

Minutes of the 202nd (overall) and 70th meeting of the Authority under DPCO, 2013 held on 30.10.2019 at 2:30 PM

The 202nd meeting of the Authority (overall), which is the 70th meeting under the DPCO, 2013, was held on the 30th of October, 2019 at 2:30 PM under the Chairmanship of Ms. Shubhra Singh, Chairman, NPPA. The following members of the NPPA were present:

- (i) Ms. Ritu Dhillon, Member Secretary
- (ii) Dr. V. G. Somani, DCGI, Deptt. of Health & Family Welfare
- (iii) Shri B. Bandyopadhyay, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure
- (iv) Ms. A. Srija, Economic Advisor, Deptt of Economic Affairs

Shri A.K.Pradhan, Deputy Drug Controller, Deptt. 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 Kalyan Nag, Advisor
- (ii) Shri Amarपाल Singh Sawhney, Director (Pricing)
- (iii) Shri R. K. Agrawal, Director (M&E, Admin)
- (iv) Shri A. K. Diwan, Dy. Director (M&E)
- (v) Shri Prasenjit Das, Asstt. Director (Pricing)
- (vi) Shri Prakash Hemani, Asstt. Director (Pricing)

Chairman, NPPA welcomed all the members of the Authority and introduced two new members Dr. V. G. Somani, DCGI, Deptt. of Health & Family Welfare and Ms. A. Srija, Advisor, Deptt of Economic Affairs. Chairman, NPPA also placed on record the contribution made by outgoing Authority members Dr. E. Reddy, DCGI, Deptt. of Health & Family Welfare and Shri Arun Kumar, Advisor, Deptt of Economic Affairs

II. Agenda items

1. Agenda item no. 1 - Confirmation of the Minutes of the 69th meeting held on 08.08.2019.

1.1 Noted.

2. Agenda item no. 2 – Action Taken Report on decisions taken by NPPA in its 69th meeting dated 08.08.2019

2.1 Noted.

3. Agenda item no. 3 – Status of New Drug applications

3.1 Noted.

4. Agenda item no. 4 - New Drug application

4.1 The Authority discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 4 (i) to 4(lii) (total 75 Form I applications) falling under the purview of para 2(u) of DPCO, 2013 and approved the retail prices in 75 (seventy five) cases (subject to clarification from CDSCO for four formulations at sl. no. xii, xiii, xxvii and xxxix as per Note: 1) under para 5 and 15 of the DPCO 2013, as detailed below:

A. Retail price fixed under para 5 of DPCO, 2013

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(i)	Acetaminophen (Paracetamol) + Tramadol Hydrochloride Tablets	Each film coated tablet contains: Acetaminophen IP (Paracetamol) 325mg, Tramadol Hydrochloride Tablets IP 37.5mg	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Dr. Reddy's Laboratories Ltd.	4.91
4(ii)	Amoxicillin + Potassium Clavulanate suspension	Each 5ml Reconstituted suspension contains: Amoxicillin Trihydrate IP eq. to Amoxicillin 400mg, Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 57mg	1 ML	M/s Medicef Pharma / M/s Emcure Pharmaceuticals Limited	3.35
4(iii)	Glimepiride + Metformine Tablet (Gluformin G 0.5)	Each film coated tablet contains: Glimepiride IP 0.5mg Metformine Hydrochloride IP 500mg (As prolonged release form)	1 Tablet	M/s Anphar Organics Private Limited / M/s Abbott Healthcare Pvt. Ltd.	3.65
4(iv)	Emtricitabine + Tenofovir Alafenamide Tablet	Each film coated tablet contains: Emtricitabine IP 200mg. Tenofovir Alafenamide Hemifumarate eq. to Tenofovir Alafenamide 10mg	1 Tablet	M/s Hetero Labs Ltd. / M/s Emcure Pharmaceuticals Ltd.	31.17
4(v)	Cefixime + Potassium Clavulanate suspension	Each 5ml of reconstituted suspension contains: Cefixime IP (As Trihydrate) eq. to Anhydrous Cefixime 100mg, Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 62.50mg	1 ML	M/s Brooks Laboratories Ltd. / M/s Intas Pharmaceuticals Limited	3.04
4(vi)	Calcium Carbonate + Vitamin D3+ Mecobalamin + L-	Each film coated Tablet contains: Calcium Carbonate IP 1250mg, eq. to Elemental Calcium 500mg,	1 Tablet	M/s Akums Drugs & Pharmaceuticals	18.58

