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

National Pharmaceutical Pricing Authority

Subject: Minutes of the 75th meeting of the Multidisciplinary Committee of Experts held on 11.02.2026 at 11:00 AM.

75th meeting of the Multidisciplinary Committee of Experts was held on 11.02.2026 at 11:00 AM 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. 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. Gaurav Pratap Singh, Sr. Principal Scientific Officer, Indian Pharmacopoeia Commission – Co-opted member,
7. Shri Sukhdeep Singh, Deputy Controller of Patent & Design, through Video Conferencing **(for Agenda 1 to 3)**

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)
6. Shri Devanshu Gupta, Assistant Director (Pricing)
7. Shri Mayur Panwar, Assistant Director (Pricing)

Agenda Item No. 1: Application for exemption of patented non-scheduled formulation Nafithromycin Tablets under Para 32(i) of DPCO, 2013 by M/s Wockhardt Limited.

1. The Committee noted that M/s Wockhardt Limited submitted an application on 14.07.2025 seeking exemption for the non-scheduled formulation Nafithromycin Tablets under Para 32(i) of the DPCO, 2013. The company had submitted the permission of the formulation granted by the Central Drugs Standard Control Organization (CDSCO) and the Patent Certificate (Patent No. 415319, granted on 23.12.2022) under the Patent Act, 1970.

2. The Committee also noted that NPPA vide letter dated 07.08.2025 sought the complete set of claims submitted to the Patent office by the company as neither the patent certificate nor the claims filed with the Patent Office explicitly mention the name 'Nafithromycin'. In response the company along with other documents furnished Summary of inventions & claims and the scientific publication from a peer reviewed journal "Chromatographia (2019) 82:1059-1068", as published in Springer Nature 2019.

3. The Committee in its 71st meeting held on 16.09.2025 noted that Patent No. 415319, granted on 23.12.2022 is registered in the name of Wockhardt Limited for an invention titled "Pharmaceutical compositions". However, the drug approval from CDSCO (Approval No. IND/MA/24/00001 dated

01.01.2025) pertains specifically to "Nafithromycin Tablets – Immediate release film-coated tablets – each film-coated tablet containing Nafithromycin 400 mg".

4. The Committee directed that inputs be obtained from CDSCO and the Office of the Controller General of Patents, Designs & Trade Marks (CGPDTM) to verify whether the formulation approved by CDSCO corresponds to the one for which the patent was granted.

5. Office of the Controller General of Patents, Designs & Trade Marks (CGPDTM) vide email dated 02.01.2026 confirmed that *"the CDSCO-approved Nafithromycin tablet formulation corresponds to the scope of the granted claims of Patent No. 415319, insofar as the claimed solid tablet composition is concerned."*

6. Accordingly, the matter was placed in the 75th MDC meeting. During the discussion the representative from CDSCO stated that as per the comments received from O/o CGPDTM, it is clear that the formulation approved by CDSCO is covered under the scope of Patent granted by Patent Office for Nafithromycin tablet 400 mg.

7. The Committee deliberated upon the matter and based on the inputs from O/o CGPDTM and CDSCO as above, noted that the applied formulation Nafithromycin Tablets – Immediate release film-coated tablets – each film-coated tablet containing Nafithromycin 400 mg is covered under patent granted. Accordingly, the committee recommended to grant exemption for tablet Nafithromycin 400 mg" under Para 32(i) of DPCO, 2013 to M/s Wockhardt Ltd for a period of five years from the date of commencement of its commercial marketing by M/s Wockhardt Ltd. in the country.

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 Committee recalled that M/s Intas Pharmaceuticals had earlier applied for exemption under para 32(iii) for the same formulations. The matter was deliberated in 44th MDC meeting held on 04.08.2022 wherein the Committee deliberated that different variant of a drug like extended release, modified release of a drug was in the market since a considerable period and also manufactured by a number of companies. Hence, it could not be considered as a 'New Delivery System' qualifying for exemption under Para 32 (iii) of DPCO, 2013. Accordingly, the Committee rejected the application of M/s Intas Pharmaceuticals Limited for exemption from the provisions of Drug Price Control Order 2013 under Para 32 (iii) for the formulations "Clozapine Extended Release Capsules 12.5mg/ 25mg / 50mg / 100mg / 200mg".

