

मिसिल स.- 8(80)/2020/डी.पी/एनपीपीए-डीवी-II  
F. No. 8(80)/2020/DP/NPPA-Div. II

कार्यवाहीस. : 212/80/2020/F

Proceeding No : 212/80/2020/F

**Minutes of the 212<sup>th</sup> (overall) and 80<sup>th</sup> meeting of the Authority under DPCO, 2013 held on 26.10.2020 at 11:00 AM**

The 212<sup>th</sup> meeting of the Authority (overall), which is the 80<sup>th</sup> meeting under the DPCO, 2013, was held on the 26<sup>th</sup> of October, 2020 at 11:00 AM under the Chairmanship of Ms. Shubhra Singh, Chairman, NPPA. The following Authority members of the NPPA were present:

- (i) Dr. Vinod Kotwal, Member Secretary
- (ii) Shri A. K. Saha, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure
- (iii) Ms. A. Srija, Economic Advisor, Department of Economic Affairs

Shri A. K. Pradhan, Deputy Drug Controller, CDSCO, Ministry of Health & Family Welfare was also present.

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

- (i) Shri N. I. Chowdhury, Advisor
- (ii) Shri S. S. Ojha, Jt. Director (Pricing)
- (iii) Shri Prasenjit Das, Asstt. Director (Pricing)
- (iv) Shri Prakash Hemani, Asstt. Director (Pricing)

## **II. Agenda items**

### **1. Agenda item no. 1 - Confirmation of the Minutes of the 79<sup>th</sup> meeting held on 25.09.2020.**

1.1 The Authority confirmed the minutes without any change.

### **2. Agenda item no. 2 - Action Taken Report on decisions taken by NPPA in its 78<sup>th</sup> meeting dated 14.09.2020 and 79<sup>th</sup> meeting dated 25.09.2020**

2.1 The Authority noted that due actions have been taken.

### **3. Agenda item no. 3 - Status of New Drug application**

3.1 Noted.

**4. Agenda item no. 4 – New Drug application Price fixation under Para 5 and Para 15 of DPCO, 2013**

4.1 The Authority discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 4 (i) to 4(xxxvi) (total 36 Form I applications containing retail price fixation of 36 new drugs) falling under the purview of Para 2(u) of DPCO, 2013 and approved the retail prices of 33 (thirty three) new drugs [except 3 formulations as per agenda no. 4(xxxi), 4(xxxii) and 4(xxxvi)] under Para 5 and 15 of the DPCO 2013, as detailed below:

**A. Retail price fixed under Para 5 of DPCO, 2013**

Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(i)	Moxifloxacin Hydrochloride + Dexamethasone Phosphate Eye Drop	<b>Composition:</b> Moxifloxacin Hydrochloride IP Eq. to Moxifloxacin 0.5% w/v, Dexamethasone Sodium Phosphate Eq. to Dexamethasone Phosphate 0.1% w/v	1 ML	M/s Skymap Healthcare Pvt. Ltd./ M/s Albert David Ltd	19.02
4(ii)	Ciprofloxacin + Dexamethasone Sodium Phosphate Eye Drops	<b>Composition:</b> Ciprofloxacin Hydrochloride IP Eq. to Ciprofloxacin 0.3% w/v, Dexamethasone IP 0.1% w/v	1 ML	M/s Skymap Healthcare Pvt. Ltd./M/s Albert David Ltd	1.35
4(iii)	Ofloxacin + Dexamethasone Phosphate Eye/Ear Drops	<b>Composition:</b> Ofloxacin IP 0.3% w/v, Dexamethasone Sodium Phosphate IP 0.1% w/v	1 ML	M/s Skymap Healthcare Pvt. Ltd./ M/s Albert David Ltd	3.77 (Note 2)
4(iv)	Ciprofloxacin Hydrochloride + Dexamethasone Sodium Phosphate Eye Drops	<b>Composition:</b> Ciprofloxacin Hydrochloride IP eq. to Ciprofloxacin 0.3% w/v, Dexamethasone Sodium Phosphate IP eq. to Dexamethasone Phosphate 0.1% w/v	1 ML	M/s Axa Parenterals Ltd. / M/s Sun Pharmaceuticals Industries Limited	1.35
4(v)	Telmisartan + Cilnidipine + Metoprolol Tablet (Telmiprime MC 25)	<b>Each film coated bilayered Tablet contains:</b> Telmisartan IP 40mg Cilnidipine IP 10mg Metoprolol Succinate IP	1 Tablet	M/s Swiss Garnier Genexia Sciences Pvt. Ltd. / M/s Primus Remedies	10.16

Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		23.75mg eq. to Metoprolol Tartrate 25 mg (as Extended Release form)		Pvt. Ltd.	
4(vi)	Telmisartan + Cilnidipine + Metoprolol Tablet (Telmiprime MC 50)	<b>Each film coated bilayered Tablet contains:</b> Telmisartan IP 40mg Cilnidipine IP 10mg Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate 50 mg (as Extended Release form)	1 Tablet	M/s Swiss Garnier Genexia Sciences Pvt. Ltd. / M/s Primus Remedies Pvt. Ltd.	12.41
4(vii)	Metformin Hydrochloride (SR) + Gliclazide (ER) + Pioglitazone Hydrochloride Tablet (Prizide MP 30)	<b>Each film coated bilayered Tablet contains:</b> Metformin Hydrochloride IP 500mg (as Sustained Release Form) Gliclazide IP 30mg (as Extended Release Form) Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg.	1 Tablet	M/s Swiss Garnier Genexia Sciences Pvt. Ltd. / M/s Primus Remedies Pvt. Ltd.	6.15
4(viii)	Metformin Hydrochloride (SR) + Gliclazide (ER) + Pioglitazone Hydrochloride Tablet (Prizide MP 60)	<b>Each film coated bilayered Tablet contains:</b> Metformin Hydrochloride IP 500mg (as Sustained Release Form) Gliclazide IP 60mg (as Extended Release Form) Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg.	1 Tablet	M/s Swiss Garnier Genexia Sciences Pvt. Ltd. / M/s Primus Remedies Pvt. Ltd.	8.69
4(ix)	Clotrimazole + Lignocaine Hydrochloride Ear Drops	<b>Composition:</b> Clotrimazole IP 1.0% w/v Lignocaine Hydrochloride IP 2.0% w/v	1 ML	M/s Skymap Healthcare Pvt. Ltd.	5.93 (Note 2)
4(x)	Moxifloxacin Hydrochloride + Dexamethasone Phosphate Eye Drops	<b>Composition:</b> Moxifloxacin Hydrochloride IP eq. to Moxifloxacin 0.5% w/v Dexamethasone Sodium Phosphate IP eq. to Dexamethasone Phosphate 0.1% w/v	1 ML	M/s Skymap Healthcare Pvt. Ltd.	19.02
4(xi)	Atorvastatin + Clopidogrel + Aspirin Capsule	<b>Each hard gelatin capsule contains:</b> Atorvastatin Calcium IP eq.	1 Capsule	M/s Akums Drugs & Pharmaceuticals Ltd. / Dr. Reddy's	5.50

Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	(Atocor Gold 20)	to Atorvastatin 20mg (As film coated tablet form), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As film coated tablet form), Aspirin IP 75mg (As enteric coated Tablet form)		Laboratories Ltd.	
4(xii)	Rosuvastatin + Aspirin + Clopidogrel Capsule	<b>Each hard gelatin capsule contains:</b> Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (As Pellets) Aspirin IP 75mg (as enteric coated pellets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As Pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Cadila Pharmaceuticals Limited	18.48
4(xiii)	Paracetamol + Caffeine Tablet	<b>Each film coated tablet contains:</b> Paracetamol IP 650mg Caffeine Anhydrous IP 50mg	1 Tablet	M/s Acme Generics LLP / M/s Cipla Limited	2.74 (Note 2)
4(xiv)	Ofloxacin + Betamethasone Sodium Phosphate Eye/Ear Drops	<b>Composition:</b> Ofloxacin IP 0.3% w/v Betamethasone Sodium Phosphate IP 0.1% w/v	1 ML	M/s Skymap Healthcare Pvt. Ltd.	4.76 (Note 2) (Note 3)
4(xxx)	Ascorbic Acid (Vitamin C) + Zinc Chewable Tablet (Bluvit-CZ Chewable)	<b>Each uncoated chewable tablet contains:</b> Ascorbic Acid IP 100mg Sodium Ascorbate IP 450mg eq. to Ascorbic Acid 400mg Zinc Citrate USP eq. to Elemental Zinc 5mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Blue Cross Laboratories Pvt. Ltd.	3.82 (Note 2)
4(xxxi)	Norethisterone Acetate Controlled Release Tablet	<b>Each film coated controlled released table contains:</b> Norethisterone Acetate USP 10mg Tablet	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Cadila Pharmaceuticals Limited	Rejected (Note 4)
4(xxxiii)	Thiocolchicoside + Aceclofenac + Paracetamol Tablet	<b>Each film coated tablet contains:</b> Thiocolchicoside IP 4mg Aceclofenac IP 100 mg Paracetamol IP 325 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals / M/s Cadila Pharmaceutical Limited	14.76 (Note 5)

Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(xxxiv)	Thiocolchicoside + Aceclofenac + Paracetamol Tablet	<b>Each film coated tablet contains:</b> Thiocolchicoside IP 8mg Aceclofenac IP 100 mg Paracetamol IP 325 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals / M/s Cadila Pharmaceutical Limited	22.52 (Note 5)

### B. Retail price fixed under Para 5 and 15 of DPCO, 2013

Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(xv)	Azelnidipine + Telmisartan Tablet	<b>Each film coated bi-layered tablet contains:</b> Azelnidipine IP 8mg Telmisartan IP 80mg	1 Tablet	M/s Synkem Pharmaceuticals Limited / M/s Glenmark Pharmaceuticals Ltd.	16.16
4(xvi)	Azelnidipine + Telmisartan Tablet	<b>Each film coated bi-layered tablet contains:</b> Azelnidipine IP 8mg Telmisartan IP 40mg	1 Tablet	M/s Synkem Pharmaceuticals Limited / M/s Glenmark Pharmaceuticals Ltd.	12.93
4(xvii)	Calcium + Vitamin D3 + Methylcobalamin + L-Methylfolate Calcium + Pyridoxal – 5- Phosphate Tablet	<b>Each Film coated tablet contains:</b> Calcium Carbonate IP 1250mg eq. to Elemental Calcium 500mg, Vitamin D3 IP 2000IU Mecobalamin IP (Methylcobalamin) 1500mcg, L-Methylfolate Calcium 1mg, Pyridoxal – 5- Phosphate 20mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Limited / M/s Cipla Limited	17.78
4(xviii)	Azelnidipine + Telmisartan Tablet	<b>Each film coated bi-layered tablet contains:</b> Azelnidipine IP 8mg Telmisartan IP 40mg	1 Tablet	M/s Synkem Pharmaceuticals Limited / M/s Emcure Pharmaceuticals Ltd.	12.93
4(xix)	Azelnidipine + Telmisartan Tablet	<b>Each film coated bi-layered tablet contains:</b> Azelnidipine IP 8mg Telmisartan IP 80mg	1 Tablet	M/s Synkem Pharmaceuticals Limited / M/s Emcure Pharmaceuticals	14.40

Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
				Ltd.	
4(xx)	Flunarizine + Domperidone Tablet	<b>Each uncoated tablet contains:</b> Flunarizine Dihydrochloride BP eq. to Flunarizine 5mg, Domperidone IP 10mg	1 Tablet	M/s Windlas Biotech Pvt. Ltd./M/s Mankind Pharma Limited	4.68 (Note 2)
4(xxi)	Budesonide + Glycopyrronium Bromide + Formoterol Fumarate Powder for Inhalation 400/25/12mcg Capsule	<b>Each Capsule contains:</b> Budesonide IP 400 mcg, Glycopyrronium (As Glycopyrrolate IP) 25mcg, Formoterol Fumarate Dihydrate IP 12 mcg	1 Capsule	M/s Cipla Limited	13.63
4(xxii)	Alogliptin + Metformin Hydrochloride Tablet	<b>Each film coated tablet contains:</b> Alogliptin Benzoate 17mg eq. to Alogliptin 12.5 mg , Metformin Hydrochloride IP 500MG	1 Tablet	M/s Indoco Remedies Limited	7.82
4(xxiii)	Alogliptin + Metformin Hydrochloride (SR) Tablet	<b>Each film coated tablet contains:</b> Alogliptin Benzoate 17mg eq. to Alogliptin 12.5 mg, Metformin Hydrochloride IP 1000 mg	1 Tablet	M/s Indoco Remedies Limited	9.49
4(xxiv)	Vildagliptin + Metformin Hydrochloride (SR) Tablet	<b>Each uncoated bilayered tablet contains:</b> Vildagliptin 50 mg, Metformin Hydrochloride 500 mg (as sustained release form)	1 Tablet	M/s Mascot Health Series Pvt. Ltd./M/s Emcure Pharmaceutical Limited	6.58 (Note 6)
4(xxv)	Vildagliptin + Metformin Hydrochloride (SR) Tablet	<b>Each uncoated bilayered tablet contains:</b> Vildagliptin 50mg, Metformin Hydrochloride IP 500mg (As sustained release form)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Intas Pharmaceuticals Ltd.	6.58 (Note 6)
4(xxvi)	Vildagliptin + Metformin Hydrochloride (SR) Tablet	<b>Each uncoated bilayered tablet contains:</b> Vildagliptin 50mg, Metformin Hydrochloride IP 500mg (As sustained release form)	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s J. B. Chemicals & Pharmaceuticals Limited	6.58 (Note 6)
	Vildagliptin +	<b>Each uncoated bilayered</b>	1 Tablet	M/s Mascot Health	

Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(xxvii)	Metformin Hydrochloride (SR) Tablet	<b>tablet contains:</b> Vildagliptin 50 mg, Metformin Hydrochloride 1000 mg (as sustained release form)		Series Pvt. Ltd./M/s Emcure Pharmaceutical Limited	7.07 (Note 6)
4(xxviii)	Vildagliptin + Metformin Hydrochloride (SR) Tablet	<b>Each uncoated bilayered tablet contains:</b> Vildagliptin 50mg, Metformin Hydrochloride IP 1000mg (As sustained release form)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Intas Pharmaceuticals Ltd.	7.07 (Note 6)
4(xxix)	Vildagliptin + Metformin Hydrochloride (SR) Tablet	<b>Each uncoated bilayered tablet contains:</b> Vildagliptin 50mg, Metformin Hydrochloride IP 1000mg (As sustained release form)	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s J. B. Chemicals & Pharmaceuticals Limited	7.07 (Note 6)
4(xxxv)	Amoxicillin + Potassium Clavulanate Oral Suspension IP (Augmentin ES)	<b>Each 5ml powder for reconstitution into suspension contains:</b> Amoxicillin Trihydrate 759.04mg eq. to Amoxicillin Free Acid 652.78 mg Potassium Clavulanate 61.48mg eq. to Clavulanate Acid 50.41mg	Each 50 ml Pack	M/s GlaxoSmithKline Pharmaceuticals Ltd.	181.50

**Note 1.** The retail prices are to be notified after 10 working days from uploading of draft working sheet/Minutes of the Multidisciplinary Committee of Experts/ Minutes of the Authority Meeting on NPPA's website, as applicable.

**Note 2.** The representative of DCGI present in the meeting confirmed that the formulations are approved by DCGI.

**Note 3.** The Authority noted that as per the provisions of DPCO 2013, the prices are fixed based on simple average of Price to Retailer (PTR ) of the products of the companies having 1% or more market share. The Authority observed that products of the companies with higher PTR and low market share distorts the price fixation by setting the price at a higher level affecting the affordability of the medicines to the consumer. Accordingly, the Authority requested that the matter may be brought to the notice of Department of Pharmaceuticals.

**Note 4.** *The Authority reiterated its observation in 78th meeting dated 14.09.2020 in which it noted that the manufacturer has got approval for the formulation from DCG (I) at a date later than the approval from State Drug Licensing Authority and accordingly, directed to obtain comments from DCG(I) to understand the latest directions in this regard and the approval status of the formulation. DCG(I) vide letter dated 23.10.2020 stated that clarification has been sought from the manufacturer with a copy to State Licensing Authority, Uttarakhand. Accordingly, the Authority decided to reject the application for retail price approval due to incomplete application.*

**Note 5.** *DCGI vide its letter dated 16.10.2020 stated that M/s Akums Drugs and Pharmaceuticals Ltd has been allowed to manufacture and market the Fixed Dose Combinations.*

**Note 6.** *(i) The Authority noted the applications for retail price fixation of Fixed Dose Combinations (FDCs) of Metformin Sustained release and Vildagliptin tablets and recalled the decision taken in its 72nd meeting dated 20.01.2020 regarding retail price fixation of Fixed Dose Combinations (FDCs) of Metformin and Vildagliptin tablets. In the meeting it was decided to fix the retail price by adding 16% retailer margin to the average Price to Retailer (PTR) based on Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Metformin and Vildagliptin tablets to give the benefits of patent expiry of the drug Vildagliptin to consumers through discovery of price of off patent drug through market dynamics.*

