मिसिल स.- 8(148)/2026/डी.पी/एनपीपीए-डीवी-II

F. No. 8(148)/2026/DP/NPPA-Div. II

कार्यवाही स. : 280/148/2026/F

Proceeding No: 280/148/2026/F

Minutes of the 280th (overall) and 148th meeting of the Authority under DPCO, 2013 held on 07.07.2026 at 12:30 PM.

The 280th meeting of the Authority (overall), which is the 148th meeting under the DPCO, 2013 was held on 07.07.2026 at 12:30 PM under the Chairmanship of Shri P. Krishnamurthy, Chairman, NPPA. The following Authority members were present during the meeting:

(i) Ms. Sai Ahlladini Panda, Member Secretary, NPPA
(ii) Shri Anand Kumar Pal, Chief Adviser (Cost), O/o Chief Adviser Cost, Department of Expenditure
(iii) Dr. Rose Mary K. Abraham, Economic Advisor, Department of Economic Affairs

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

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

(i) Shri Rajiv Wadhawan, Adviser (Cost)
(ii) Ms. Priyanka Sachdeva, Joint Director (Pricing)
(iii) Shri Bhiva Ram Yadav, Assistant Director (Pricing)
(iv) Shri Mayur Panwar, Assistant Director (Pricing)

At the outset, the Authority members were briefed on the recent amendments to the DPCO, 2013 which was notified vide S.O. 3516(E) dated 30th June, 2026.

1. Agenda item no. 1 - Confirmation of the minutes of the 147th Meeting held on 11.06.2026.

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

2. Agenda item no. 2 – Action Taken Report (ATR) on decisions taken by NPPA in its 147th Meeting held on 11.06.2026.

2.1 Noted.

3. Agenda item no. 3 – Status of new drug application.

3.1 Noted.

4. Agenda item no. 4 – New Drug application for price fixation under Paragraph 5 and 15 of DPCO, 2013.

4.1 The Authority took note of the Drugs (Prices Control) Amendment Order, 2026 which came into force from 01.07.2026, the date of publication in the Official Gazette. The Authority

further noted that, pursuant to the said amendment, any other existing manufacturer launching the same new drug within twelve months of retail price fixation of such new drug under paragraph 15 shall not be required to apply to NPPA for retail price fixation, provided that such manufacturer launching the new drug shall intimate the details of launch to NPPA in Form-IA within one month of the launch.

4.2 The Authority noted that, as per the existing practice, the retail price is notified as the lower of the 'worked out price' and the 'claimed price' furnished by the applicant. Such retail price is applicable only to the individual manufacturer/marketer who has applied for retail price fixation by submitting Form-I.

The Authority further noted that, pursuant to the recent amendments to the Drugs (Prices Control) Order, 2013, the retail price notified by NPPA shall also be applicable to other existing manufacturers launching the same new drug within twelve months from the date of fixation of the retail price, subject to filing Form-IA within one month from the date of such launch.

In view of the above, the Authority decided that, henceforth, the 'worked out price' shall be notified as the 'retail price'. Accordingly, the applicant, as well as any other existing manufacturer covered under the said provisions, shall launch the new drug formulation at a price not exceeding the notified retail price. The applicant, however, is at liberty to launch the new drug formulation at 'claimed price' in case the 'claimed price' is lower than the notified 'retail price'.

4.3 Accordingly, the Authority deliberated on 47 (Forty-Seven) cases of retail price fixation of new drugs as presented in Agenda no. 4(1) to 4(47) falling under the purview of paragraph 2(1)(u) of DPCO, 2013. The Authority approved the retail prices of 47 (Forty-Seven) new drugs under paragraph 5 and 15 of DPCO, 2013 as given in **Table 1 below:**