	Methylfolate + Pyridoxal – 5-Phosphate Tablet	Vitamin D3 IP 2000 IU Mecobalamin IP (Methylcobalamin) 1500mcg L-Methylfolate Calcium 1mg, Pyridoxal – 5-Phosphate 20mg		Ltd. / M/s Torrent Pharmaceuticals Ltd.	
4(vii)	Budesonide Capsule	Each hard gelatine capsule contains: Budesonide (as controlled release pellets) IP 3mg	1 Capsule	M/s Cipla Limited	14.50
4(viii)	Diclofenac Diethylamine + Methyl Salicylate + Menthol + Absolute Alcohol Spray	Spray contains: Diclofenac Diethylamine IP 2.32%w/v eq. to Diclofenac Sodium IP 2.00%w/v, Methyl Salicylate IP 10% w/v, Menthol IP 5%w/v, Absolute Alcohol IP 10%v/v	Per GM for 25gm Pack	M/s Pontika Aerotech Limited / M/s Cipla Limited	3.96
4(ix)	Dolutegravir + Lamivudine + Tenofovir Disoproxil Tablet	Each film coated tablet contains: Dolutegravir Sodium eq. to Dolutegravir 50mg, Lamivudine IP 300mg, Tenofovir Disoproxil Fumarate IP 300mg eq. to Tenofovir Disoproxil 245mg	1 Tablet	M/s Cipla Limited	114.06
4(x)	Telmisartan + Metoprolol Tablet	Each uncoated Bilayered Tablet contains: Telmisartan IP 40mg Metoprolol Succinate IP 23.75 eq. to Metoprolol Tartrate (in Prolonged Release form) 25mg	1 Tablet	M/s Eris Lifesciences Ltd.	9.93
4(xi)	Telmisartan + Metoprolol Tablet	Each uncoated Bilayered Tablet contains: Telmisartan IP 40mg Metoprolol Succinate IP 47.5 eq. to Metoprolol Tartrate (in Prolonged Release form) 50mg	1 Tablet	M/s Eris Lifesciences Ltd.	12.23
4(xii)	Glimepiride + Metformin Tablet	Each un coated bilayered tablet contains: Glimepiride IP 3mg, Metformin Hydrochloride IP 500mg (As Prolonged Release form)	1 Tablet	M/s Micro Labs Limited	7.85
4(xiii)	Glimepiride + Metformin Tablet	Each un coated bilayered tablet contains: Glimepiride IP 4mg, Metformin Hydrochloride IP 500mg (As sustained Release form)	1 Tablet	M/s Micro Labs Limited	9.18
4(xiv)	Metformin Hydrochloride + Gliclazide + Pioglitazone Tablet (Reclimet PG-30)	Each uncoated bilayered tablet contains: Metformin Hydrochloride IP (in sustained release form) 500mg, Gliclazide IP (in sustained release form) 30mg, Pioglitazone HCL IP eq. to Pioglitazone 15mg	1 Tablet	M/s Inventia Healthcare Ltd. / M/s Dr. Reddy's Laboratories Limited	5.98
4(xv)	Metformin Hydrochloride + Gliclazide +	Each uncoated bilayered tablet contains: Metformin Hydrochloride IP (in	1 Tablet	M/s Inventia Healthcare Ltd. / M/s Dr. Reddy's	8.30