*(ii) The Authority further noted that the retail price applications of FDCs of Metformin Sustained release and Vildagliptin tablets had been placed before the Multidisciplinary Committee of Experts. The Multidisciplinary Committee of Experts in its 22<sup>nd</sup> meeting dated 07.10.2020 recommended the retail price of Metformin 500 mg (sustained release) + Vildagliptin 50 mg tablet and Metformin 1000 mg (sustained release) + Vildagliptin 50 mg tablet at Rs. 6.58 per tablet (excluding GST) and Rs. 7.07 per tablet (excluding GST) respectively as per the following methodology:*

*a) Calculation of the price of Metformin 500 mg + Vildagliptin 50 mg tablet and Metformin 1000 mg + Vildagliptin 50 mg tablet as per the methodology decided by the Authority in its 72<sup>nd</sup> meeting dated 20.01.2020.*

*b) Adding the maximum of the difference in presently applicable notified ceiling price of Metformin IR & CR 500mg and 1000 mg tablet i.e. Rs. 0.41 to the amount derived as per the methodology mentioned in note 4(ii)(a) above.*

*(iii) The Authority deliberated upon the matter in detail and observed that the benefit of price reduction due to medicines going off-patent needs to be passed on to the consumers. Accordingly, the Authority accepted the recommendations of the Multidisciplinary Committee*



*of Experts and approved the retail price of Metformin 500 mg (sustained release) + Vildagliptin 50 mg tablet and Metformin 1000 mg (sustained release) + Vildagliptin 50 mg tablet at Rs. 6.58 per tablet (excluding GST) and Rs. 7.07 per tablet (excluding GST) respectively.*

*(iv) The Authority also noted the representation of M/s Emcure Pharmaceuticals Ltd regarding retail price fixation of Metformin 500 mg (sustained release) + Vildagliptin 50 mg tablet and Metformin 1000 mg (sustained release) + Vildagliptin 50 mg tablet for M/s Emcure Pharmaceuticals Ltd (Agenda item no. 4(xxiv) and 4(xxvii). Authority was of the view if the present methodology of retail price fixation is not followed then it will deprive the benefit of passing price reduction due to medicine going off-patent to consumers, which is not in public interest. Accordingly, the Authority decided not to consider the representation of M/s Emcure Pharmaceuticals Ltd and the same be treated as closed.*

*(v) The Authority observed that the extant provisions of DPCO 2013 do not provide for passing of benefit of price reduction to consumers in case of medicines going off-patent. Accordingly, the Authority decided that the matter be highlighted to Department of Pharmaceuticals.*

**4.2 Agenda item no. 4(xxxii):** The Authority noted that the retail price application of M/s Cipla Limited (Marketing) and M/s Bliss GVS Pharma Ltd. (Manufacture) regarding Mesalazine 1g Suppository is pending for want of clarification from CDSCO. The Authority directed that the matter be placed in its next meeting after obtaining clarification from CDSCO.

**4.3 Agenda item no. 4(xxxvi):** The Authority noted that retail price application of M/s Win Medicare Pvt. Ltd. (marketer) and M/s G.S. Pharmbutor Pvt. Ltd (manufacturer) for Betadine Alcoholic Handrub is pending for examination before the Multidisciplinary Committee of Experts. Accordingly, the Authority directed that the matter be placed in its next meeting after obtaining the recommendation of the Multidisciplinary Committee of Experts.

4.4 The Authority noted that the retail price applications of new drugs mainly consist of Fixed Dose Combinations (FDCs) of two or more drugs. The Authority deliberated upon the matter in detail and expressed its concern that approval of these FDCs may compromise the rationale in the usage of the drugs and may lead to over medication. The Authority also apprehended that fixation of retail price of these FDCs may lead to a higher price being fixed than the sum of the price of their individual components resulting in profiteering by the companies. The Authority is of the view that guidelines in the usage of these FDCs needs to be looked into. Accordingly, the Authority requested that matter may be highlighted to Indian Council of Medical research (ICMR), New Delhi.

