

मिसिलस.- 8(99)/2022/डी.पी/एनपीपीए-डीवी-II  
F. No. 8(99)/2022/DP/NPPA-Div. II

कार्यवाहीस. : 231/99/2022/F  
Proceeding No: 231/99/2022/F

**Minutes of the 231<sup>st</sup>(overall) and 99<sup>th</sup>meeting of the Authority under DPCO, 2013 held on 28.06.2022 at 3:30 PM**

The 231<sup>st</sup>meeting of the Authority (overall), which is the 99<sup>th</sup> meeting under the DPCO, 2013, was held on 28<sup>th</sup> of June 2022 at 3:30 PM under the Chairmanship of Shri Kamlesh Kumar Pant, Chairman, NPPA. Following Authority members of NPPA were present during the meeting:

- (i) Dr. Vinod Kotwal, Member Secretary, NPPA
- (ii) Shri Amardeep Singh Chowdhary, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure
- (iii) Ms. Manisha Sensarma, Advisor, Department of Economic Affairs

Shri A. K. Pradhan, Jt. 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 Manmohan Sachdeva, Advisor (Cost-I)
- (ii) Shri Sanjay Kumar, Advisor (Cost-II)
- (iii) Ms. Rashmi Tahiliani, Jt. Director (Pricing)
- (iv) Shri R. Jegan, Jt Director (Overcharging)
- (v) Shri Prasenjit Das, Deputy Director (Pricing)
- (vi) Shri Mahaveer Saini, Deputy Director (Pricing)
- (vii) Shri Rajesh Kumar T., Deputy Director (Medical Device, Legal & IT)
- (viii) Ms. Yuvika Panwar, Asstt. Director ( Overcharging)

**II. Agenda items**

**1. Agenda item no. 1 - Confirmation of the Minutes of the 98th Meeting held on 24.05.2022**

1.1 The Authority confirmed the minutes without any change.

**2. Agenda item no. 2 - (a) Action Taken Report (ATR) on decisions taken by NPPA in its 97th Meeting held on 06.05.2022 and (b) Action Taken Report (ATR) on decisions taken by NPPA in its 98th Meeting held on 24.05.2022**

2.1 The Authority noted that due action has been taken.

**3. Agenda item no. 3 - Status of New Drug applications**

3.1 Noted.

**4. Agenda item no. 4 – New Drug applications for 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(xlviii)(e)(total 85 Form I applications containing retail price fixation of 85 new drugs) falling under the purview of Para 2(u) of DPCO, 2013 and approved the retail prices of 85(eighty five new drugs under Para 5 and 15 of the DPCO 2013, as detailed below:

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
1.	Voglibose and (SR) Metformin Hydrochloride Tablet	<b>Each uncoated bilayered tablet contains:</b> Voglibose IP 0.3mg Metformin Hydrochloride IP 500mg (As Sustained Release Form)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s German Remedies Pharmaceuticals Private Limited	10.47
2.	Olmesartan Medoxomil, Amlodipine & Hydrochlorothiazide Tablet	<b>Each film coated tablet contains:</b> Olmesartan Medoxomil 20mg Amlodipine Besilate IP eq. to Amlodipine 5mg Hydrochlorothiazide IP 12.50 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s German Remedies Pharmaceuticals Private Limited	12.91
3.	Hydroxychloroquine Sulphate Tablet	<b>Each film coated tablet contains:</b> Hydroxychloroquine Sulphate IP 300 mg	1 Tablet	M/s Hetero Healthcare Ltd.	11.74
4.	Linezolid for Oral Suspension (combipack with Steril Water)	<b>Each Combi pack Contains:</b> (A) Linezolid for oral Suspension Each 5 ml of Constituted Suspension Contains : Linezolid IP 100 mg (B) 1 vial of Sterile water for Injection IP Each Vial Contains : Sterile water for Injection IP 30 ml	Per Combi pack	M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Eris Healthcare Pvt. limited	102.00 <b>(Note 1)</b>
5.	Paracetamol and Caffeine Tablets	<b>Each uncoated tablet contains:</b> Paracetamol IP 650mg Caffeine Anhydrous IP 50mg	1 Tablet	M/s Rivpra Formulation Pvt. Ltd. / M/s Dabur India Ltd.	2.88
6.	Paracetamol & Ibuprofen Suspension	<b>Each 5ml contains:</b> Paracetamol IP 162.50mg Ibuprofen IP 100mg	1 ML	M/s Bioconic Remedies. / M/s Dales Laboratories Pvt. Ltd.	0.33 <b>(Note 2)</b>
7.	Metformin Hydrochloride	<b>Each uncoated bilayered tablet contains:</b>	1 Tablet	M/s Swiss Garnier Genexiaa Sciences	11.43