2. Subsequently, the company vide its letter dated 07.10.2024 stated the "Clozapine Extended Release Capsules 12.5mg/ 25mg / 50mg / 100mg / 200mg" are being produced in the country by a new process through indigenous research and development and is patented under the Indian Patent Act, 1970. The company submitted the patent certificate No. 437433 titled "Extended Release pharmaceutical composition of Clozapine".

3. The matter was deliberated in the 69th meeting of MDC held on 03.07.2025. 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 30.10.2024, 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 taking the final decision in the matter.

5. In response, the applicant vide mail dated 22.07.2025 stated that they had inadvertently submitted wrong claim documents and requested to reconsider the revised claim documents submitted on 23.04.2025. Accordingly, revised claim documents were sent to the O/o CGPTDM. In response, O/o CGPTDM submitted their inputs on the revised claim documents as follows:

> "*It has been found that, subject-matter as submitted by applicant company before NPPA, and the subject-matter that is approved by DGCA i.e. "Clozapine Extended Release 12.5 mg/25mg/50mg/100mg/200 mg Capsule", fall within the scope of granted Claim 1 of the patent application*".

6. Accordingly, based on the inputs received from O/o CGPTDM, the matter was deliberated in 75th MDC meeting. The committee noted that the company has already launched the said formulations in 2025. In the meeting representative from the O/o CGPDTM reiterated that the applied formulation falls within the scope of granted claims of patent application. Accordingly, the committee recommended to grant exemption for the formulations Clozapine Extended Release 12.5 mg/ 25 mg/ 50 mg/ 100 mg/200 mg capsule under Para 32(ii) of DPCO, 2013 to M/s Intas Pharmaceuticals Private Limited for a period of 5 years from the date of the commencement of commercial production in the country.

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 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 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 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 DPIIT before final taking the final decision in the matter.

2. Accordingly, inputs were sought from 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 01.8.2025. 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 placed before the 75th MDC meeting 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.

Agenda Item No. 4: 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.

3. Accordingly, the matter was placed in 75th MDC meeting. However, no representative from the company appeared for the demonstration in the meeting. Therefore, the Committee decided to defer matter and call the representative from company in next meeting.

Agenda Item No. 5: 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	

2. The Committee deliberated upon the application of the company and 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.

Agenda Item No. 6: Retail price fixation for 'Each 5 ml Contains: Paracetamol IP 125 mg + Chlorpheniramine Maleate IP 1.5 mg Syrup' for M/s Indoco Remedies Ltd. (Manufacturer & Marketer) (F. No. 4950)

1. The Committee deliberated on the application of the company and recommended retail price as below:

Calculation of Retail Price			
S.N.	**Particulars**	**Source / Method**	**Amount (Rs.)**
	Each 5 ml Contains: Paracetamol IP 125 mg Chlorpheniramine Maleate IP 1.5 mg		
A.	Ceiling price of Paracetamol Oral Liquid 125 mg/5 mL	Ceiling price as on 6 months prior to application date i.e. May 2025 (SO 1489(E) dated 27.03.2025)	0.38
B.	Retail price of Chlorpheniramine Maleate IP 1.5 mg/5 mL	Note-1	0.50
C.	Total		0.88
D.	Less: 20% of lower of A&B taking inference from the Pronab Sen Committee Report		0.08
E.	Worked out Price of applied FDC		0.80
F.	Claimed Price		1.72
G.	**Recommended Price (Lower of worked out and claimed price) per ML**		**0.80**

Note-1:

(i) The retail price of 'Chlorpheniramine Maleate IP 1.5 mg/5ml' based on formula recommended in the Pronab Sen Committee report is as below:

Retail price of 'Chlorpheniramine Maleate IP 2 mg/5ml' as on 6 months prior to application date i.e., MAT & PTR for May 2025, is Rs. 0.60 per ML.