## **5. Agenda item no. 5 – Status of implementation of Review cases**

5.1 Noted.

### **6.1 Agenda item no. 6 – Application for extension of ceiling price for I.V. Fluids with packaging in Non-glass with special feature.**

6.1 The Authority deliberated upon the matter in detail and noted that one company namely, M/s R. K. Laboratories Pvt. Ltd has applied for separate ceiling price of I.V. Fluids for packages in non-glass having special features. The Authority noted that the matter was deliberated in the 22nd meeting of the Multidisciplinary Committee of Experts held on 07.10.2020 and M/s R. K. Laboratories Pvt. Ltd had made demonstration before the Multidisciplinary Committee of Experts. The Authority further noted that the Committee recommended to extend the ceiling prices and the formulations mentioned in SO.1215 (E) dated 25.03.2020 to M/s R. K. Laboratories Pvt. Ltd for I.V. fluids in packages in non-glass with special features as (i) Self collapsibility and self-seal ability; (ii) not having air-vent; and (iii) having no chance of contamination during manufacture / infusion / admixing levels.

6.2 The Authority also deliberated upon the application of M/s Eurolife Healthcare Pvt. Ltd for separate ceiling price of I.V. Fluids for packages in non-glass having special features and noted that M/s Eurolife Healthcare Pvt. Ltd had made a demonstration before the Multidisciplinary Committee of Experts in its 20th meeting held on 17.07.2020 and the Committee sought information from M/s Eurolife Healthcare Pvt. Ltd regarding the availability of license for manufacturing of IV fluids with packaging in non-glass having special features. The documents submitted by M/s Eurolife Healthcare Pvt. Ltd was examined by the Committee in its 22nd meeting held on 07.10.2020 in which it recommended to extend the ceiling prices and the formulations mentioned in SO. 1215(E) dated 25.03.2020 to M/s Eurolife Healthcare Pvt. Ltd for I.V. fluids in packages in non-glass with special features.

6.3 Accordingly, the Authority decided to extend the ceiling prices and the formulations mentioned in S.O.1215(E) dated 25.03.2020 to (i) M/s R. K. Laboratories Pvt. Ltd for its product “Eurohead bottle” and (ii) M/s Eurolife Healthcare Pvt. Ltd for its product ‘Lifeport’ in respect of I.V. fluids in packages in non-glass with special features as (i) Self collapsibility and self-seal ability; (ii) not having air-vent; and (iii) having no chance of contamination during manufacture / infusion / admixing levels.

**7.1 Agenda item no. 7(i) - Fixation of Ceiling Price for Tacrolimus 0.5mg / 1mg / 2mg tablets**

7.1.1 The Authority deliberated upon the matter in detail and approved the ceiling price of Tacrolimus 0.5 mg, 1 mg and 2 mg tablet as detailed below:

S. No.	Name of the Scheduled Formulation	Dosage form & Strength	Unit	Ceiling Price excluding GST (Rs.)
1.	Tacrolimus	0.5 mg tablet	1 tablet	Rs. 18.68
2.	Tacrolimus	1 mg tablet	1 tablet	Rs. 34.31
3.	Tacrolimus	2 mg tablet	1 tablet	Rs. 67.77

**7.2 Agenda item no. 7(ii) - Ceiling Price fixation of Tetanus + Diphtheria (TD) Vaccine**

7.2.1 The Authority deliberated upon the matter in detail and approved the ceiling price of Tetanus + Diphtheria (TD) Vaccine as detailed below:

S. No.	Formulation	Dosage and strength	Unit	Approved ceiling price (ex. GST)
1.	TD vaccine	Each dose of 0.5 ml contains: Diphtheria Toxoid $\leq$ 5Lf ( $\geq$ 2IU) Tetanus Toxoid $\geq$ 5Lf ( $\geq$ 40IU)	Per 0.5 ml pack	Rs. 18.69
2.	TD vaccine	Each dose of 0.5 ml contains: Diphtheria Toxoid $\leq$ 5Lf ( $\geq$ 2IU) Tetanus Toxoid $\geq$ 5Lf ( $\geq$ 40IU)	Per 5 ml pack	Rs. 175.59
3.	TD vaccine	Each dose of 0.5 ml contains: Diphtheria Toxoid $\leq$ 25Lf ( $\geq$ 30IU) Tetanus Toxoid $\geq$ 5Lf ( $\geq$ 40IU)	Per 0.5 ml pack	Rs. 16.02

