मिसिल स.- 8(144)/2026/डी.पी/एनपीपीए-डीवी-II

F. No. 8(144)/2026/DP/NPPA-Div. II

कार्यवाही स. : 276/144/2026/F

Proceeding No: 276/144/2026/F

Minutes of the 276th (overall) and 144th meeting of the Authority under DPCO, 2013 held on 24.03.2026 at 12:00 PM.

The 276th meeting of the Authority (overall), which is the 144th meeting under the DPCO, 2013 was held on 24th March, 2026 at 12:00 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 Vijay Kumar, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure

Shri Ranga Chandrashekar, Joint Drug Controller, CDSCO, Ministry of Health & Family Welfare through video conferencing

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

(i) Shri Sanjay Kumar, Adviser (Cost)
(ii) Ms. Rashmi Tahiliani, Director (Pricing)
(iii) Ms. Priyanka Sachdeva, Joint Director (Pricing)
(iv) Shri Mahaveer Saini, Joint Director (Pricing) – Additional Charge
(v) Ms. Yuvika Panwar, Deputy Director (Pricing) – Additional Charge
(vi) Shri Bhiva Ram Yadav, Assistant Director (Pricing)
(vii) Shri Devanshu Gupta, Assistant Director (Pricing)
(viii) Shri Mayur Panwar, Assistant Director (Pricing)

1. Agenda item no. 1 - Confirmation of the Minutes of the 143rd Meeting held on 27.02.2026.

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 143rd Meeting held on 27.02.2026.

2.1 Noted.

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

3.1 Noted.

Panda

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

4.1 The Authority deliberated on 32 (Thirty-Two) cases of retail price fixation of new drugs as presented in Agenda no. 4(1) to 4(32) falling under the purview of paragraph 2(1)(u) of DPCO, 2013. The Authority approved the retail prices of 31 (Thirty-One) 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 (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
1	4(1)	Aceclofenac, Paracetamol and Chlorzoxazone Tablets	Each film coated tablet contains: Aceclofenac IP 100 mg Paracetamol IP 325 mg Chlorzoxazone USP 250 mg	1 Tablet	M/s Innova Captab Ltd./ M/s. Dr. Reddys Laboratories Ltd.	4.95
2	4(2)	Alpha Lipoic Acid, Pyridoxine Hydrochloride, Mecobalamin, Folic Acid and Vitamin D3 Tablets	Each film coated tablet contains: Alpha Lipoic Acid coated Eq. to Alpha Lipoic Acid IP 100 mg Pyridoxine Hydrochloride IP 3 mg Mecobalamin IP 1500 mcg Folic Acid IP 1.5 mg Vitamin D3 Stabilized Eq. to Vitamin D3 IP 1000 IU	1 Tablet	M/s Windlas Biotech Limited/ M/s Alkem Laboratories Ltd.	16.62
3	4(3)	Atorvastatin Calcium and Clopidogrel Capsules	Each hard gelatin capsule contains: Atorvastatin Calcium IP Eq. to Atorvastatin (as pellets) 10 mg Clopidogrel Bisulphate IP Eq. to Clopidogrel (as pellets) 75 mg	1 Capsule	M/s Synokem Pharmaceuticals Limited/ M/s Alkem Wellness Limited	15.20
4	4(4)	Bilastine and Montelukast Tablets	Each film coated bilayered tablet contains: Bilastine IP 40 mg Montelukast Sodium IP Eq. to Montelukast 10 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Hetero Healthcare Ltd.	16.67
5	4(5)	Bisoprolol Fumarate and Telmisartan Tablets	Each film coated Bi-layered tablet contains: Bisoprolol Fumarate IP 2.5mg Telmisartan IP 40 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd./ M/s Indchemie Health Specialities Pvt. Ltd.	10.68
6	4(6)	Calcium, Cholecalciferol	Each Film Coated Tablet Contains:	1 Tablet	M/s Pure and Cure	11.86