	Pioglitazone Tablet (Reclimet PG-60)	sustained release form) 500mg, Gliclazide IP (in sustained release form) 60mg, Pioglitazone HCL IP eq. to Pioglitazone 15mg		Laboratories Limited	
4(xvi)	Diclofenac Diethylamine + Methyl Salicylate + Menthol + Absolute Alcohol Spray	Spray contains: Diclofenac Diethylamine IP 2.32%w/v eq. to Diclofenac Sodium IP 2.00%w/v, Methyl Salicylate IP 10% w/v, Menthol IP 5%w/v, Absolute Alcohol IP 10%v/v	Per GM for 55gm Pack	M/s Pontika Aerotech Limited / M/s Cipla Limited	3.54
4(xvii)	Dextromethorphan Hydrobromide + Chlorpheniramine Maleate Syrup	Each 5ml Contains: Dextromethorphan Hydrobromide IP 5mg, Chlorpheniramine Maleate IP 1mg	1 ML	M/s Tirupati Medicare Ltd. / M/s Intas Pharmaceuticals Limited	1.25
4(xviii)	Dextromethorphan Hydrobromide + Chlorpheniramine Maleate Syrup	Each 5ml Contains: Dextromethorphan Hydrobromide IP 10mg, Chlorpheniramine Maleate IP 2mg	1 ML	M/s Tirupati Medicare Ltd. / M/s Intas Pharmaceuticals Limited	0.59
4(xix)	Gatifloxacin + Prednisolone Eye Drops	Each ml contains: Gatifloxacin 3.0mg, Prednisolone Acetate IP 10.0mg, Benzalkonium Chloride Solution (as preservative) 0.06mg	1 ML	M/s Micro Labs Limited	3.35
4(xx)	Budesonide Nebuliser respule	Each 2ml respule contains: Budesonide IP 0.5mg	Per 2ml Respule	M/s Sun Pharmaceutical Medicare Ltd. / M/s Sun Pharmaceutical Industries Ltd.	17.09
4(xxi)	Clarithromycin for Oral Suspension	Each 5ml of reconstituted suspension contains: Clarithromycin coated eq. to Clarithromycin IP 250mg	1 ML	M/s Medibios Laboratories Limited / M/s Abbott Healthcare Pvt. Ltd.	5.59
4(xxii)	Metformin Hydrochloride + Glimepiride Tablet (O GLIMADAY FORTE 1)	Each film coated tablet contains: Metformin Hydrochloride IP 1000mg (in prolonged release form) Glimepiride IP 1mg	1 Tablet	M/s Wockhardt Limited	6.61
4(xxiii)	Metformin Hydrochloride + Glimepiride Tablet (O GLIMADAY FORTE 2)	Each film coated tablet contains: Metformin Hydrochloride IP 1000mg (in prolonged release form) Glimepiride IP 2mg	1 Tablet	M/s Wockhardt Limited	9.08
4(xxiv)	Pantoprazole Tablet	Each Dual-Release Gastro-Resistant tablet contains: Pantoprazole Sodium IP eq. to Pantoprazole 80mg	1 Tablet	M/s Sun Pharma Laboratories Limited	18.22
4(xxv)	Atorvastatin Calcium + Clopidogrel Capsule (MACTOR CV 10)	Each hard gelatine capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 10mg (As Pellets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As Pellets)	1 Capsule	M/s Synokem Pharmaceuticals Limited / M/s Macleods Pharmaceuticals Limited	11.14

4(xxvi)	Telmisartan + Amlodipine + Hydrochlorothiazide Tablet (Telmiduce AMH)	Each uncoated bi-layered tablet contains: Telmisartan IP 40mg, Amlodipine Besylate IP eq. to Amlodipine 5mg Hydrochlorothiazide IP 12.5mg	1 Tablet	M/s Macleods Pharmaceuticals Limited	8.36
4(xxvii)	Escitalopram + Clonazepam Tablet	Each film coated Tablet contains: Escitalopram Oxalate IP eq. to Escitalopram 10mg, Clonazepam IP 0.25mg	1 Tablet	M/s Eris Lifesciences Limited	8.40
4(xxviii)	Darunavir + Ritonavir Tablet	Each film coated tablet contains: Darunavir Ethanolate eq. to Darunavir 800mg, Ritonavir IP 100mg Tablet	1 Tablet	M/s Hetero Labs Limited / M/s Emcure Pharmaceuticals Ltd.	197.55
4(xxxv)	Vildagliptin + Metformin Tablet	Each Tablet contains: Vildagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Zydus Healthcare Limited	22.82
	Vildagliptin + Metformin Tablet	Each film coated Tablet contains: Vildagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Emcure Pharmaceuticals Ltd.	22.82
	Vildagliptin + Metformin Tablet	Each film coated Tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 500mg	1 Tablet	M/s Micro Labs Limited	17.85
	Vildagliptin + Metformin Tablet	Each uncoated Tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 500mg	1 Tablet	M/s Torrent Pharmaceuticals Ltd.	16.10
	Vildagliptin + Metformin Tablet	Each film coated Tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 500mg,	1 Tablet	M/s Natco Pharma Limited	6.07
	Vildagliptin + Metformin Tablet (GLUVILDA M 500 / VIGLUCOZ M 500)	Each film coated tablet contains: Metformin Hydrochloride IP 500mg Vildagliptin IP 50mg	1 Tablet	M/s Alkem Healthscience / M/s Alkem Laboratories Ltd.	19.54
	Vildagliptin + Metformin Tablet	Each film coated Tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 500mg	1 Tablet	M/s Panacea Biotech Ltd.	8.48
	Vildagliptin + Metformin Tablet (Vildamac M50/500)	Each film coated Tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 500mg	1 Tablet	M/s Macleods Pharmaceuticals Limited	20.00
	Vildagliptin + Metformin Tablet	Each film coated Tablet contains: Vildagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Obsurge Biotech Limited	15.00
4(xxxvi)	Vildagliptin + Metformin Tablet	Each Tablet contains: Vildagliptin 50mg Metformin Hydrochloride IP 850mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Zydus Healthcare Limited	22.68