**7.3 Agenda item no. 7(iii) - Fixation of Ceiling Price of scheduled formulations under DPCO 2013 with respect to certain formulations whose ceiling price is fixed under NLEM 2011 but yet to be fixed under NLEM 2015**

7.3.1 The Authority deliberated upon the matter in detail and approved the ceiling price of 2 (two) scheduled formulations as detailed below:

S. No.	Formulation	Dosage and strength	Unit	Approved ceiling price (ex. GST)
1.	Sodium nitrite	Injection 30 mg/ml	Per ml	25.91
2.	Praziquantel	Tablet 600 mg	Per tablet	34.63

7.3.2 The Authority observed that further examination is required regarding Oral poliomyelitis vaccine and accordingly decided to defer the ceiling price fixation of Oral poliomyelitis vaccine.

7.3.3 The Authority further noted the representation received from M/s Zydus Healthcare Ltd and observed that as per provisions of DPCO 2013, the revision of ceiling prices shall be carried out as and when the National List of Essential Medicines is revised by the Ministry of Health and Family Welfare or five years from the date of fixing the ceiling price under this Order, whichever is earlier. Since the ceiling price of the three formulations namely, Oral poliomyelitis vaccine, Sodium nitrite injection 30mg/ml and Praziquantel tablet 600 mg is being fixed for the first time under amended schedule I of DPCO 2013, it is in accordance with the provisions of DPCO 2013. Hence, the representation has no merit and may be treated as closed.

**8. Agenda item no. 8 - Intimation of Minutes of 22nd & 23rd meeting of Multidisciplinary Committee of Experts held on 07.10.2020 & 20.10.2020 respectively**

8.1 Noted.

**9. Agenda item no. 9 - Application for extension of ceiling price for Ringer Lactate Injection in packaging with special feature**

9.1 The Authority deliberated upon the matter in detail and noted that one company namely, M/s R. K. Laboratories Pvt. Ltd had applied for separate ceiling price of ringer lactate injection in packages having special features. The Authority further noted that the matter was deliberated in the 22nd meeting of the Multidisciplinary Committee of Experts held on 07.10.2020 and M/s R. K. Laboratories Pvt. Ltd had made demonstration before the Multidisciplinary Committee of Experts. The Authority further noted that the Committee recommended to extend the ceiling prices and the formulations mentioned in SO.1216 (E) dated 25.03.2020 to M/s R. K. Laboratories Pvt. Ltd for ringer lactate injection in packages with special features as (i) Self collapsibility and self-seal ability; (ii) not having air-vent; and (iii) having no chance of contamination during manufacture / infusion / admixing levels.

9.2 Accordingly, the Authority decided to extend the ceiling prices and the formulations mentioned in S.O.1216(E) dated 25.03.2020 to M/s R. K. Laboratories Pvt. Ltd for ringer lactate injection in packages with special features as (i) Self collapsibility and self-seal

ability;(ii) not having air-vent; and (iii) having no chance of contamination during manufacture / infusion / admixing levels.

**10. Agenda item no. 10 - Price fixation as per Pharmaceuticals Purchase Policy (PPP) for products of Pharma Central Public Sector Enterprises (CPSEs) and their subsidiaries.**

Record note of discussion for circulation among the members.

**11. Agenda item no. 11 - Retail price fixation under Para 5, 15 & 11(3) of DPCO, 2013 - Recombinant Rabies G Protein Vaccine for M/s Cadila Pharmaceuticals Ltd. (manufacturer and marketer).**

11.1 The Authority noted that the application of M/s Cadila Pharmaceuticals Ltd under Para 11(3) and Para 5 of DPCO 2013 for Recombinant Rabies G Protein Vaccine was placed before the Multidisciplinary Committee of Experts. The Multidisciplinary Committee of Experts in its 22nd meeting dated 07.10.2020 deliberated upon the matter in detail and observed that the formulation is innovative formulation for which incremental price be allowed under Para 11(3) of DPCO 2013 and accordingly the Committee recommended the retail price of Recombinant Rabies G Protein Vaccine in which each vial of 0.5 ml contains rRabies G Protein 50.00 µg, Disodium Hydrogen Phosphate Anhydrous IP 0.87 mg, Monobasic Sodium Phosphate Monohydrate BP 0.88 mg, Sodium Chloride IP 8.76 mg, and Tergitol NP9 0.1 µl. under Para 11(3) of DPCO, 2013 for M/s Cadila Pharmaceuticals Ltd. (manufacturer and marketer) at Rs. 681.44 per vial excluding GST.