Derived retail price as per recommendation of Pronab Sen Committee:

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

Where P(s) = Retail Price of the strength s

P*= Retail Price 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.

$=0.60\ [1+0.7\{(1.5-2)/2\}]$

=Rs. 0.50 per mL (excluding GST)

Agenda Item No. 7: Retail price fixation for 'Each uncoated tablet contains: Paracetamol IP 650 mg + Caffeine Anhydrous IP 30 mg + Phenylephrine Hcl IP 10 mg + Chlorpheniramine Maleate IP 2 mg' for M/s Dallas Drugs Pvt. Ltd. (Manufacturer) & M/s Centaur Pharmaceuticals Pvt. Ltd. (Marketer) (F.No.: 4989)

1. The Committee deliberated on the application of the company and recommended retail price as below:

Calculation of Retail Price			
S.N.	**Particulars**	**Source / Method**	**Amount (Rs.)**
	Each uncoated tablet contains: Paracetamol IP 650 mg Caffeine Anhydrous IP 30 mg Phenylephrine Hcl IP 10 mg Chlorpheniramine Maleate IP 2 mg		
A.	Retail price of Paracetamol 650 mg + Caffeine Anhydrous 30 mg + Chlorpheniramine Maleate 2 mg	Retail price as on 6 months prior to application date i.e. MAT & PTR of June 2025	3.82
B.	Retail price of Phenylephrine Hcl 10 mg		4.72
C.	Total		8.54
D.	Less: 20% of lower of A&B taking inference from the Pronab Sen Committee Report		0.76
E.	Worked out Price of applied FDC		7.78
F.	Claimed Price		7.50
G.	**Recommended Price (Lower of worked out and claimed price) per tablet**		**7.50**

Agenda Item No. 8 to 14: Retail price fixation for 'Each Film Coated Tablet contains: Relugolix 40 mg + Estradiol (As Hemihydrate) USP eq. to Anhydrous Estradiol 1 mg + Norethindrone Acetate USP 0.5 mg' for

i. M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) & M/s Mankind Pharma Ltd. (Marketer) (F.No.: 4955)
ii. M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) & M/s Dr. Reddys Laboratories Ltd. (Marketer) (F.No.: 4976)
iii. M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) & M/s Torrent Pharmaceuticals Ltd. (Marketer) (F.No.: 4964)
iv. M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) & M/s La Renon Healthcare Pvt. Ltd. (Marketer) (F.No.: 4962)
v. M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) & M/s Eris Lifesciences Ltd. (Marketer) (F.No.: 4978)
vi. M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) & M/s Akumentis Healthcare Ltd. (Marketer)' (F.No.: 4968)
vii. M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) & M/s Aurobindo Pharma Ltd. (Marketer)' (F.No.: 4984)

1. The Committee noted that M/s. Takeda Pharmaceutical was the patent holder of *Relugolix* and the drug became off-patented on 29.01.2024. Based on the available market data, it is found that:

(i) The patent holder has not launched the drug in India.

(ii) The drug has been launched in India as generic version under different brands by M/s. Abbott Healthcare, M/s. Cipla., M/s IPCA Laboratories and M/s. Sun Pharma at different prices after the drug became off-patented.