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	(SR), Glimepiride and Voglibose Tablets	Metformin Hydrochloride IP 1000mg (in Sustained Release form), Glimepiride IP 1mg Voglibose IP 0.2mg Tablets		/ M/s Sun Pharmaceutical Industries Limited	
8.	Metformin Hydrochloride (SR), Glimepiride and Voglibose Tablets	<b>Each uncoated bilayered tablet contains:</b> Metformin Hydrochloride IP 1000mg (in Sustained Release form), Glimepiride IP 2mg Voglibose IP 0.2mg Tablets	1 Tablet	M/s Swiss Garnier Genexiaa Sciences / M/s Sun Pharmaceutical Industries Limited	13.30
9.	Metformin Hydrochloride (SR), Glimepiride and Voglibose Tablets	<b>Each uncoated bilayered tablet contains:</b> Metformin Hydrochloride IP 1000mg (in Sustained Release form), Glimepiride IP 1mg Voglibose IP 0.2mg Tablets	1 Tablet	M/s Swiss Garnier Genexiaa Sciences / M/s Sun Pharma Laboratories Limited	11.43
10.	Metformin Hydrochloride (SR), Glimepiride and Voglibose Tablets	<b>Each uncoated bilayered tablet contains:</b> Metformin Hydrochloride IP 1000mg (in Sustained Release form), Glimepiride IP 2mg Voglibose IP 0.2mg Tablets	1 Tablet	M/s Swiss Garnier Genexiaa Sciences / M/s Sun Pharma Laboratories Limited	13.30
11.	Sucralfate &Oxetacaine Oral Suspension	<b>Each 10ml contains:</b> Sucralfate IP 1gm Oxetacaine BP 20mg	1 ML	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s German Remedies Pharmaceuticals Private Limited	1.76
12.	Rosuvastatin, Aspirin & Clopidogrel Capsule	<b>Each Hard Gelatin Capsule contains:</b> Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg (as film coated tablet) Aspirin IP 75mg (as Gastro- resistant tablet) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (as film coated tablet)	1 Capsule	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s German Remedies Pharmaceuticals Private Limited	13.91
13.	Rosuvastatin, Aspirin & Clopidogrel Capsule	<b>Each Hard Gelatin Capsule contains:</b> Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (as film coated tablet) Aspirin IP 75mg (as Gastro- resistant tablet) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (as film coated tablet)	1 Capsule	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s German Remedies Pharmaceuticals Private Limited	20.27

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
14.	Glimepiride, Pioglitazone Hydrochloride & Metformin Hydrochloride (SR) Tablet	<b>Each uncoated bilayered tablet contains:</b> Glimepiride IP 1 mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg Metformin Hydrochloride IP 500 mg (In Sustained Release Form)	1 Tablet	M/s Akum Drugs & Pharmaceuticals Limited/M/s German Remedies Pharmaceuticals Pvt. Ltd.	8.03
15.	Glimepiride, Pioglitazone Hydrochloride & Metformin Hydrochloride (SR) Tablet	<b>Each uncoated bilayered tablet contains:</b> Glimepiride IP 2 mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg Metformin Hydrochloride IP 500 mg (In Sustained Release Form)	1 Tablet	M/s Akum Drugs & Pharmaceuticals Limited/M/s German Remedies Pharmaceuticals Pvt. Ltd.	11.10
16.	Amoxicillin & Potassium Clavulanate Tablets IP	<b>Each film coated tablet contains:</b> Amoxicillin Trihydrate eq. to Amoxicillin IP 875mg Potassium Clavulanate Diluted eq. to Clavulanic Acid IP 125mg	1 Tablet	M/s Medicef Pharma /M/s Themis Medicare Limited	34.03
17.	Amoxicillin & Potassium Clavulanate Oral Suspension	<b>Each 5ml of reconstituted suspension contains:</b> Amoxicillin Trihydrate eq. to Amoxicillin IP 400mg Potassium Clavulanate Diluted eq. to Clavulanic Acid IP 57mg Steril water for injection 30ml	1 ML	M/s Medicef Pharma M/s Themis Medicare Limited	3.90
18.	Paracetamol & Thiocolchico side Tablet	<b>Each uncoated tablet contains:</b> Paracetamol IP 500 mg Thiocolchicoside IP 8 mg	1 Tablet	M/s Micro Labs Limited	27.90
19.	Ferrous Ascorbate and Folic Acid Oral Drops	<b>Each ml contains:</b> Ferrous Ascorbate IP eq. to Elemental Iron 10mg Folic Acid IP 100mcg	1 ML	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s German Remedies Pharmaceuticals Private Limited	5.06
20.	Ferrous Ascorbate and Folic Acid Suspension IP	<b>Each 5 ml contains:</b> Ferrous Ascorbate IP eq. to Elemental Iron 30mg Folic Acid IP 500mcg	1 ML	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s German Remedies Pharmaceuticals Private Limited	0.87
21.	Amlodipine and Telmisartan	<b>Each uncoated bilayered tablet contains:</b> Amlodipine Besilate IP eq. to	1 Tablet	M/s Akums Drugs & Pharmaceuticals Pvt. Ltd. / M/s	17.33