Table No. 1: Retail price fixation of new drugs

Sl. No.	Agenda Item No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (₹)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
1	4(1)	Amlodipine, Telmisartan and Metoprolol Succinate (Extended Release) Tablets	Each Film Coated Bilayered Tablet Contains: Amlodipine Besilate IP Eq. to Amlodipine 5 mg Telmisartan IP 40 mg Metoprolol Succinate IP 23.75 mg Eq. to Metoprolol Tartrate 25 mg (As Extended Release Form)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Ipca Laboratories Ltd.	12.03
2	4(2)	Amoxicillin and Potassium Clavulanate Dispersible Tablets	Each Uncoated Dispersible Tablet contains: Amoxicillin Trihydrate IP Eq. to Amoxicillin 400 mg Potassium Clavulanate Diluted IP Eq. to Clavulanic Acid 57 mg	1 Tablet	M/s Malik Lifesciences Pvt. Ltd./ M/s Mankind Pharma Ltd.	27.31
3	4(3)	Amoxycillin and Potassium Clavulanate Tablets	Each film coated tablet contains: Amoxicillin Trihydrate IP equivalent to Amoxicillin 250 mg	1 Tablet	M/s Alkem Health Science (A unit of Alkem Laboratories Ltd.)/	19.53

			Potassium Clavulanate Diluted IP equivalent to Clavulanic Acid 125 mg		M/s Alkem Wellness Ltd.	
4	4(4)	Aspirin Gastro-Resistant and Atorvastatin Capsules	Each hard gelatin capsule contains: Aspirin IP 75 mg (as gastro-resistant white colored pellets) Atorvastatin Calcium IP eq. to Atorvastatin 20 mg (as green colored spherical pellets)	1 Capsule	M/s Windlas Biotech Ltd./ M/s Aristo Pharmaceuticals Pvt. Ltd.	3.67
5	4(5)	Aspirin, Atorvastatin and Clopidogrel Capsules	Each hard gelatin capsule contains: Aspirin IP 75mg (As Gastro-resistant tablet) Atorvastatin Calcium IP equivalent to Atorvastatin 20mg (As film coated tablet) Clopidogrel Bisulphate IP equivalent to Clopidogrel 75mg	1 Capsule	M/s Safetab Life Science/ M/s Alkem Wellness Ltd.	8.86
6	4(6)	Atorvastatin and Ezetimibe Tablets	Each Film Coated Tablet Contains: Atorvastatin Calcium IP Eq. to Atorvastatin 20 mg Ezetimibe IP 10 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd./ M/s Primus Remedies Pvt. Ltd.	31.73
7	4(7)	Atorvastatin and Ezetimibe tablets	Each Film Coated Tablet Contains: Atorvastatin Calcium IP Eq. to Atorvastatin 10 mg Ezetimibe IP 10 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd./ M/s Primus Remedies Pvt. Ltd.	21.36
8	4(8) & 4(10)	Atorvastatin and Clopidogrel Tablets	Each uncoated bilayer tablet contains: Atorvastatin Calcium IP equivalent to Atorvastatin 10 mg Clopidogrel Bisulphate IP equivalent to Clopidogrel 75 mg	1 Tablet	(i) M/s Sun Pharma Laboratories Limited/ M/s Sun Pharmaceutical Industries Ltd. and (ii) M/s Sun Pharma Laboratories Limited	14.87
9	4(9) & 4(11)	Atorvastatin and Clopidogrel Tablets	Each uncoated bilayer tablet contains: Atorvastatin Calcium IP equivalent to Atorvastatin 20 mg Clopidogrel Bisulphate IP equivalent to Clopidogrel 75 mg	1 Tablet	(i) M/s Sun Pharma Laboratories Limited/ M/s Sun Pharmaceutical Industries Ltd. and (ii) M/s Sun Pharma Laboratories Limited	15.01
10	4(12)	Bisoprolol Fumarate and Telmisartan Tablets	Each Film Coated Tablet Contains: Bisoprolol Fumarate IP 5 mg Telmisartan IP 40 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Workcell Solutions Pvt. Ltd.	12.71
11	4(13)	Bisoprolol Fumarate and Telmisartan Tablets	Each Film Coated Tablet Contains: Bisoprolol Fumarate IP 2.5 mg Telmisartan IP 40 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Workcell Solutions Pvt. Ltd.	10.83
12	4(14)	Cetirizine Hydrochloride Drops	Each ml contains: Cetirizine Hydrochloride IP 10 mg	1 ML	M/s Indoco Remedies Limited	8.55
13	4(15)	Clobazam Oral Suspension	Each ml contains: Clobazam IP 2.5 mg	1 ML	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Linux Laboratories Private Limited	2.80
14	4(16)	Dapagliflozin and Telmisartan Tablets	Each film coated tablet contains:	1 Tablet	M/s Exemed Pharmaceuticals/	19.30