2. The Committee deliberated on the matter in detail and recommended that fixation of retail prices of the applied FDC may be done by considering the market data of Relugolix 6 months prior to the month of application. Accordingly, the Committee worked out price of the FDC of **Each Film Coated Tablet contains Relugolix 40 mg + Estradiol (As Hemihydrate) USP eq. to Anhydrous Estradiol 1 mg + Norethindrone Acetate USP 0.5 mg** as below:

Calculation of Retail Price of Each Film Coated Tablet contains: Relugolix 40 mg + Estradiol (As Hemihydrate) USP eq. to Anhydrous Estradiol 1 mg + Norethindrone Acetate USP 0.5 mg			
S.N.	**Particulars**	**Source / Method**	**Amount (Rs.)**
A.	Derived Retail price of Relugolix 40 mg Tablet	Retail price 6 months prior to application date i.e. MAT & PTR for May/ June 2025 **Note-1**	107.13
B.	Retail price of Estradiol 1 mg Tablet	Retail price 6 months prior to application date i.e. MAT & PTR for May/ June 2025	12.27
C.	Derived Retail price of Norethindrone 0.5 mg Tablet	Ceiling price of 'Norethindrone 5 mg Tablet' (SO 1489(E) dated 27.03.2025) **Note-2**	1.53
D.	Total		120.93
E.	Less: 20% of lower of A,B&C taking inference from the Pronab Sen Committee Report		0.31
F.	Worked out Price of applied FDC		120.62

3. The Committee recommended the retail price for various applicants as below:

Sr No.	**Applicants**	**Claimed Price per tablet (Rs.)**	**Worked out Price per tablet (Rs.)**	**Recommended Price Lower of worked out and claimed price per tablet (Rs.)**
1	M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) & M/s Mankind Pharma Ltd. (Marketer)	140.00	120.62	120.62
2	M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) & M/s Dr. Reddys Laboratories Ltd. (Marketer)	140.00	120.62	120.62
3	M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) & M/s Torrent Pharmaceuticals Ltd. (Marketer)	156.80	120.62	120.62
4	M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) & M/s La Renon Healthcare Pvt. Ltd. (Marketer)	133.33	120.62	120.62
5	M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) & M/s Eris Lifesciences Ltd. (Marketer)	140.00	120.62	120.62
6	M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) & M/s Akumentis Healthcare Ltd. (Marketer)	125.00	120.62	120.62
7	M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) & M/s Aurobindo Pharma Ltd. (Marketer)	135.00	120.62	120.62

Note -1:

(i) The retail price of 'Relugolix 40 mg tablet' based on formula recommended in the Pronab Sen Committee report is as below:

Retail price of 'Relugolix 120 mg tablet' as on 6 months prior to application date i.e. MAT & PTR for May 2025, is Rs. 229.56 per Tablet.
Derived retail price as per recommendation of Pronab Sen Committee:

P(s) = P*[1+a.{(s-s*)/s*}]
Where P(s) = Retail Price of the strength s
P*= Retail Price 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.
=229.56 [1+0.8{(40-120)/120}]
=Rs. 107.13 per Tablet (excluding GST)

Note-2:
(i) The retail price of 'Norethindrone 0.5 mg Tablet' based on formula recommended in the Pronab Sen Committee report is as below:
Ceiling price of 'Norethindrone 5 mg Tablet' as on 6 months prior to application date i.e. May 2025, is Rs. 5.48 per Tablet. (SO 1489(E) dated 27.03.2025)
Derived retail price as per recommendation of Pronab Sen Committee:

P(s) = P*[1+a.{(s-s*)/s*}]
Where P(s) = Retail Price 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.
=5.48 [1+0.8{(0.5-5)/5}]
=Rs. 1.53 per Tablet (excluding GST)

Agenda Item No. 15: 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.

1. The Committee noted that M/s G.S. Pharmbutor Private Limited on 30.04.2025 submitted the application for exemption of Povidone Iodine Throat Spray 0.45% w/v under Para 32(iii) of the DPCO, 2013. The matter was placed in the 70th meeting and 71st meeting of the Multidisciplinary Committee (MDC) held on 05.08.2025 and 16.09.2025 respectively. The representative of company, gave a presentation in 71st meeting and also demonstrated the product. The matter was deliberated wherein the Committee directed the applicant to provide evidence in support of its claim that povidone iodine throat spray (0.45%) is superior than existing gargles and also to furnish the Clinical Trial Protocol, CMC (Chemistry, Manufacturing & Control) Data, and other relevant data records demonstrating better efficacy that have been submitted to CDSCO for clinical trial.