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	tablets	Amlodipine 5mg Telmisartan IP 80mg		German Remedies Pharmaceuticals Private Limited	
22.	Amlodipine and Telmisartan tablets	<b>Each uncoated bilayered tablet contains:</b> Amlodipine Besilate IP eq. to Amlodipine 5mg Telmisartan IP 40mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Pvt. Ltd. / M/s German Remedies Pharmaceuticals Private Limited	9.76
23.	Clopidogrel & Aspirin Tablets	<b>Each uncoated bilayered tablet contains:</b> Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg Aspirin IP 150mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd.	4.34 <b>(Note 3)</b>
24.	Aceclofenac, Paracetamol & Trypsin Chymotrypsin Tablets	<b>Each enteric coated tablet contains:</b> Proteolytic enzymes Trypsin & Chymotrypsin In the ratio of Approximately 6:1 and provides enzymatic activity eq. to 150000 Armour Units Aceclofenac IP 100mg Paracetamol IP 325mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Ipca Laboratories Limited	13.85
25.	Ferrous Ascorbate, Folic Acid & Zinc Tablets	<b>Each film coated tablet contains:</b> Ferrous Ascorbate IP eq. to Elemental Iron 100mg Folic Acid IP 1.5mg Zinc Sulphate Monohydrate IP eq. to Elemental Zinc 22.5mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s German Remedies Pharmaceuticals Private Limited	9.65
26.	Calcium Carbonate, Calcitriol & Zinc Capsules	<b>Each soft Gelatin Capsule contains:</b> Calcium Carbonate IP 500mg eq. to Elemental Calcium 200mg Calcitriol IP 0.25mcg Zinc Sulphate Monohydrate IP eq. to Elemental Zinc 7.5mg	1 Capsule	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s German Remedies Pharmaceuticals Private Limited	14.07
27.	Cilnidipine & Telmisartan Tablets	<b>Each film coated tablet contains</b> Cilnidipine IP 10 mg Telmisartan IP 40 mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Troikaa Pharmaceuticals Limited	9.92
28.	Cilnidipine, Telmisartan & Metoprolol (ER) Tablets	<b>Each film coated bilayered tablet contains</b> Telmisartan IP 40 mg Cilnidipine IP 10 mg Metoprolol Succinate IP 23.75mg eq. to Metoprolol	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Troikaa Pharmaceuticals Limited	10.24