11.2 The Authority deliberated upon the matter in detail and noted that the formulation Recombinant Rabies G Protein Vaccine is an innovative formulation for which M/s Cadila Pharmaceuticals Ltd have applied for separate price fixation under Paras 5, 11(3) and 15 of DPCO 2013. Accordingly, the Authority approved the retail price of Recombinant Rabies G Protein Vaccine under Para 5, 11(3) and 15 of DPCO 2013 at Rs. 681.44 per vial excluding GST for M/s Cadila Pharmaceuticals Ltd. ( manufacturer and marketer) and each vial of 0.5 ml contains::

- a. rRabies G Protein 50.00 µg
- b. Disodium Hydrogen Phosphate Anhydrous IP 0.87 mg
- c. Monobasic Sodium Phosphate Monohydrate BP 0.88 mg
- d. Sodium Chloride IP 8.76 mg
- e. Tergitol NP9 0.1 µl

**12. Agenda item no. 12 - Application for grant of separate price/ special price for “Synchrobreathe inhaler device” under the provision of Para 11(3) or para 32(3) of DPCO 2013.**

12.1 The Authority noted that the application of M/s Cipla Ltd for separate/ special price for “Synchrobreathe Inhaler Device” under Para 11(3) of DPCO 2013 with respect to the formulation Tiotropium Inhalation (MDI) 9mcg/dose 120 MDI was placed before the Multidisciplinary Committee of Experts. The Multidisciplinary Committee of Experts in its 23rd meeting held on 20.10.2020 recommended an additional price of Rs. 67.20 (excluding GST) for “Synchrobreathe inhaler device” on the ceiling price of Tiotropium inhalation (MDI) 9mcg/dose 120 MDI with Synchrobreathe inhaler device.

12.2 The Authority also noted that based on the recommendation of the Multidisciplinary Committee of Experts 14th meeting dated 04.12.2019, the Authority in its 71st meeting dated 09.12.2019 had approved the additional price of Rs. 67.20 (excluding GST) of ‘Synchrobreathe inhaler device’ of M/s Cipla Ltd on the applicable ceiling price of the Inhalation having the formulation (a) Budesonide 200mcg+ Formeterol 6mcg per dose Inhaler 120 MDI and (b) Budesonide 400mcg+ Formeterol 6mcg per dose Inhaler 120 MDI.

12.3 The Authority deliberated upon the matter in detail and observed that since the “Synchrobreathe inhaler device” in respect of which M/s Cipla Ltd has sought separate price for Tiotropium Inhalation (MDI) 9mcg/dose 120 MDI is the same device in respect of which the Authority in its 71st meeting dated 09.12.2019 had earlier approved the separate price of Rs. 67.20 per unit excluding GST. Accordingly, the Authority approved the additional price for ‘Synchrobreathe inhaler device’ of M/s Cipla Ltd at Rs. 67.20 (excluding GST) on the ceiling price of the Inhalation having the formulation Tiotropium Inhalation (MDI) 9mcg/dose 120 MDI, based on the recommendations of the Multidisciplinary Committee of Experts.

12.4 The Authority also noted the decision taken in its 71st meeting dated 09.12.2019 that the additional price of Rs. 67.20 (excluding GST) for “Synchrobreathe inhaler device” would remain fixed irrespective of the change in the ceiling price of the Inhalation and the recommendation made by the Multidisciplinary Committee of Experts in its 23rd meeting dated 20.10.2020 that since “Synchrobreathe inhaler device” is a component of the scheduled formulation Tiotropium inhalation (MDI) 9mcg/dose 120 MDI, Wholesale Price Index (WPI), as applicable for scheduled formulation, be allowed on the additional price of “Synchrobreathe inhaler device” from the next year. The Authority deliberated upon the matter in detail and approved the recommendation of the Multidisciplinary Committee of Experts that Wholesale Price Index (WPI), as applicable for scheduled formulation, be

allowed on the additional price of “Synchrobreathe inhaler device” of M/s Cipla Ltd at Rs. 67.20 (excluding GST) on the ceiling price of the inhalation having the formulation Tiotropium Inhalation (MDI) 9mcg/dose 120 MDI from the next year.

The meeting ended with a vote of thanks to the Chair.

**Sd/-**  
**(Dr. Vinod Kotwal)**  
Member Secretary