	Vildagliptin + Metformin Tablet	Each film coated Tablet contains: Vildagliptin 50mg Metformin Hydrochloride IP 850mg	1 Tablet	M/s Emcure Pharmaceuticals Ltd.	22.68
	Vildagliptin + Metformin Tablet	Each uncoated Tablet contains: Vildagliptin 50mg Metformin Hydrochloride IP 850mg	1 Tablet	M/s Torrent Pharmaceuticals Ltd.	16.10
	Vildagliptin + Metformin Tablet	Each film coated Tablet contains: Vildagliptin 50mg Metformin Hydrochloride IP 850mg	1 Tablet	M/s Panacea Biotec Ltd.	8.61
	Vildagliptin + Metformin Tablet (Vildamac M50/850)	Each film coated Tablet contains: Vildagliptin 50mg Metformin Hydrochloride IP 850mg	1 Tablet	M/s Macleods Pharmaceuticals Limited	20.60
	Vildagliptin + Metformin Tablet	Each film coated Tablet contains: Vildagliptin 50mg Metformin Hydrochloride IP 850mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Obsurge Biotech Limited	18.00
4(xxxvii)	Vildagliptin + Metformin Tablet	Each Tablet contains: Vildagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Zydus Healthcare Limited	22.94
	Vildagliptin + Metformin Tablet	Each film coated Tablet contains: Vildagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Emcure Pharmaceuticals Ltd.	23.37
	Vildagliptin + Metformin Tablet	Each film coated Tablet contains: Vildagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Micro Labs Limited	18.92
	Vildagliptin + Metformin Tablet	Each uncoated Tablet contains: Vildagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Torrent Pharmaceuticals Ltd.	16.10
	Vildagliptin + Metformin Tablet	Each film coated Tablet contains: Vildagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Natco Pharma Limited	6.16
	Vildagliptin + Metformin Tablet (GLUVILDA M 1000 / VIGLUCOZ M 1000)	Each film coated Tablet contains: Vildagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Alkem Healthscience / M/s Alkem Laboratories Ltd.	20.83
	Vildagliptin + Metformin Tablet	Each film coated Tablet contains: Vildagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Panacea Biotec Ltd.	8.70
	Vildagliptin + Metformin Tablet (Vildamac M50/1000)	Each film coated Tablet contains: Vildagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Macleods Pharmaceuticals Limited	21.33
4(xxxviii)	Cilnidipine + Metoprolol Succinate Tablet	Each film coated bilayerd Tablet contains: Cilnidipine IP 10mg,	1 Tablet	M/s Micro Labs Limited	8.89

		Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate 50mg (As Extended Release)			
4(xxxix)	Cilnidipine + Metoprolol Succinate Tablet	Each film coated bilayerd Tablet contains: Cilnidipine IP 10mg, Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate 25mg (As Extended Release)	1 Tablet	M/s Micro Labs Limited	7.10
4(xl)	Rosuvastatin + Clopidogrel Capsule	Each Hard gelatine capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg (As pellets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As Pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Cipla Limited	13.75
4(xli)	Rosuvastatin + Clopidogrel Capsule	Each Hard gelatine capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (As pellets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As Pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Cipla Limited	18.04
4(xlii)	Linezolid Suspension	Each 5ml of reconstituted suspension contains: Linezolid IP 100mg	1 ML	M/s Innova Captab Ltd. / M/s Brinton Pharmaceuticals Limited	3.04
4(xliii)	Fluconazole Tablet	Each uncoated tablet contains: Fluconazole IP 300mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd.	16.16
4(xlv)	Atorvastatin + Aspirin + Clopidogrel Capsule	Each hard gelatine capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 20mg (As two white coloured film coated tablets, each containing 10mg Atorvastatin Tablets IP), Aspirin IP 75mg (As enteric coated white coloured pellets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As two brown coloured film coated tablets, Each containing 37.5mg Clopidogrel tablet IP)	1 Capsule	M/s Windlas Biotech Pvt. Ltd. / M/s Mankind Pharma Limited	5.27
4(xlvi)	Atorvastatin + Aspirin + Clopidogrel Capsule	Each hard gelatine capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 10mg (As Pellets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As Pellets) Aspirin IP 75mg (As enteric coated pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Emcure Pharmaceuticals Limited	3.80
4(xlvii)	Atorvastatin + Aspirin + Clopidogrel Capsule	Each hard gelatine capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 20mg (As Pellets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As Pellets) Aspirin IP 75mg (As enteric	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Emcure Pharmaceuticals Limited	5.27