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Tartrate 25mg (as extended release)			
29.	Cilnidipine, Telmisartan & Metoprolol (ER) Tablets	<b>Each film coated bilayered tablet contains</b> Telmisartan IP 40 mg Cilnidipine IP 10 mg Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate 50mg (as extended release)	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Troikaa Pharmaceuticals Limited	12.77
30.	Clopidogrel & Aspirin Tablets	<b>Each film coated tablet contains:</b> Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg Aspirin IP 150mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd.	4.34 <b>(Note 3)</b>
31.	Ceftriaxone & Tazobactam for Injection	<b>Each vial contains:</b> Sterile Ceftriaxone Sodium IP eq. to Ceftriaxone 1000mg Sterile Tazobactam Sodium IP eq. to Tazobactam 125mg	Per Vial	M/s Theon Pharmaceuticals Ltd. / M/s Cadila Pharmaceuticals Ltd.	168.43
32.	Ceftriaxone & Tazobactam Injection	<b>Each vial contains:</b> Ceftriaxone Sodium IP (Sterile) eq. to anhydrous Ceftriaxone 1000mg Tazobactam Sodium IP (Sterile) eq. to Anhydrous Tazobactam 125mg	Per Vial	M/s Skymap Healthcare Pvt. Ltd.	168.43
33.	Diclofenac Injection IP	<b>Each ml contains:</b> Diclofenac Sodium IP 75mg water for Injection	1 ML	M/s Nichepharm Lifesciences Pvt. Ltd. / M/s Cipla Ltd.	20.72
34.	Atorvastatin and Fenofibrate Tablets	<b>Each film coated tablet contains:</b> Atorvastatin Calcium IP eq. to Atorvastatin 10mg Fenofibrate IP (Micronized) 160mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Cipla Ltd.	13.87
35.	Budesonide & Formoterol Fumarate Respirator Suspension	<b>Each 2ml contains:</b> Budesonide IP 0.5mg Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumaret 20mcg	1 ML	M/s Aishwarya Healthcare / M/s Torrent Pharmaceuticals Ltd.	22.75
36.	Ceftriaxone & Sulbactam water for injection	<b>Each vial contains :</b> Sterile Ceftriaxone Sodium IP eq. to Ceftriaxone 1000mg, Sterile Sulbactam Sodium IP eq. to Sulbactam 500mg Each ampoule contains: Sterile water for injection IP 10ml	Per Pack	M/s Inject Care Parenterals Pvt. Ltd. / Torrent Pharmaceuticals Ltd.	143.52

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
37.	Ceftriaxone & Tazobactam for Injection 1125mg	<b>Each Combipack Contains:</b> Part-I Each vial contains : Ceftriaxone Sodium IP (Sterile) eq. to Ceftriaxone 1gm, Tazobactam Sodium Sterile eq. to Tazobactam (Sterile) 125mg Part-II (For Reconstitution) Each FFS Ampoule contains: Sterile Water for Injection IP 10ml	Per Pack	M/s Nitin Lifesciences Limited / M/s Softdeal Pharmaceutical Private Limited	168.43
38.	Metformin Hydrochloride (SR), Glimepiride and Voglibose Tablets	<b>Each uncoated bilayered tablet contains:</b> Metformin Hydrochloride IP 1000mg (In Sustained Release form) Glimepiride IP 1mg Voglibose IP 0.2mg	1 Tablet	M/s Swiss Garnier Genexiaa Sciences Pvt. Ltd. / M/s Abbott Healthcare Pvt. Ltd.	11.43
39.	Metformin Hydrochloride (SR), Glimepiride and Voglibose Tablets	<b>Each uncoated bilayered tablet contains:</b> Metformin Hydrochloride IP 1000mg (In Sustained Release form) Glimepiride IP 2mg Voglibose IP 0.2mg	1 Tablet	M/s Swiss Garnier Genexiaa Sciences Pvt. Ltd. / M/s Abbott Healthcare Pvt. Ltd.	13.85
40.	Rabeprazole Sodium (gastro-resistant) & Domperidone (SR) Capsules	<b>Each hard gelatin capsule contains:</b> Rabeprazole Sodium IP 40mg (as reddish brown coloured enteric coated pellets) Domperidone IP 30mg (as orange coloured sustained release pellets)	1 Capsule	M/s Windlas Biotech Limited / M/s Intas Pharmaceuticals Ltd.	10.83
41.	Metformin Hydrochloride (SR), Glimepiride and Voglibose Tablets	<b>Each uncoated bilayered tablet contains:</b> Metformin Hydrochloride IP 1000mg (In Sustained Release form) Glimepiride IP 2mg Voglibose IP 0.2mg	1 Tablet	M/s Swiss Garnier Genexiaa Sciences Pvt. Ltd. / M/s Intas Pharmaceuticals Ltd.	13.85
42.	Metformin Hydrochloride (SR), Glimepiride and Voglibose Tablets	<b>Each uncoated bilayered tablet contains:</b> Metformin Hydrochloride IP 1000mg (In Sustained Release form) Glimepiride IP 1mg Voglibose IP 0.2mg	1 Tablet	M/s Swiss Garnier Genexiaa Sciences Pvt. Ltd. / M/s Intas Pharmaceuticals Ltd.	11.43
43.	Sitagliptin Phosphate & Metformin	<b>Each Film Coated tablet contains:</b> Sitagliptin Phosphate	1 Tablet	M/s Alembic Pharmaceuticals Limited	16.96 <b>(Note 4)</b>

