloride 0.9% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm & Sodium Chloride IP 900mg	500ml	1485(E) dt. 27.03.25	87.01
5	Dextrose Injection IP 5% w/v & Sodium Chloride 0.9% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm & Sodium Chloride IP 900mg	1000ml	1485(E) dt. 27.03.25	101.68
6	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	100ml	1485(E) dt. 27.03.25	42.79
7	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	500ml	1485(E) dt. 27.03.25	89.47
8	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	1000ml	1485(E) dt. 27.03.25	100.22
9	Compound Sodium Lactate Injection	500ml	1474(E) dt. 27.03.25	66.09
10	Compound Sodium Lactate Injection	1000ml	1474(E) dt. 27.03.25	116.20
11	Mannitol Injection 20%: Each 100ml contains Mannitol IP 20gm	100ml	1486(E) dt. 27.03.25	41.00
12	Dextrose Injection IP 25%: Each 100ml contains Dextrose anhydrous IP 25gm	100ml	1486(E) dt. 27.03.25	24.00

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 additional benefits claimed in the application.

Agenda Item No. 9: Application for exemption of 'New Drug'- Povidone Iodine Throat Spray 0.45 % w/v under Paragraph 32(iii) of the Drugs (Prices Control) Order 2013 by M/s G.S. Pharmbutor Private Limited

1. The Committee noted that M/s G.S. Pharmbutor Private Limited applied on 30.04.2025 for exemption of Povidone Iodine Throat Spray 0.45% w/v under Para 32(iii) of the DPCO, 2013.

2. The applicant claimed that the new drug product, Betadine Throat Spray 0.45% w/v, combines Povidone Iodine with ethanol and is formulated using an innovative, indigenous drug delivery system

developed by the company's in-house R&D team. This novel delivery system ensures precise dosage at the infection site, optimizing anti-infective action for enhanced treatment and patient compliance. The formulation underwent rigorous quality tests for characteristics such as pH, viscosity, spreadability, and droplet size, distinguishing it from traditional mouthwashes and gargles. Following clinical trials and approval by the CDSCO, the product is the first of its kind in India. It qualifies as a "new drug" and benefits from non-application of price control under Para 32(iii) of the DPCO 2013 for five years.

3. The Committee noted that Povidone Iodine Solution 4% to 10% and Drops 5% are scheduled formulation. 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 exemption from the DPCO, 2013 under Para 32(iii).

Agenda Item No. 10: 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 the application of M/s Biodeal Pharmaceuticals Limited 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 was deliberated in 68th & 69th meeting of MDC held on 03.06.2025 and 03.07.2025 respectively.

2. In 69th meeting of MDC, the committee has directed the applicant to provide supporting documents for their claim regarding a new delivery system. In response, on 22.07.2025, the company provided the minutes of the SEC (Neurology & Psychiatry) meeting held on 18.04.2024. They emphasized that Midazolam Nasal Spray had not previously been approved by the CDSCO, only the tablet and parenteral forms were approved. They also claimed that since the first approval for Intranasal Midazolam was granted to Biodeal Pharmaceuticals by the CDSCO, this validated their new delivery system as a novel one. In view of the same, inputs were sought from the O/o CDSCO vide letter dated 28.07.2025.

3. O/o CDSCO vide letter dated 01.08.2025, confirmed that Biodeal Pharmaceuticals was granted new drug permission for Midazolam Nasal Spray 1.25% w/v on 05.05.2025, confirming that the nasal spray 1.25% w/v was not previously approved by them.

4. The Committee deliberated on the application of the company and inputs of DCGI office and directed that the applicant may be asked to appear before the Committee in next meeting along with product development documents justifying the claim under Para 32(iii).

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 recalled that the retail price for the applied formulation was recommended in the 69th meeting of MDC held on 03.07.2025 at Rs.13 per tablet being lower of claimed (13.00) and worked out price (Rs.71.71). The price was worked out by applying Pronab Sen formula on Ceiling price of Clarithromycin tablet 500mg (Rs. 39.84 per tablet) applicable on 6 months prior to date of application i.e., November 2024 as below:

Derived retail price as per recommendation of Pronab Sen committee:

$$P(s) = P^*[1 + a \cdot \{(s - s^*)/s^*\}]$$

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.

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

2. M/s Abbott Healthcare Pvt. Ltd. has submitted a representation on 16.07.2025, stating that there was a typographical error in their Form I submission on IPDMS and claimed price was incorrectly stated as Rs. 13 per tablet (Rs.91/ per strip of 7 tablets) instead of the correct Rs. 91 per tablet.

3. The Committee deliberated up on the matter. It was noted that ceiling price for Clarithromycin Tablet 250mg and 500mg applicable on 6 months prior to date of application i.e., November 2024 was Rs. 23.89 & 39.84 per tablet respectively. Further, there is no other company marketing the applied formulation.

4. In view of the above, the Committee observed that M/S Abbott Healthcare Pvt. Ltd. in its representation on page 1, last paragraph mentioned "On analysis, it is observed that there has been a typographical error on our side while filing the form I in IPDMS". Committee noted the serious error committed by the applicant and recommended the retail price for each extended-release film coated tablets contains: Clarithromycin IP 1000 mg at Rs.71.71 per tablet, as worked out by applying the Pronab Sen formula as detailed at para 1 above. The committee also directed the applicant to ensure avoiding such negligence which could affect the committee deliberations and unnecessarily delay the disposal of Form I applications.

The meeting ended with a vote of thanks to all.

(Rashmi Tahiliani)
Director (Pricing)

Copy to:
All members of the Committee.