		coated pellets)			
4(xlviii)	Atorvastatin + Aspirin + Clopidogrel Capsule	Each hard gelatine capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 10mg (As Pellets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As Pellets) Aspirin IP 75mg (As enteric coated pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Cipla Limited	3.80
4(xlix)	Atorvastatin + Aspirin + Clopidogrel Capsule	Each hard gelatine capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 20mg (As Pellets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As Pellets) Aspirin IP 75mg (As enteric coated pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Cipla Limited	5.27
4(l)	Vildagliptin + Metformin Tablet	Each film coated Tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 500mg,	1 Tablet	M/s Mediforce Healthcare Pvt. Ltd. / M/s Mankind Pharma Limited	22.77
	Vildagliptin + Metformin Tablet (Vidalog M 500)	Each film coated Tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 500mg,	1 Tablet	M/s Exemed Pharmaceuticals / M/s Wockhardt Limited	12.26
4(li)	Vildagliptin + Metformin Tablet	Each film coated Tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 850mg,	1 Tablet	M/s Mediforce Healthcare Pvt. Ltd. / M/s Mankind Pharma Limited	22.75
	Vildagliptin + Metformin Tablet (Vidalog M 850)	Each film coated Tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 850mg,	1 Tablet	M/s Exemed Pharmaceuticals / M/s Wockhardt Limited	12.26
4(lii)	Vildagliptin + Metformin Tablet	Each film coated Tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 1000mg,	1 Tablet	M/s Mediforce Healthcare Pvt. Ltd. / M/s Mankind Pharma Limited	23.40
	Vildagliptin + Metformin Tablet (Vidalog M 1000)	Each film coated Tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 1000mg,	1 Tablet	M/s Exemed Pharmaceuticals / M/s Wockhardt Limited	12.53

B. Retail price fixed under para 15 of DPCO, 2013

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(xxix)	Amoxicillin + Docloxacillin Capsule (Almox C LB)	Each hard gelatine capsule contains: Amoxicillin Trihydrate IP eq. to Amoxicillin 250mg Dicloxacillin Sodium IP eq. to Dicloxacillin 250mg	1 Capsule	M/s Theon Pharmaceuticals Ltd. / M/s Alkem Laboratories Limited	7.64

		Lactic Acid Bacillus 2.5 billion spores			
4(xxx)	Atorvastatin + Aspirin + Clopidogrel Capsule	Each hard gelatine capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 40mg (As coloured pellets), Aspirin IP 75mg (As enteric coated white coloured pellets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As two brown coloured film coated, each containing 37.5mg Clopidogrel tablet IP)	1 Capsule	M/s Windlas Biotech Private Limited / M/s Intas Pharmaceuticals Limited	12.78
4(xxxi)	Glycopyrronium + Formoterol Dry powder for inhalation (Capsule)	Each capsule contains: Glycopyrronium (as Glycopyrrolate USP) 25mcg, Formoterol Fumarate (As Formoterol Fumarate Dihydrate) 12mcg	1 Capsule	M/s Cipla Limited	10.96
4(xxxii)	Levetiracetam in 0.82% Sodium Chloride Injection	Each 100ml infusion contains: Levetiracetam IP 500mg	Each Pack	M/s Intas Pharmaceuticals Limited	98.98
4(xxxiii)	Levetiracetam in 0.75% Sodium Chloride Injection	Each 100ml infusion contains: Levetiracetam IP 1000mg	Each Pack	M/s Intas Pharmaceuticals Limited	160.68
4(xxxiv)	Levetiracetam in 0.54% Sodium Chloride Injection	Each 100ml infusion contains: Levetiracetam IP 1500mg	Each Pack	M/s Intas Pharmaceuticals Limited	222.39
4(xliv)	Paracetamol + Phenylephrine Sachet	Each 6gm Sachet contains: Paracetamol IP 500mg, Phenylephrine Hydrochloride IP 10mg	1 Sachet	M/s Maneesh Pharmaceuticals Ltd.	1.89

Explanatory Notes:

Note 1 : Approval and notification of the retail price of the four formulations at sl. no. xii, xiii, xxvii and xxxix would be subject to clarification to be received from CDSCO w.r.t approval status of the subject formulations.