Sl. No.	Agenda Item No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
		and Folic Acid Tablets	Calcium Citrate Maleate IP Eq. to Elemental Calcium 250 mg Cholecalciferol (Vitamin D3) IP 100 IU Folic Acid IP 50 mcg		Healthcare Pvt. Ltd./ M/s J.B Chemicals & Pharmaceuticals Ltd.	
7	4(7)	Cefuroxime Axetil and Potassium Clavulanate Tablets	Each film coated tablet contains: Cefuroxime Axetil IP eq. to Cefuroxime 500 mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 125 mg	1 Tablet	M/s Alps Communication Pvt. Ltd./ M/s Jagsonpal Pharmaceuticals Ltd.	63.94
8	4(8)	Cholecalciferol (Vitamin D3) Drops	Each ml contains: Cholecalciferol IP 800 IU (In a nano droplet form)	1 ML	M/s Tirupati Medicare Ltd./ M/s Galpha Laboratories Ltd.	6.09
9	4(9)	Clopidogrel, Aspirin and Atorvastatin Capsules	Each hard gelatin capsule contains: Atorvastatin Calcium IP Eq. to Atorvastatin 40 mg (as two film coated tablet) Clopidogrel Bisulphate IP Eq. to Clopidogrel 75 mg Aspirin IP 75mg (As Gastro-resistant tablet)	1 Capsule	M/s Safetab Life Science/ M/s Corona Remedies Pvt. Ltd.	13.66
10	4(10)	Dried Factor VIII Fraction/ Lyophilized	Each vial contains: - Factor VIII IP (1000 IU) - Protein Content IP (≤ 80 g/L) - Sodium Chloride IP (≤ 250 mM) - Sodium Citrate IP (≤ 10 mM) - Calcium Chloride IP (≤ 1 mM) - Mannitol IP (≤7.6 % W/V) - Glycine IP (≤ 300 mM) - Lycine HCL BP (≤ 25 mM) - Sucrose IP (≤ 1% W/V) - Sodium ion content IP (≤ 200 mM/L) - Fibrinogen content (of total protein) (≤ 80%)	1 Vial	M/s Reliance Life Sciences Pvt. Ltd.	14666.35
11	4(11)	Empagliflozin, Linagliptin and Metformin	Each film coated bilayer tablet contains: Empagliflozin 25 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Unison	14.05

Sharda

Sl. No.	Agenda Item No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
		Hydrochloride Extended-Release Tablets	Linagliptin 5 mg Metformin Hydrochloride (As Extended Release) IP 1000 mg		Pharmaceuticals Pvt. Ltd.	
12	4(12)	Empagliflozin, Sitagliptin and Metformin Hydrochloride Extended-Release Tablets	Each film coated bilayer tablet contains: Empagliflozin 10 mg Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg Metformin Hydrochloride (As Extended Release) IP 1000 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Primus Remedies Pvt. Ltd.	16.12
13	4(13)	Empagliflozin, Sitagliptin and Metformin Hydrochloride Extended-Release Tablets	Each film coated bilayer tablet contains: Empagliflozin 25 mg Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg Metformin Hydrochloride (As Extended Release) IP 1000 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Primus Remedies Pvt. Ltd.	22.77
14	4(14)	Magnesium and Vitamin D3 Tablets	Each film coated tablet contains: Magnesium bisglycinate Eq. to elemental Magnesium 250 mg Vitamin D3 IP 1000 IU	1 Tablet	M/s Alkem Health Science (A Unit of Alkem Laboratories Ltd)/ M/s Alkem Laboratories Ltd.	21.66
15	4(15)	Olmesartan Medoxomil, Amlodipine and Hydrochlorothiazide Tablets	Each film coated tablet contains: Olmesartan Medoxomil IP 20 mg Amlodipine Besilate IP Eq. to Amlodipine 5 mg Hydrochlorothiazide IP 12.5 mg	1 Tablet	M/s Windlas Biotech Limited/ M/s Alkem Wellness Limited	16.74
16	4(16)	Olmesartan Medoxomil, Amlodipine and Hydrochlorothiazide Tablets	Each film coated tablet contains: Olmesartan Medoxomil IP 40 mg Amlodipine Besilate IP Eq. to Amlodipine 5 mg Hydrochlorothiazide IP 12.5 mg	1 Tablet	M/s Windlas Biotech Limited/ M/s Alkem Wellness Limited	21.29
17	4(17)	Paracetamol and Mefenamic Acid Suspension	Each 5 ml contains: Paracetamol IP 250 mg	1 ML	M/s Mistair Health & Hygiene Pvt.	0.93