2. Accordingly, the Committee in its 73rd meeting held on 25.11.2025 noted the additional submission made by the applicant company vide letter dated 11.10.2025 and observed that similar products are already available in the market. In this regard, the applicant in the meeting informed that the other product available in the market are not approved by CDCSO and that these are banned and recalled from the market. The company also claimed that their company is the first company to get the CDCSO approval. The Committee deliberated on the matter in view of other brands available in the market and the claim made by the company and directed to seek clarification from CDSCO on the approval status of other Povidone Iodine throat sprays available in the market and whether Povidone Iodine Throat Spray manufactured by M/s G.S. Pharmbutor Private Limited is a new drug involving novel delivery system and the first company to get the approval from CDSCO.

3. Accordingly, clarification was sought from CDSCO. CDSCO vide letter dated 06.02.2026 informed that *'CDSCO has granted first time permission for manufacture and marketing of Povidone Iodine Throat Spray 0.45% w/v as a new drug to M/s G.S. Pharmbutor Pvt. Ltd. on 17.12.2024. Further, no other firm was granted permission to manufacture and market the said formulation by CDSCO'.*

4. Accordingly, the matter was deliberated in 75th MDC meeting wherein it was noted that the other products available in the market are not approved by CDSCO, therefore their quality, safety, efficacy cannot be established and they cannot be compared with the product which has been approved by CDSCO following due process based on clinical trial conducted by the company. The Committee also noted that the applied formulation Povidone Iodine Throat Spray 0.45% w/v is a new drug involving novel delivery system developed through indigenous research and development in a lab approved by DSIR. The Committee deliberated upon the matter in detail and recommended to grant exemption under Para 32(iii) of DPCO, 2013 to M/s G.S. Pharmbutor Private Limited for "Povidone Iodine Throat Spray 0.45% w/v" for a period of five years from the date of its market approval in India.

Agenda Item No. 16: Requests from Knee Implant Manufacturers/Importers for separate price category for Cementless Knee Implants

1. The Committee noted that the matter was deliberated in 69th MDC held on 03.07.2025 and 68th MDC held on 03.06.2025 wherein it was decided to sought following information / documents:

i. Studies/Surveys/Published literature in support of their claims.
ii. DCGI approval copy (import and manufacturing licenses).
iii. MRP of both cemented and cementless knee implants as sold in other countries.
iv. Data of landed cost, Price to Dealer (PTD)/ Price to Hospital (PTH), Price to Retailer (PTR) and MRP of cemented and uncemented hip implant from the applicant companies as well as other companies.

2. The Committee noted that information / documents have been submitted by applicant companies (except data relating to hip implant by M/s. Meril Life Sciences Pvt. Ltd.). Further, the Committee was informed that M/s. Meril Life Science Pvt. Ltd. vide email dated 14.01.2026 requested for withdrawal for 3D-Printed Uncemented knee implant by stating that its product has already been launched in market, within the ceiling price prescribed by NPPA.

3. The Committee deliberated upon the matter and directed to invite subject experts and companies in the next MDC meeting for further deliberations.

The meeting ended with a vote of thanks to all.

RASHMI TAHILIANI
Digitally signed by RASHMI TAHILIANI
Date: 2026.02.16 16:26:42 +05'30'

(Rashmi Tahiliani**)**
Director (Pricing)

Copy to:
All members of the Committee.