Note 2 : The retail prices of Agenda item no. 4 (xliii, xlv, xlvi, xlvii, xlviii, xlix, l, li, lii) are to be notified after 10 days of uploading the draft working sheet.

5. Agenda item no. 5 – Status of implementation of Review Cases

5.1 It was noted that only 2 review cases were pending with NPPA and both were listed on the agenda separately.

6. Agenda item no. 6 - Review application against retail price fixation of (a) Emtricitabine IP 200 mg + Tenofovir Alafenamide Hemifumarate eq to Tenofovir

Alafenamide 25 mg tablet (b) Tenofovir Alafenamide Hemifumarate eq to Tenofovir Alafenamide 25 mg tablet and (c) Emtricitabine IP 200 mg + Tenofovir Alafenamide Hemifumarate eq to Tenofovir Alafenamide 10 mg tablet for M/s Cipla Ltd vide S.O. 1489(E) dated 29.03.2019.

6.1 The Authority deliberated upon the matter and revised the retail prices of the new drugs of M/s Cipla Ltd by giving WPI increase for implementation of review order no. 31015/10/2019-Pricing dated 30.08.2019, as follows:

a) Emtricitabine IP 200 mg + Tenofovir Alafenamide Hemifumarate eq to Tenofovir Alafenamide 25 mg tablet at Rs. 57.69 per tablet excluding GST

b) Tenofovir Alafenamide Hemifumarate eq to Tenofovir Alafenamide 25 mg tablet at Rs. 46.18 per tablet excluding GST

c) Emtricitabine IP 200 mg + Tenofovir Alafenamide Hemifumarate eq to Tenofovir Alafenamide 10 mg tablet at Rs. 32.49 per tablet excluding GST.

6.2 The Authority also deliberated on the representations received from various companies namely, M/s Cadila Healthcare Ltd, M/s Mylan Pharmaceuticals Pvt. Ltd, M/s Emcure Pharmaceuticals Ltd and M/s Sun Pharma Laboratories Ltd with a request for revision of retail price of Emtricitabine IP 200 mg + Tenofovir Alafenamide Hemifumarate eq to Tenofovir Alafenamide 25 mg tablet, Tenofovir Alafenamide Hemifumarate eq to Tenofovir Alafenamide 25 mg tablet and Emtricitabine IP 200 mg + Tenofovir Alafenamide Hemifumarate eq to Tenofovir Alafenamide 10 mg tablet based on Wholesale Price Index (WPI) in line with the review orders no. 31015/10/2019-Pricing of M/s Cipla Ltd dated 30.08.2019 and decided to extend the retail prices of the three formulations as mentioned in (a), (b), (c) to all manufacturers/ marketers to whom the same retail price, as that of the retail price of M/s Cipla Ltd, had been given earlier.

7. Agenda item no. 7 - Fixation of Ceiling Price for Povidone Iodine Ointment 10%.

7.1 The Authority deliberated upon the matter in detail and approved the ceiling price of Povidone Iodine Ointment 10% at Rs. 5.09 per gm excluding GST.

8. Agenda item no. 8 - Ceiling Price notified by the NPPA for Oxygen Gas is being supplied to the various Hospitals through composite contract

8.1 The Authority deliberated upon the issue in detail and observed that this is a case of violation of the provisions of DPCO. The Authority also noted that the Multidisciplinary

Committee of Experts in its 11th meeting held on 24.06.2019 opined that there is no need to revisit the ceiling price of oxygen since DPCO 2013 follows a policy of market based pricing. The Authority also noted that the matter is sub-judice at Hon'ble High Court of Himachal Pradesh, Shimla. Accordingly, the Authority decided that the case be pursued as per the provisions of DPCO.