			Dapagliflozin Propanediol USP eq. to Dapagliflozin 10 mg Telmisartan IP 40 mg		M/s Mankind Pharma Ltd.	
15	4(17)	Empagliflozin, Sitagliptin and Metformin Hydrochloride (ER) Tablets	Each Film Coated Bilayered Tablet Contains: Empagliflozin 10 mg Sitagliptin Phosphate Monohydrate IP Eq. to Sitagliptin 100 mg Metformin Hydrochloride IP 1000 mg (As Extended Release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Medley Pharmaceuticals Ltd.	14.88
16	4(18)	Empagliflozin, Sitagliptin and Metformin Hydrochloride (ER) Tablets	Each Film Coated Bilayered Tablet Contains: Empagliflozin 25 mg Sitagliptin Phosphate Monohydrate IP Eq. to Sitagliptin 100 mg Metformin Hydrochloride IP 1000 mg (As Extended Release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Medley Pharmaceuticals Ltd.	17.17
17	4(19)	Nebivolol Hydrochloride and Amlodipine Tablets	Each uncoated tablet contains: Nebivolol Hydrochloride IP equivalent to Nebivolol 5 mg Amlodipine Besilate IP equivalent to Amlodipine 5 mg	1 Tablet	M/s Windlas Biotech Ltd./ M/s Alkem Wellness Ltd.	13.72
18	4(20)	Olmesartan Medoxomil and Amlodipine Tablets	Each film coated tablet contains: Olmesartan Medoxomil IP 20 mg Amlodipine Besilate IP eq. to Amlodipine 5 mg	1 Tablet	M/s Windlas Biotech Ltd./ M/s Alkem Wellness Ltd.	14.80
19	4(21)	Phenylephrine HCI, Chlorpheniramine Maleate, Boric Acid and Hydroxypropylmethyl Cellulose Eye Drops	Composition: Phenylephrine HCI IP 0.12%w/v Chlorpheniramine Maleate IP 0.2% w/v Boric Acid IP 1.25%w/v Hydroxypropylmethyl Cellulose IP 0.3% w/v Benzalkonium Chloride IP 0.01%w/v	1 ML	M/s Appasamy Ocular Devices Pvt. Ltd./ M/s Mankind Pharma Ltd.	8.35
20	4(22)	Polmacoxib and Paracetamol tablets	Each uncoated tablet contains: Polmacoxib IH 2 mg Paracetamol IP 325 mg	1 Tablet	M/s Hetero Labs Ltd./ M/s La Renon Healthcare Pvt. Ltd.	11.79
21	4(23)	Telmisartan and Chlorthalidone Tablets	Each uncoated bilayered tablet contains: Telmisartan IP 40 mg Chlorthalidone IP 12.5 mg	1 Tablet	M/s Windlas Biotech Ltd./ M/s Alkem Wellness Ltd.	13.03
22	4(24)	Telmisartan and Chlorthalidone Tablets	Each uncoated bilayered tablet contains: Telmisartan IP 80 mg Chlorthalidone IP 12.5 mg	1 Tablet	M/s Windlas Biotech Ltd./ M/s Alkem Wellness Ltd.	21.40
23	4(25)	Telmisartan and Chlorthalidone Tablets	Each uncoated bilayered tablet contains: Telmisartan IP 40 mg Chlorthalidone IP 6.25 mg	1 Tablet	M/s Windlas Biotech Ltd./ M/s Alkem Wellness Ltd.	11.80
24	4(26) & 4(41)	Telmisartan and Cilnidipine Tablets	Each Film coated tablet contains: Telmisartan IP 40mg Cilnidipine IP 10mg	1 Tablet	(i) M/s Synokem Pharmaceuticals Limited/ M/s FDC Limited; and (ii) M/s Synokem Pharmaceuticals Ltd./	13.24