Computation of Retail Price based on May 2025 Data under Para 5 of DPCO, 2013

Chlorpheniramine Maleate IP 2 mg	Number of Companies cosisting of Market Share of 1% & Above	1
	Sum of MAT value considered for price calculation (in Lakhs)	0.22
	Sum of PTR per unit considered for price calculation	0.52
	Number of Packs considered	1
	Average PTR	0.52
	Add : 16% Retailer Margin	0.08
	Retail Price (without local taxes)	0.60
	% Reduction with compared to Highest Price	0.00%

Minimum Price (Rs.)	0.52
Maximum Price (Rs.)	0.52
Average of all considered (Rs.)	0.52
Retail Price (Rs.)	0.6

TOTAL MAT **21,549** 100% M3

S.No.	पैक विवरण Pack Description	छाप BRAND	कंपनी Company	Strength	Pack Size	Unit	PTR (Rs.)	MAT(Rs.)	SKU wise MAT %	Brandwise MAT (ignoring O% MAT)	Qualify (Y/N) Y=Yes N=No	Price per Unit (Rs.)	Price per Unit (Rs.) Considered
1	PIRITON U 2 MG SYRUP 60 ML	PIRITON U	GLAXOSMITHKLINE PHARMACEUTICAL	2 MG	60	SYRUP	31.14	21549	100.00%	100.00%	Y	0.52	0.52
		Rs. Per mL											
	Worked out Retail Price	0.60	Excluding GST										

Computation of Retail Price based on June 2025 Data under Para 5 of DPCO, 2013

PARACETAMOL 650 MG + CAFFEINE 30 MG + CHLORPHENIRAMINE 2 MG	Number of Companies cosisting of Market Share of 1% & Above	1
	Sum of MAT value considered for price calculation (in Lakhs)	9.12
	Sum of PTR per unit considered for price calculation	3.29
	Number of Packs considered	1
	Average PTR	3.29
	Add : 16% Retailer Margin	0.53
	Retail Price (without local taxes)	3.82
	% Reduction with compared to Highest Price	0.00%

Minimum Price (Rs.)	3.29
Maximum Price (Rs.)	3.29
Average of all considered (Rs.)	3.29
Retail Price (Rs.)	3.82

TOTAL MAT **9,11,974** 100% M3

S.No.	पैक विवरण Pack Description	छाप BRAND	कंपनी Company	Strength	Pack Size	Unit	PTR (Rs.)	MAT(Rs.)	SKU wise MAT %	Brandwise MAT (ignoring O% MAT)	Qualify (Y/N) Y=Yes N=No	Price per Unit (Rs.)	Price per Unit (Rs.) Considered
1	DPC PLUS 650/30/2 MG TABLET 10	DPC PLUS	SUNIJ PHARMA PVT LTD	650/30/2 MG	10	TABLET	32.92	911974	100.00%	100.00%	Y	3.29	3.29
		Rs. Per Tablet											
	Worked out Retail Price	3.82	Excluding GST										

Computation of Retail Price based on June 2025 Data under Para 5 of DPCO, 2013

PHENYLEPHRINE 10MG	Number of Companies cosisting of Market Share of 1% & Above	1
	Sum of MAT value considered for price calculation (in Lakhs)	728.14
	Sum of PTR per unit considered for price calculation	4.07
	Number of Packs considered	1
	Average PTR	4.07
	Add : 16% Retailer Margin	0.65
	Retail Price (without local taxes)	4.72
	% Reduction with compared to Highest Price	0.00%

Minimum Price (Rs.)	4.07
Maximum Price (Rs.)	4.07
Average of all considered (Rs.)	4.07
Retail Price (Rs.)	4.72

TOTAL MAT **7,28,13,662** 100% M3

S.No.	पैक विवरण Pack Description	छाप BRAND	कंपनी Company	Strength	Pack Size	Unit	PTR (Rs.)	MAT(Rs.)	SKU wise MAT %	Brandwise MAT (ignoring O% MAT)	Qualify (Y/N) Y=Yes N=No	Price per Unit (Rs.)	Price per Unit (Rs.) Considered
1	SOLVIN DECONG 10 MG TABLET 15	SOLVIN DECONG	IPCA LABORATORIES PVT LTD.	10 MG	15	TABLET	61.11	72813662	100.00%	100.00%	Y	4.07	4.07
		Rs. Per Tablet											
	Worked out Retail Price	4.72	Excluding GST										