9. Agenda item no. 9 – Fixation of Ceiling Price of Calcium Carbonate 500mg Tablets under para 19 of DPCO, 2013 based on Institutional Data received from Hospitals

9.1 The Authority deliberated upon the matter in detail in the context of DoP's directions vide letter dated 05.02.2019 regarding fixation of ceiling price on the basis of institutional data where no market data was available. The Authority also noted that even after making lot of efforts for collection of data from the various Central/State Government agencies, State Government Hospitals and Private Hospitals, NPPA was able to collect requisite data for only one formulation.

Accordingly, the Authority directed to refer the matter to DoP with its observations, for further clarification.

10.1 Agenda item no. 10 (i) – Submission of Form IV application by M/s Sanofi Synthelabo (India) Pvt. Ltd. for discontinuation of scheduled formulation Adenocor 6mg/2ml (Pack of 6 vials of 2ml each) under para 21 (2) of DPCO, 2013

10.1.I Authority was informed about communication of DoP dated 14.03.2019, emphasizing that the guidelines for dealing with cases of discontinuation of scheduled formulations should be as per the requirements of DPCO 2013. The Authority took note of the communication and it was decided to make suitable changes in the guidelines.

Authority considered the request of M/s Sanofi Synthelabo (India) Pvt. and noted that it is the largest player with 43.62% market share. As sudden discontinuation of this formulation could lead to shortages, it was decided to direct the Company to issue a public notice and continue production/import/sale for a period of 12 months beyond intended date of discontinuation or date of public notice whichever is later.

10.2 Agenda item no. 10(ii) - Submission of Form-IV application by M/s Abbott Healthcare Pvt. Ltd in respect 2 scheduled formulations (i) Hansepran 50 mg (Clofazimine Capsule IP 50mg) and (ii) Hansepran 100 mg (Clofazimine Capsule IP 100mg) under para 21(2) of DPCO, 2013.

10.2.1 Authority considered the request of M/s Abbott Healthcare Pvt. Ltd and noted that Company has near monopoly (around 98% market share) for these critical medicines for leprosy and a sudden discontinuation could lead to shortages. It was therefore, decided to direct the Company to issue a public notice and continue production/import/sale for a period of 12 months beyond intended date of discontinuation or date of public notice whichever is later. Authority also directed to simultaneously request DoP to invoke Para 3 of DPCO 2013 and in case Company applies for upward price revision under Para 19 of DPCO 2013 the same shall be considered as per modalities to be decided by SCAMHP for cases already under their consideration.

10.3 Agenda item no. 10(iii) - Submission of Form-IV applications by M/s Mankind Pharma Limited & M/s Lifestar Pharma Private Limited (A Mankind Group Company) for discontinuation 2 scheduled formulations (i) Mefkind-P Suspension (Mefenamic Acid 100mg per 5ml) and (ii) Clindatime-300 Capsules (Clindamycin 300mg) under para 21 (2) of DPCO, 2013.

10.3.1 Authority considered the request of M/s Mankind Pharma Limited & M/s Lifestar Pharma Private Limited and in view of less than 10% market share of the Company it was decided to direct the Company to issue a public notice and continue production/import/sale for a period of 6 months beyond intended date of discontinuation or date public notice whichever is later.

10.4 Agenda item no. 10(iv) - Submission of Form IV application by M/s Bayer Zydus Pharma for discontinuation of scheduled formulation Resochin (Chloroquine Phosphate Tablet IP 250mg Tablet) under para 21 (2) of DPCO, 2013.

10.4.1 Authority considered the request of M/s Bayer Zydus Pharma and noted that the Company has about a 12% market share for this critical medicine for Malaria whose major producer M/s. IPCA Laboratories Ltd has also applied for discontinuation. Accordingly, Authority decided to direct the Company to issue a public notice and continue

production/import/sale for a period of 12 months beyond intended date of discontinuation or date public notice whichever is later.

11. Agenda item No. 11 - Intimation of Minutes of 13th meeting of Multidisciplinary Committee of Experts held on 24.09.2019

11.1 Noted.

12. Agenda item No. 12 - Review application against ceiling price fixation of Tiotropium Inhalation (MDI) 9 mcg/dose vide S.O. 1028(E) dated 26.02.2019 filed by M/s Zydus Healthcare Ltd.

12.1 The Authority deliberated upon the matter in detail and approved the revised ceiling price of Tiotropium Inhalation (MDI) 9mcg/dose at Rs. 2.36 per metered dose excluding GST towards implementation of review order no. 31015/07/2019-Pricing dated 21.06.2019.

13. Agenda item No. 13 - Anti Tetanus Vaccine - Filing of LPA against part of judgment dated 19.02.2019 of Hon'ble Delhi High Court in WP 3126/2015.