					M/s Alkem Wellness Ltd.	
25	4(27)	Telmisartan, Cilnidipine and Chlorthalidone Tablets	Each film coated tablet contains: Telmisartan IP 40 mg Cilnidipine IP 10 mg Chlorthalidone IP 6.25 mg	1 Tablet	M/s Synokem Pharmaceuticals Limited/ M/s Alkem Wellness Ltd.	16.17
26	4(28)	Torsemide and Spironolactone Tablets	Each Uncoated Tablet Contains: Torsemide IP 10 mg Spironolactone IP 25 mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s RPG Life Sciences Ltd.	3.71
27	4(29)	Trypsin-Chymotrypsin, Aceclofenac and Paracetamol Tablets	Each film coated tablet contains: 50,000 Armour units of enzymatic activity (Supplied by a purified concentrate which has specific Trypsin & Chymotrypsin activity in a ratio of approximately Six to One) (As enteric coated granules) Aceclofenac IP 100 mg Paracetamol IP 325 mg	1 Tablet	M/s Synokem Pharmaceuticals Limited/ M/s Medley Pharmaceuticals Limited	13.02
28	4(30), 4(31) & 4(46)	Vitamin D3 Oral Solution	Each 5 ml contains: Cholecalciferol IP 60000 IU (In Nano Droplet Form)	1 ML	(i) M/s Tirupati Medicare Ltd./ M/s German Remedies Pharmaceuticals Pvt. Ltd.; (ii) M/s Windlas Biotech Limited/ M/s FDC Limited; and (iii) M/s Tirupati Medicare Ltd./ M/s Aristo Laboratories Pvt. Ltd.	15.88
29	4(32)	Tenecteplase (TNK-TPA) Injection	Each vial contains: Tenecteplase 50 mg (10000 units)	1 Vial	M/s Boehringer Ingelheim India Pvt. Ltd.	60238.27
30	4(33)	Netarsudil & Latanoprost Ophthalmic Solution	Each ml contains: Netarsudil Mesylate Eq. to Netarsudil 0.2 mg Latanoprost IP 0.05 mg Benzalkonium Chloride IP 0.2 mg (As preservative)	1 ML	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Sun Pharma Laboratories Ltd.	362.57
31	4(34)	Imatinib Oral Solution	Each ml contains: Imatinib Mesylate IP Eq. to Imatinib 80 mg	1 ML	M/s Beta Drugs Ltd.	59.61
32	4(35) & 4(37)	Amlodipine, Bisoprolol & Telmisartan Tablets	Each film coated tablet contains: Amlodipine Besylate IP eq. to Amlodipine 5 mg Bisoprolol FumarateIP 2.5 mg Telmisartan IP 40 mg	1 Tablet	(i) M/s Ravenbhel Healthcare Pvt. Ltd./ M/s Glenmark Pharmaceuticals Ltd.; and (ii) M/s Ravenbhel Healthcare Pvt. Ltd./ M/s Torrent Pharmaceuticals Ltd.	12.81
33	4(36) & 4(38)	Amlodipine, Bisoprolol & Telmisartan Tablets	Each film coated tablet contains: Amlodipine Besylate IP eq. to Amlodipine 5 mg Bisoprolol FumarateIP 5 mg Telmisartan IP 40 mg	1 Tablet	(i) M/s Ravenbhel Healthcare Pvt. Ltd./ M/s Glenmark Pharmaceuticals Ltd.; and (ii) M/s Ravenbhel Healthcare Pvt. Ltd./	14.74