Sl. No.	Agenda Item No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
			Mefenamic Acid IP 100 mg		Ltd./ M/s Zorvia Healthcare Ltd.	
18	4(18)	Sitagliptin, Glimepiride and Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP Equivalent to Sitagliptin 50 mg Glimepiride IP 1 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Unison Pharmaceuticals Pvt. Ltd.	10.39
19	4(19)	Sitagliptin, Glimepiride and Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP equivalent to Sitagliptin 50 mg Glimepiride IP 2 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Unison Pharmaceuticals Pvt. Ltd.	11.90
20	4(20)	Tacrolimus Ointment	Composition: Tacrolimus IP 0.03%w/w	1 GM	M/s Skymap Pharmaceuticals Pvt. Ltd./ M/s German Remedies Pharmaceuticals Pvt. Ltd.	21.44
21	4(21)	Telmisartan, Cilnidipine and Metoprolol Succinate (ER) Tablets	Each film coated bilayer tablet contains: Telmisartan IP 40 mg Cilnidipine IP 10 mg Metoprolol Succinate IP 47.5 mg Eq. to Metoprolol Tartrate 50 mg (As extended-release form)	1 Tablet	M/s Mascot Health Series Pvt. Ltd./ M/s Intas Pharmaceuticals Ltd.	14.49
22	4(22)	Telmisartan, Cilnidipine and Metoprolol Succinate (ER) Tablets	Each film coated bilayer tablet contains: Telmisartan IP 40 mg Cilnidipine IP 10 mg Metoprolol Succinate IP 23.75 mg Eq. to Metoprolol Tartrate 25 mg (As extended-release form)	1 Tablet	M/s Mascot Health Series Pvt. Ltd./ M/s Intas Pharmaceuticals Ltd.	11.77
23	4(23)	Vitamin D3 (Cholecalciferol) Drops	Each ml contains: Vitamin D3 (Cholecalciferol) IP 800 IU	1 ML	M/s Tirupati Medicare Ltd./ M/s Zorvia Healthcare Limited	6.09
24	4(24)	Paracetamol, Caffeine	Each uncoated tablet contains:	1 Tablet	M/s Dallas Drugs Pvt.	7.50

Sl. No.	Agenda Item No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
		Anhydrous, Phenylephrine Hcl and Chlorpheniramine Maleate Tablets	Paracetamol IP 650 mg Caffeine Anhydrous IP 30 mg Phenylephrine Hcl IP 10 mg Chlorpheniramine Maleate IP 2 mg		Ltd./ M/s Centaur Pharmaceuticals Pvt. Ltd.	
25	4(25)	Relugolix, Estradiol and Norethindrone Acetate Tablets	Each Film Coated Tablet contains: Relugolix 40 mg Estradiol (As Hemihydrate) USP eq. to Anhydrous Estradiol 1 mg Norethindrone Acetate USP 0.5 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Mankind Pharma Ltd.	120.62
26	4(26)	Relugolix, Estradiol and Norethindrone Acetate Tablets	Each Film Coated Tablet contains: Relugolix 40 mg Estradiol (As Hemihydrate) USP eq. to Anhydrous Estradiol 1 mg Norethindrone Acetate USP 0.5 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Dr. Reddys Laboratories Ltd.	120.62
27	4(27)	Relugolix, Estradiol and Norethindrone Acetate Tablets	Each Film Coated Tablet contains: Relugolix 40 mg Estradiol (As Hemihydrate) USP eq. to Anhydrous Estradiol 1 mg Norethindrone Acetate USP 0.5 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Torrent Pharmaceuticals Ltd.	120.62
28	4(28)	Relugolix, Estradiol and Norethindrone Acetate Tablets	Each Film Coated Tablet contains: Relugolix 40 mg Estradiol (As Hemihydrate) USP eq. to Anhydrous Estradiol 1 mg Norethindrone Acetate USP 0.5 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s La Renon Healthcare Pvt. Ltd.	120.62
29	4(29)	Relugolix, Estradiol and Norethindrone Acetate Tablets	Each Film Coated Tablet contains: Relugolix 40 mg Estradiol (As Hemihydrate) USP eq. to Anhydrous Estradiol 1 mg Norethindrone Acetate USP 0.5 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Eris Lifesciences Ltd.	120.62
30	4(30)	Relugolix, Estradiol and	Each Film Coated Tablet contains: Relugolix 40 mg	1 Tablet	M/s Akums Drugs & Pharmaceutical	120.62