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Hydrochloride Tablets	Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500 mg			
44.	Sitagliptin Phosphate & Metformin Hydrochloride Tablets	<b>Each Film Coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000 mg	1 Tablet	M/s Alembic Pharmaceuticals Limited	18.75 <b>(Note 4)</b>
45.	Sitagliptin and Metformin Hydrochloride SR Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg (as sustained release form)	1 Tablet	M/s Akums drugs & Pharmaceuticals Limited / M/s Abbott Healthcare Pvt. Ltd.	20.06 <b>(Note 4)</b>
46.	Sitagliptin and Metformin Hydrochloride SR Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg (as sustained release form)	1 Tablet	M/s Akums drugs & Pharmaceuticals Limited / M/s Abbott Healthcare Pvt. Ltd.	18.34 <b>(Note 4)</b>
47.	Sitagliptin and Metformin Hydrochloride SR Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (as sustained release form)	1 Tablet	M/s Akums drugs & Pharmaceuticals Limited / M/s Abbott Healthcare Pvt. Ltd.	19.81 <b>(Note 4)</b>
48.	Sitagliptin and Metformin Hydrochloride Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Torrent Pharmaceuticals Limited	18.34 <b>(Note 4)</b>
49.	Sitagliptin and Metformin Hydrochloride Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 850mg	1 Tablet	M/s Torrent Pharmaceuticals Limited	19.14 <b>(Note 4)</b>
50.	Sitagliptin and Metformin	<b>Each film coated tablet contains:</b>	1 Tablet	M/s Torrent Pharmaceuticals	20.02 <b>(Note 4)</b>



S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Hydrochloride Tablets	Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg		Limited	
51.	Sitagliptin Phosphate and Metformin Hydrochloride Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd.	18.34 <b>(Note 4)</b>
52.	Sitagliptin Phosphate and Metformin Hydrochloride Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd.	20.02 <b>(Note 4)</b>
53.	Sitagliptin Phosphate and Metformin Hydrochloride Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s Glensmith Labs Pvt. Ltd.	18.34 <b>(Note 4)</b>
54.	Sitagliptin Phosphate and Metformin Hydrochloride Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s Glensmith Labs Pvt. Ltd.	20.02 <b>(Note 4)</b>
55.	Sitagliptin and Metformin Hydrochloride Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Micro Labs limited	18.34 <b>(Note 4)</b>
56.	Sitagliptin and Metformin Hydrochloride Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Micro Labs limited	20.00 <b>(Note 4)</b>
57.	Sitagliptin and Metformin Hydrochloride (SR) Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Zydus Healthcare Limited	20.06 <b>(Note 4)</b>

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S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Sitagliptin 50mg Metformin Hydrochloride IP 1000mg (as sustained release form)			
58.	Sitagliptin and Metformin Hydrochloride (SR) Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg (as sustained release form)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Zydus Healthcare Limited	18.67 <b>(Note 4)</b>
59.	Sitagliptin and Metformin Hydrochloride (extended release) Tablets	<b>Each film coated bilayered tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride IP (In extended release form) 500mg	1 Tablet	M/s Zydus Healthcare Limited	20.17 <b>(Note 4)</b>
60.	Sitagliptin and Metformin Hydrochloride (extended release) Tablets	<b>Each film coated bilayered tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride IP (In extended release form) 1000mg	1 Tablet	M/s Zydus Healthcare Limited	21.56 <b>(Note 4)</b>
61.	Sitagliptin and Metformin Hydrochloride (as extended release) Tablets	<b>Each film coated bilayered tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride IP (as extended release form) 500mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Glenmark Pharmaceuticals Limited	20.17 <b>(Note 4)</b>
62.	Sitagliptin and Metformin Hydrochloride (as extended release) Tablets	<b>Each film coated bilayered tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride IP (as extended release form) 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Glenmark Pharmaceuticals Limited	21.56 <b>(Note 4)</b>
63.	Sitagliptin and Metformin Hydrochloride (as extended release) Tablets	<b>Each film coated bilayered tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride IP (as extended release form) 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Emcure Pharmaceuticals Limited	21.56 <b>(Note 4)</b>