					M/s Torrent Pharmaceuticals Ltd.	
34	4(39)	Nepafenac& Moxifloxacin Ophthalmic Solution	Composition: Nepafenac IP 0.1% w/v Moxifloxacin Hydrochloride IP Eq. Moxifloxacin 0.5% w/v Benzalkonium Chloride Solution IP 0.01% w/v (As Preservative)	1 ML	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Cipla Ltd.	68.64
35	4(40)	Combikit of Darunavir, Ritonavir & Dolutegravir Tablets	Part A- Each film coated tablet contains: Darunavir Ethanolate IP Eq. to Darunavir 800 mg Ritonavir IP 100 mg Part B- Each film coated tablet contains Dolutegravir Sodium IP Eq. to Dolutegravir 50 mg	1 Kit	M/s Emcure Pharmaceuticals Ltd.	330.40
36	4(42)	Clopidogrel, Aspirin and Atorvastatin Capsules	Each hard gelatin capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 10 mg (As film coated tablet) Clopidogrel Bisuiphate IP eq. to Clopidogrel 75mg Aspirin IP 75mg (As Gastro-resistant tablet)	1 Capsule	M/s Safetab Life Science/ M/s Alkem Wellness Ltd.	6.37
37	4(43)	Glimepiride, Voglibose and Metformin Hydrochloride (SR) Tablets	Each uncoated bilayered tablet contains: Glimepiride IP 0.5 mg Voglibose IP 0.2 mg Metformin Hydrochloride IP 500 mg (as sustained release form)	1 Tablet	M/s Windlas Biotech Ltd./ M/s Primus Remedies Pvt. Ltd.	8.85
38	4(44)	Sitagliptin, Metformin Hydrochloride and Glimepiride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 2mg	1 Tablet	M/s Synokem Pharmaceuticals Limited/ M/s Alkem Wellness Ltd.	13.27
39	4(45)	Sitagliptin, Metformin Hydrochloride and Glimepiride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg Metformin Hydrochloride IP 1000 mg Glimepiride IP 1mg	1 Tablet	M/s Synokem Pharmaceuticals Limited/ M/s Alkem Wellness Ltd.	11.75
New drug launched without prior price approval case						
40	4(47)	Calcium and Vitamin D3 Tablets IP	Each film coated tablet contains: Calcium Carbonate IP eq. to Elemental Calcium 500 mg Vitamin D3 IP 2000 IU.	1 Tablet	M/s. Akums Drugs & Pharmaceuticals Ltd/ M/s. Eris Lifesciences Ltd.	8.93 **(Note-1)**

Note-1: *The applicant had already launched the formulation without obtaining prior price approval from NPPA; therefore, the said retail price is applicable only to the individual manufacturer/marketer.*

5. Agenda item no. 5: Minutes of the 77th meeting of the Multidisciplinary Committee of Experts held on 15.05.2026.

5.1 Noted.

6. Agenda item no. 6: 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)

6.1 The Authority noted that M/s Biological E Limited submitted an application vide email dated 22.02.2024 seeking exemption under Para 32(i), (ii) and (iii) of DPCO, 2013 for 'Pneumococcal Polysaccharide Conjugate Vaccine (PNEUBEVAX 14)'. The company submitted that the product is a new drug approved by CDSCO and furnished CDSCO approval, State Licensing Authority permission and Patent Certificate granted under the Indian Patents Act, 1970.

6.2 The Authority noted that the matter was placed before the Multidisciplinary Committee (MDC) in its 61st, 64th, 66th, 67th, 69th, 75th, 76th and 77th MDC meetings wherein after detailed deliberations upon the matter in light of the clarifications furnished by the company and the views of O/o CGPDTM, it was concluded that the formulation Pneumococcal Polysaccharide Conjugate Vaccine (PNEUBEVAX 14) is covered under the granted patent. Accordingly, the Committee recommended grant of exemption under Para 32(i) and Para 32(ii) of DPCO, 2013 to M/s Biological E Limited for a period of five years from the date of commencement of its commercial marketing or commercial production in the country, whichever is earlier.