Sl. No.	Agenda Item No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
		Norethindrone Acetate Tablets	Estradiol (As Hemihydrate) USP eq. to Anhydrous Estradiol 1 mg Norethindrone Acetate USP 0.5 mg		s Ltd. / M/s Akumentis Healthcare Ltd.	
31	4(31)	Relugolix, Estradiol and Norethindrone Acetate Tablets	Each Film Coated Tablet contains: Relugolix 40 mg Estradiol (As Hemihydrate) USP eq. to Anhydrous Estradiol 1 mg Norethindrone Acetate USP 0.5 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Aurobindo Pharma Ltd.	120.62
32	4(32)	Paracetamol and Chlorpheniramine Maleate Syrup	Each 5 ml Contains: Paracetamol IP 125 mg Chlorpheniramine Maleate IP 1.5 mg	1 ML	M/s Indoco Remedies Ltd.	**(Note 1)**

Note 1- *The Authority noted that M/s Indoco Remedies Ltd vide letter dated 11.03.2026 requested for withdrawal of Form I application. Accordingly, the Authority accepted the withdrawal request of the company.*

5. Agenda No. 5: Minutes of 75th meeting of the Multidisciplinary Committee of Experts held on 11.02.2026.

5.1 Noted.

6 Agenda No. 6: Application for exemption of patented non-scheduled formulation Nafithromycin 400 mg Tablets under Para 32(i) of DPCO, 2013 by M/s Wockhardt Limited.

6.1 The Authority noted that M/s Wockhardt Limited submitted an application on 14.07.2025 seeking exemption under Para 32(i) of the DPCO, 201 for the non-scheduled formulation Nafithromycin tablets duly approved by CDSCO. 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 Indian Patent Act, 1970.

6.2 The Authority noted that the matter was deliberated by the MDC in its 71st meeting held on 16.09.2025 wherein the Committee 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 in Form CT-23 (Approval No. IND/MA/24/00001 dated 01.01.2025) specifically pertains to "Nafithromycin Tablets – Immediate release film-coated tablets – each film-coated tablet containing Nafithromycin 400 mg." The Committee also noted that neither the patent certificate nor the claims filed with the Patent Office explicitly mentioned the name 'Nafithromycin'.

6.3 In respect of this the company along with other documents furnished the summary of inventions & claims and the scientific publication from a peer reviewed journal "Chromatographia (2019) 82:1059-1068", as published in Springer Nature 2019. The Committee sought inputs from CDSCO and O/o the Office of the Controller General of Patents, Designs & Trade Marks (CGPDTM) so as to verify whether the formulation approved by CDSCO corresponds to the one for which the patent was granted.