13.1 The Authority deliberated the matter in detail and decided that an LPA may be filed against some aspects of judgement dated 19.02.2019 of Hon'ble Delhi High Court.

14. Agenda item No. 14 - Submission of Form-IV application by M/s. Neon Laboratories Ltd. for discontinuation of 18 scheduled formulations under para 21 (2) of DPCO, 2013.

14.1 Authority considered the request of M/s. Neon Laboratories Ltd and noted that Company has assured to continue the same formulations in different pack form/sizes. Therefore, it was decided to direct the Company to issue a public notice and continue production/import/sale for a period of 6 months beyond intended date of discontinuation or public notice whichever is later.

15. Agenda item No. 15 - Application of M/s s Meril Life Sciences Pvt. Ltd. for Exemption under para 32(ii) of DPCO, 2013 for their product Sirolimus Eluting BioResorbable vascular scaffold system (MeRes100)

15.1 The Authority deliberated upon the matter in detail and noted that AIDAN has raised health and safety concerns regarding the usage of MeRes100 stents. The Authority also noted that the matter had been referred to DCGI, DG-ICMR and MoH&FW vide letter dated 21.10.2019 to examine these concerns and that their replies were still awaited. Therefore, the agenda was deferred.

16. Agenda item No. 16 - Application of M/s Sun Pharmaceutical Industries Ltd for Exemption under para 32 of DPCO, 2013 for their product Gemcitabine hydrochloride injection 10mg/ml (Ready to use infusion bags 1200mg/120ml, 1400mg/140ml and 1600mg/160ml)

16.1 The Authority deliberated upon the matter in detail and noted that the application has been received under para 32 (ii) of DPCO 2013. The imperatives of para 32(ii) of DPCO 2013 are:

- a) The drug should be a new drug as per the definition given in rule 122E of the Drugs and Cosmetic Rules, 1945
- b) The drug is produced by a new process
- c) developed through indigenous Research and Development, and
- d) patented under the Indian Patent Act, 1970 (process patent).

16.2 The Authority noted that the matter was referred to the Multidisciplinary Committee of Experts which in its 7th meeting dated 07.02.2019 stated that the submission of the documents by M/s Sun Pharmaceutical Industries Ltd meets the requirements of para 32 (ii) of DPCO, 2013.

16.3 Thereafter, it was noted that the Authority in its 63rd meeting held on 21.02.2019 had referred the applications to Standing National Committee on Medicines for revision of NLEM (SNCM) with a request to examine the products from the perspective of any significant therapeutic advantage and increased efficacy that may merit exemption under para 32 of DPCO 2013.

16.4 SNCM stated that there is no clinical study to suggest that Gemcitabine hydrochloride injection 10mg/ml (ready to use infusion bags 1200mg/120ml, 1400mg/140ml and 1600mg/160 ml) offers significant therapeutic advantage and increases efficacy. The availability of gemcitabine in infusion bags is only helpful in the practical sense of administration to patients.

16.5 The Authority discussed and noted that establishing significant therapeutic advantage and increased efficacy is not a requirement or pre-condition for obtaining exemption under para 32(ii) of DPCO, 2013 and further as the company fulfills the conditions as per para 32(ii) of DPCO2013, the Authority decided that exemption may be granted to M/s Sun Pharmaceutical Industries Ltd under para 32(ii) of DPCO, 2013 for their product Ready to use infusion bags Gemcitabine hydrochloride injection 10mg/ml (Ready to use infusion bags 1200mg/120ml, 1400mg/140ml and 1600mg/160ml).

17. Agenda item No. 17 - Clearance of pendency of overcharging cases under DPCO 2013 and DPCO 1995

17.1 Noted and approved the Action Plan of NPPA to address the pending cases of overcharging under DPCO 2013 and DPCO 1995.

17.2 The Authority noted that in cases of overcharging, where a significant reduction in amount demanded accrued on account of CA certified data produced by the company (ies), the DoP would be requested to depute an officer for a pre-check on randomized sampling basis before finalization of these cases.

18. Agenda item No. 18 - Amendment in the Guidelines for Overcharging Cases dated 07.10.2016.

18.1 The Authority deliberated upon the matter in detail and reiterated that CA audited data would be the final determinant of the extent of overcharging by manufacturer as against Pharmatrac data. Guidelines be suitably amended, if needed.

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

Sd/-
(Ritu Dhillon)
Member Secretary