Computation of Retail Price based on May 2025 Data under Para 5 of DPCO, 2013

Relugolix 120 mg	Number of Companies cosisting of Market Share of 1% & Above	3
	Sum of MAT value considered for price calculation (in Lakhs)	957.14
	Sum of PTR per unit considered for price calculation	593.71
	Number of Packs considered	3
	Average PTR	197.90
	Add : 16% Retailer Margin	31.66
	Retail Price (without local taxes)	229.56
	% Reduction with compared to Highest Price	16.80%

Minimum Price (Rs.)	166.67
Maximum Price (Rs.)	237.86
Average of all considered (Rs.)	197.90
Retail Price (Rs.)	229.56

TOTAL MAT **9,57,49,403** 100% M3

S.No.	पैक विवरण Pack Description	छाप BRAND	कंपनी Company	Strength	Pack Size	Unit	PTR (Rs.)	MAT(Rs.)	SKU wise MAT %	Brandwise MAT (ignoring O% MAT)	Qualify (Y/N) Y=Yes N=No	Price per Unit (Rs.)	Price per Unit (Rs.) Considered
1	TESPROLIX 120 MG TABLET 10	TESPROLIX	ABBOTT HEALTHCARE PVT. LTD	120 MG	10	TABLET	5000	35000	0.04%	0.04%	N	500.00	
2	XELUCIP 120 MG TABLET 30	XELUCIP	CIPLA LTD.	120 MG	30	TABLET	5675.34	1995231	2.08%	2.08%	Y	189.18	189.18
3	RGOLIX 120 MG TABLET 30	RGOLIX	IPCA LABORATORIES PVT LTD.	120 MG	30	TABLET	5000	12070000	12.61%	12.61%	Y	166.67	166.67
4	ORGONIST 120 MG TABLET 10	ORGONIST	SUN PHARMA LABORATORIES LTD.	120 MG	10	TABLET	2378.57	81649172	85.27%	85.27%	Y	237.86	237.86
		Rs. Per Tablet											
	Worked out Retail Price	229.56	Excluding GST										

Computation of Retail Price based on May 2025 Data under Para 5 of DPCO, 2013

Estradiol 1 mg	Number of Companies cosisting of Market Share of 1% & Above	3
	Sum of MAT value considered for price calculation (in Lakhs)	493.92
	Sum of PTR per unit considered for price calculation	31.73
	Number of Packs considered	3
	Average PTR	10.58
	Add : 16% Retailer Margin	1.69
	Retail Price (without local taxes)	12.27
	% Reduction with compared to Highest Price	11.24%

Minimum Price (Rs.)	9.17
Maximum Price (Rs.)	11.92
Average of all considered (Rs.)	10.58
Retail Price (Rs.)	12.27

TOTAL MAT **4,93,91,553** 100% M3

S.No.	पैक विवरण Pack Description	छाप BRAND	कंपनी Company	Strength	Pack Size	Unit	PTR (Rs.)	MAT(Rs.)	SKU wise MAT %	Brandwise MAT (ignoring O% MAT)	Qualify (Y/N) Y=Yes N=No	Price per Unit (Rs.)	Price per Unit (Rs.) Considered
1	ESTRABET 1 MG TABLET 28	ESTRABET	ABBOTT INDIA LTD.	1 MG	28	TABLET	256.74	2613084	5.29%	5.29%	Y	9.17	9.17
2	PROGYNOVA 1 MG TABLET 28	PROGYNOVA	BAYER PHARMACEUTICALS PVT. LTD.	1 MG	28	TABLET	297.86	39587471	80.15%	80.15%	Y	10.64	10.64
3	VALEST 1 MG TABLET 28	VALEST	WALTER BUSHNELL	1 MG	28	TABLET	333.84	7190998	14.56%	14.56%	Y	11.92	11.92
		Rs. Per Tablet											
	Worked out Retail Price	12.27	Excluding GST										