6.3 The Authority deliberated on the recommendation of the Committee and approved grant of exemption under Para 32(i) and Para 32(ii) of DPCO, 2013 to M/s Biological E Limited in respect of Pneumococcal Polysaccharide Conjugate Vaccine (PNEUBEVAX 14) for a period of five years from the date of commencement of its commercial marketing or date of commencement of commercial production in the country or till the validity of the relevant patent, whichever is earlier. The Authority further directed the company to inform NPPA of the date of commercial marketing, date of commercial production and furnish the PTR and MRP through Form-V under DPCO, 2013. The company shall also comply with the applicable provisions of DPCO, 2013 upon expiry of the exemption period.

7. Agenda item no. 7: 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.

7.1 The Authority noted that M/s Glenmark Pharmaceuticals Limited vide letter dated 22.01.2026 applied under Para 11(3) of DPCO, 2013 seeking fixation of a separate retail price for 'Glycopyrronium 25 mcg + Formoterol Fumarate 20 mcg + Budesonide 500 mcg Smartules'. The retail price, as recommended by the MDC, of subject formulation was approved by the Authority in its 141st meeting held on 23.12.2025 and notified vide S.O. No. 5975(E) dated 24.12.2025. The applicant claimed that the formulation is a unique nebulized fixed-dose triple therapy for COPD and highlighted various technological and therapeutic advantages including specialized manufacturing through Blow Fill Seal technology, stability

enhancement measures, optimization of particle size and formulation composition, clinical evaluation in COPD patients, ease of administration, improved patient compliance, and reduced treatment burden.

7.2 The Authority further noted that the matter was examined by the Multidisciplinary Committee (MDC) in its 76th meeting held on 08.04.2026, and 77th meeting held on 15.05.2026 wherein the representatives of the company demonstrated the product and explained the technological challenges involved in combining three active ingredients with different formulation requirements into a single nebulized fixed-dose combination. The Committee observed that the formulation offered advantages such as administration of triple therapy through a single nebulization product, improved patient adherence, reduced nebulization time, lower risk of contamination due to sterile sealed packaging, reduced wastage and improved convenience for patients, particularly elderly patients suffering from severe COPD. The Committee further noted that the formulation represented incremental innovation, though published clinical studies supporting certain claims were yet to be submitted. Accordingly, the Committee recommended fixation of a separate retail price under Para 11(3) at ₹56.35 per ml for a pack size of 2 ml by allowing an additional 15% over the existing notified retail price of ₹49/- per ml.

7.3 The Authority deliberated upon the matter and the recommendation of the MDC, and approved a separate retail price under Para 11(3) at ₹56.35 per ml for 'Glycopyrronium 25 mcg + Formoterol Fumarate 20 mcg + Budesonide 500 mcg Smartules (pack size 2 ml)'.

8. Agenda item no. 8: 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)

8.1 The Authority noted that M/s Sachin Parenteral Pvt. Ltd. vide letter dated 13.11.2025 (complete application on 21.11.2025) applied for extension of separate ceiling price under Para 11(3) of the DPCO, 2013 for IV Fluids packed in Non-glass Euro Head/SafePort Bottles with special features for the following formulations:

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

8.2 The Authority noted that the matter was deliberated by the Multidisciplinary Committee (MDC) in its 74th meeting held on 18.12.2025, 75th meeting held on 11.02.2026, 76th meeting held on 08.04.2026 and 77th meeting held on 15.05.2026. The Committee examined the documents submitted by the company including flow rate data, certificate of analysis of plastic used in manufacturing of the bottles, revised test reports and clarification furnished regarding discrepancies observed in the earlier test reports. The Committee further noted the company's clarification that the products demonstrated before the Committee were trial/validation batches and had not been commercially launched. Based on the product demonstration and documents submitted, the Committee observed that the products possess the features of self-sealability, self-collapsibility and dual ports to prevent contamination. Accordingly, the Committee

recommended extension of the present applicable separate ceiling price for the applied formulations.