6.4 The matter was again deliberated in the 75th MDC meeting held on 11.02.2026 wherein the Committee deliberated upon the inputs from O/o CGPDTM vide email dated 20.01.2026 confirming that "*the CDSCO approved Nafithromycin tablet formulation corresponds to the scope of the granted claims of Patent No. 415319, in so far as the claimed solid tablet composition is concerned.*" Further, the representative from CDSCO also confirmed 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.

6.5 It was noted that the Committee deliberated upon the matter and based on the inputs from O/o CGPDTM and CDSCO, noted that the applied formulation Nafithromycin Tablets – Immediate release film-coated tablets – each film-coated tablet containing Nafithromycin 400 mg is covered under the 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 in the country.

6.6 The Authority deliberated on the recommendation of the Committee and approved the recommendation of MDC for grant of exemption for Nafithromycin Tablets – Immediate release film-coated tablets – each film-coated tablet containing 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 in the country or expiry of the Indian patent, **whichever may be earlier.**

6.7 The Authority further directed that M/s Wockhardt Limited shall inform NPPA, the date of commercial marketing of the said formulation in the country and the Price to Retailer (PTR) and Maximum Retail Price fixed by the company in respect of the said formulation by issuing a price list in Form V under DPCO, 2013.

6.8 The Authority also directed that M/s Wockhardt Limited, after the expiry of period of exemption granted under para 32(i) of DPCO, 2013, shall follow the notified ceiling price or seek retail price approval three months before the expiry of the exemption, if applicable, for the said formulation.

7 Agenda No. 7: Application by M/s Intas Pharmaceuticals 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"

7.1 The Authority noted that M/s Intas Pharmaceuticals Limited had earlier applied for exemption under Para 32 (iii) and 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

Sharda

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 MDC 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".

7.2 The Authority noted that now, the company vide its letter dated 07.10.2024 & clarification dated 30.10.2024 submitted that 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 also submitted the Patent Certificate No. 437433 titled "Extended Release pharmaceutical composition of Clozapine" granted on 05.07.2023 and requested exemption under sub-para (ii) & (iii) of Para 32 of DPCO, 2013. The Authority also noted that the applicant submitted revised claim dated 23.04.2025 and vide email dated 22.07.2025 requested to consider the same.

7.3 In order to ascertain whether process patent granted to the company covers the formulations in respect of which the exemption is sought by the company, inputs were sought from the office of CGPTDM. The inputs were received from O/o CGPTDM vide letter dated 2.01.2026 which mentioned that it has been found that the subject-matter as submitted by applicant company before NPPA, and the subject-matter that is approved by DGCI 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.

7.4 The Authority further noted that the matter was deliberated in 75th MDC meeting held on 11.02.2026 along with the inputs from the office of CGPTDM. In the meeting, the representative from the O/o CGPDTM reiterated that the applied formulations fall within the scope of granted claims of patent application. It was also noted by the MDC that the company has already launched the said formulations. 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 Limited for a period of 5 years from the date of the commencement of commercial production in the country.

7.5 The Authority deliberated the matter in detail and approved the recommendation of MDC to grant exemption for formulations Clozapine Extended Release 12.5 mg/ 25 mg/ 50 mg/ 100 mg/200 mg capsule to M/s Intas Pharmaceuticals Limited under Para 32(ii) of DPCO, 2013 for a period of five years from the date of the commencement of commercial production in the country or expiry of the Indian patent, whichever may be earlier.

7.6 The Authority further directed that M/s Intas Pharmaceuticals Limited shall inform NPPA the date of commercial production of the formulations "Clozapine Extended Release Capsules 12.5 mg / 25 mg / 50 mg / 100 mg / 200 mg" in the country and the Price to Retailer (PTR) and Maximum Retail Price fixed by the company in respect of above said formulation by issuing a price list in Form V under DPCO, 2013.

7.7 The Authority also directed that M/s Intas Pharmaceuticals Limited shall, after the expiry of period of exemption granted under para 32(ii) of DPCO, 2013 follow the notified ceiling price or seek retail price approval, three months before the expiry of the exemption, as applicable, for

Panda

the formulations "Clozapine Extended Release Capsules 12.5 mg / 25 mg / 50 mg / 100 mg / 200 mg.