Computation of Retail Price based on June 2025 Data under Para 5 of DPCO, 2013

Relugolix 120 mg	Number of Companies cosisting of Market Share of 1% & Above	3
	Sum of MAT value considered for price calculation (in Lakhs)	1,035.41
	Sum of PTR per unit considered for price calculation	593.71
	Number of Packs considered	3
	Average PTR	197.90
	Add : 16% Retailer Margin	31.66
	Retail Price (without local taxes)	229.56
	% Reduction with compared to Highest Price	16.80%

Minimum Price (Rs.)	166.67
Maximum Price (Rs.)	237.86
Average of all considered (Rs.)	197.90
Retail Price (Rs.)	229.56

TOTAL MAT **10,35,76,335** 100% M3

S.No.	पैक विवरण Pack Description	छाप BRAND	कंपनी Company	Strength	Pack Size	Unit	PTR (Rs.)	MAT(Rs.)	SKU wise MAT %	Brandwise MAT (ignoring O% MAT)	Qualify (Y/N) Y=Yes N=No	Price per Unit (Rs.)	Price per Unit (Rs.) Considered
1	TESPROLIX 120 MG TABLET 10	TESPROLIX	ABBOTT HEALTHCARE PVT. LTD	120 MG	10	TABLET	5000	35000	0.03%	0.03%	N	500.00	
2	XELUCIP 120 MG TABLET 30	XELUCIP	CIPLA LTD.	120 MG	30	TABLET	5675.34	2353681	2.27%	2.27%	Y	189.18	189.18
3	RGOLIX 120 MG TABLET 30	RGOLIX	IPCA LABORATORIES PVT LTD.	120 MG	30	TABLET	5000	12555000	12.12%	12.12%	Y	166.67	166.67
4	ORGONIST 120 MG TABLET 10	ORGONIST	SUN PHARMA LABORATORIES LTD.	120 MG	10	TABLET	2378.57	88632654	85.57%	85.57%	Y	237.86	237.86
		Rs. Per Tablet											
	Worked out Retail Price	229.56	Excluding GST										

Computation of Retail Price based on June 2025 Data under Para 5 of DPCO, 2013

Estradiol 1 mg	Number of Companies cosisting of Market Share of 1% & Above	3
	Sum of MAT value considered for price calculation (in Lakhs)	505.49
	Sum of PTR per unit considered for price calculation	31.73
	Number of Packs considered	3
	Average PTR	10.58
	Add : 16% Retailer Margin	1.69
	Retail Price (without local taxes)	12.27
	% Reduction with compared to Highest Price	11.24%

Minimum Price (Rs.)	9.17
Maximum Price (Rs.)	11.92
Average of all considered (Rs.)	10.58
Retail Price (Rs.)	12.27

TOTAL MAT **5,05,48,919** 100% M3

S.No.	पैक विवरण Pack Description	छाप BRAND	कंपनी Company	Strength	Pack Size	Unit	PTR (Rs.)	MAT(Rs.)	SKU wise MAT %	Brandwise MAT (ignoring O% MAT)	Qualify (Y/N) Y=Yes N=No	Price per Unit (Rs.)	Price per Unit (Rs.) Considered
1	ESTRABET 1 MG TABLET 28	ESTRABET	ABBOTT INDIA LTD.	1 MG	28	TABLET	256.74	2713299	5.37%	5.37%	Y	9.17	9.17
2	PROGYNOVA 1 MG TABLET 28	PROGYNOVA	BAYER PHARMACEUTICALS PVT. LTD.	1 MG	28	TABLET	297.86	39750040	78.64%	78.64%	Y	10.64	10.64
3	VALEST 1 MG TABLET 28	VALEST	WALTER BUSHNELL	1 MG	28	TABLET	333.84	8085580	16.00%	16.00%	Y	11.92	11.92
		Rs. Per Tablet											
	Worked out Retail Price	12.27	Excluding GST										