8.3 The Authority deliberated upon the matter and approved the recommendation of the MDC to extend the present applicable separate ceiling price to M/s Sachin Parenteral Pvt. Ltd. under the provisions of Para 11(3) of DPCO, 2013 as below:

Sr. No.	Name of Product	Pack Size	Ceiling Price (Excluding GST)	Notification
1	Dextrose Injection IP 5% w/v	1000 ml	₹97.40 / Pack	S.O. 1583(E) dated 25.03.2026
2	Sodium Chloride Injection IP 0.9% w/v	1000 ml	₹100.87 / Pack	
3	Dextrose Injection IP 5% w/v + Sodium Chloride Injection IP 0.9% w/v	1000 ml	₹102.34 / Pack	
4	Compound Sodium Lactate Injection IP	1000 ml	₹116.95 / Pack	S.O. 1584(E) dated 25.03.2026

9. Agenda item no. 9: Status of implementation of Review cases

9.1 Noted.

10. Agenda item no. 10: Revision of ceiling prices of 'Anti-Rabies Immunoglobulin 300 IU/ml' based on review order.

10.1 The Authority noted that the Department of Pharmaceuticals (DoP) has issued Review Order No. 31015/02/2025-Pricing (E-30115) dated 27.03.2026 in respect of the scheduled formulation 'Anti-Rabies Immunoglobulin 300 IU/ml', wherein the matter was referred back to NPPA for examination under the extant provisions of DPCO, 2013. The Review Order, *inter alia*, observed that NPPA may exercise powers under Paragraphs 9(1) and 9(7) of DPCO, 2013 to access alternative data sources or obtain data directly from manufacturers for capturing a representative market while fixing the ceiling price of the subject formulation.

10.2 The Authority noted that M/s Bharat Serums and Vaccines Limited had filed a review application against NPPA Notification S.O. No. 5497(E) dated 19.12.2024 contending that the ceiling price of 'Anti-Rabies Immunoglobulin 300 IU/ml' was fixed without considering the brands 'Vinrig 1500 IU/5 ml' and 'Premi RAB 1500 IU/5 ml' having the same composition.

10.3 In compliance with the Review Order, NPPA obtained PTR and MAT data for October 2023 directly from M/s Vins Bioproducts Ltd. and M/s Premium Serums and Vaccines Pvt. Ltd. vide emails dated 19.05.2026. Based on the data furnished by the companies, the draft working sheet was revised and uploaded on NPPA website on 10.06.2026 inviting comments from stakeholders. The Authority noted that no representation has been received against the revised draft working sheet uploaded on the website.

10.4 The Authority noted the details of the prevailing ceiling price and the revised ceiling price worked out based on the Review Order, as shown below:

Particulars	Ceiling Price notified (₹/ml)	Revised Ceiling Price based on Review Order (₹/ml)
Fixed in December 2024 (based on October 2023 data)	109.55	116.67
Add: WPI @ 0.00551%	0.01	0.01
w.e.f. 01.04.2024	109.56	116.68
Add: WPI @ 1.74028%	1.91	2.03
w.e.f. 01.04.2025	111.47	118.71
Add: WPI @ 0.64956%	0.72	0.77
w.e.f. 01.04.2026	112.19	119.48

10.5 Accordingly, the Authority approved the revised ceiling price of 'Anti-Rabies Immunoglobulin 300 IU/ml' at ₹119.48 per ml, inclusive of WPI revision applicable from 01.04.2026.

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

SAI AHLLADINI PANDA

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Date: 2026.07.08 16:30:30 +05'30'

(Sai Ahlladini Panda)
Member Secretary