8 Agenda No. 8: 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.

8.1 The Authority 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. In the 71st MDC meeting, the representative of company, gave a presentation and also demonstrated the product and the MDC directed the applicant to provide evidence in support of its claim.

8.2 It was noted that the MDC in its 70th, 71st, 73rd and 75th meetings held on 05.08.2025, 16.09.2025, 25.11.2025 and 11.02.2026 respectively deliberated the submissions made by the applicant and inputs received from the CDSCO. In view of the same, MDC 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.

8.3 The Authority deliberated upon the recommendation of the MDC and decided to defer the matter for further examination.

9 Agenda No. 9(a): Application by M/s Sun Pharma Laboratories Ltd. for extension of notified retail price for the formulation 'Each film coated tablet contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg + Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg' due to in house shifting of product from third party.

9.1.1 The Authority noted that NPPA has notified retail price for M/s Pure and Cure Healthcare Pvt. Ltd (manufacturer) and M/s Sun Pharma Laboratories Ltd (marketer) vide S.O. 575 (E) dated 09.02.2021 at Rs.16.97 per tablet for the formulation Each film coated tablet contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg + Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg.

9.1.2 The company has submitted loan license in its own name at the premises of M/s Pure and Cure Healthcare Pvt. Ltd and has requested to allow extension of already notified retail prices with M/s Sun Pharma Laboratories Ltd as manufacturer and marketer.

9.1.3 The Authority deliberated upon the matter and noted that manufacturing the said formulation in its own name under a loan license is a commercial decision of the applicant. Hence, the Authority decided that the company may be permitted to market the said formulation at the approved retail price , not exceeding the present applicable retail price.

Agenda 9(b): Application by M/s Sun Pharmaceutical Industries Ltd. for extension of notified retail price for the formulation 'Each film coated tablet contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg/20mg + Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg' due to in house shifting of product from third party.

Nanda

9.2.1 The Authority noted that NPPA has notified retail price for M/s Pure and Cure Healthcare Pvt. Ltd (manufacturer) and M/s Sun Pharmaceutical Industries Ltd (marketer) as below-

(i) Rs.11.43 per tablet for the formulation Each film coated tablet contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg + Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg vide S.O. 5635(E) dated 02.11.2018.

(ii) Rs.16.97 per tablet for the formulation Each film coated tablet contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg + Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg and vide S.O. 575 (E) dated 09.02.2021.

9.2.2 The company has submitted loan license in its own name at the premises of M/s Pure and Cure Healthcare Pvt. Ltd and has requested to allow extension of already notified retail prices with M/s Sun Pharmaceutical Industries Ltd as manufacturer and marketer.

9.2.3 The Authority deliberated upon the matter and noted that manufacturing the said formulations in its own name under a loan license is a commercial decision of the applicant. Hence, the Authority decided that the company may be permitted to market the said formulations at the approved retail price, not exceeding the present applicable retail price.

10 Agenda No. 10: Wholesale Price Index as per Para 16 of DPCO, 2013 to be applicable from 01.04.2026.

10.1 The Authority noted that DPIIT, Ministry of Commerce and Industry, Government of India has confirmed the monthly final Wholesale Price Indices (WPI) of all commodities for the year 2024 and 2025 vide O.M. OEA-11025(13)/18/2017-WPD-Part(256) (E-27557) dated 18.3.2026. The Authority deliberated upon the matter in detail and as per provisions of DPCO, 2013 approved the WPI @ (+) 0.64956% to be applicable on scheduled formulations w.e.f. 1.4.2026. The Authority further decided to issue an Office Memorandum intimating the WPI to be applicable w.e.f. 1.4.2026 and to issue notification(s) for revised ceiling price of scheduled formulations based on WPI @ (+) 0.64956% to be effective from 1.4.2026.

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

(Sai Ahlladini Panda)
Member Secretary