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
64.	Sitagliptin and Metformin Hydrochloride Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Synokem Pharmaceuticals Limited / M/s FDC Limited	10.41 <b>(Note 4)</b>
65.	Sitagliptin and Metformin Hydrochloride Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Synokem Pharmaceuticals Limited / M/s FDC Limited	8.92 <b>(Note 4)</b>
66.	Sitagliptin and Metformin Hydrochloride (as extended release) Tablets	<b>Each film coated bilayered tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride IP (as extended release form) 500mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Emcure Pharmaceuticals Limited	20.17 <b>(Note 4)</b>
67.	Sitagliptin Phosphate and Metformin Hydrochloride Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP 64.25 eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Unison Pharmaceuticals Pvt. Limited	18.34 <b>(Note 4)</b>
68.	Sitagliptin and Metformin Hydrochloride (extended release) Tablets	<b>Each film coated bilayered tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP (As Extended Release form) 500mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Eris Life Sciences Limited	18.67 <b>(Note 4)</b>
69.	Sitagliptin and Metformin Hydrochloride (extended release) Tablets	<b>Each film coated bilayered tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP (As Extended Release form) 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Eris Life Sciences Limited	20.06 <b>(Note 4)</b>
70.	Sitagliptin and Metformin Hydrochloride (extended release) Tablets	<b>Each film coated bilayered tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Eris Life Sciences Limited	20.17 <b>(Note 4)</b>

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Tablets	Metformin Hydrochloride (As Extended Release) IP 500mg			
71.	Sitagliptin and Metformin Hydrochloride (extended release) Tablets	<b>Each film coated bilayered tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride IP (As Extended Release form) 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Eris Life Sciences Limited	21.56 <b>(Note 4)</b>
72.	Sitagliptin Phosphate and Metformin Hydrochloride Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP 64.25 eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Unison Pharmaceuticals Pvt. Limited	20.02 <b>(Note 4)</b>
73.	Sitagliptin and Metformin Hydrochloride (as extended release) Tablets	<b>Each film coated bilayered tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP (As Extended Release form) 500mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Zydus Healthcare Limited	18.67 <b>(Note 4)</b>
74.	Sitagliptin and Metformin Hydrochloride (as extended release) Tablets	<b>Each film coated bilayered tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP (As Extended Release form) 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Zydus Healthcare Limited	20.06 <b>(Note 4)</b>
75.	Sitagliptin and Metformin Hydrochloride (as extended release) Tablets	<b>Each film coated bilayered tablet contains:</b> Sitagliptin Phosphate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP (As Extended Release form) 500mg	1 Tablet	M/s Alkem Healthscience (A unit of Alkem Laboratories Ltd.) M/s Alkem Laboratories Ltd.	18.67 <b>(Note 4)</b>
76.	Sitagliptin and Metformin Hydrochloride (as extended release) Tablets	<b>Each film coated bilayered tablet contains:</b> Sitagliptin Phosphate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP (As Extended Release form) 1000mg	1 Tablet	M/s Alkem Healthscience (A unit of Alkem Laboratories Ltd.)/ M/s Alkem Laboratories Ltd.	20.06 <b>(Note 4)</b>
77.	Medroxyprogesterone Acetate SR	<b>Each uncoated sustained release tablet contains:</b> Medroxyprogesterone	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Obsurge	14.04

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Tablets	Acetate IP 30mg		Biotech Ltd.	
78.	Cefixime and Potassium Clavulanate Oral Suspension	<b>Each 5ml of the reconstituted suspension contains:</b> Cefixime (As Trihydrate) IP eq. to Anhydrous Cefixime 50mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 31.25mg	1 ML	M/s Prosperity Drugs Pvt. Ltd. / M/s Intas Pharmaceuticals Ltd.	2.70
79.	Diclofenac, Virgin Linseed Oil, Methyl Salicylate, Menthol & Capsaicin Gel	<b>Composition:</b> Diclofenac Diethylamine IP 1.16%w/w (eq. to Diclofenac Sodium 1%w/w), Virgin Linseed Oil BP 3%w/w (Containing Predominantly Alpha Linolenic Acid), Methyl Salicylate IP 10% w/w Menthol IP 5%w/w Capsaicin USP 0.025% w/w	1 Gram	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s German Remedies Pharmaceuticals Private Limited	3.12
80.	Ofloxacin and Metronidazole suspension	<b>Each 5ml contains:</b> Ofloxacin IP 50mg Metronidazole Benzoate IP eq. to Metronidazole 100mg	1 ML	M/s Hema Laboratories Pvt. Ltd. / M/s Abbott Healthcare Pvt. Ltd.	0.70
81.	Dapagliflozin and Metformin Hydrochloride (IR) Tablets	<b>Each film coated tablet contains:</b> Dapagliflozin propanediol monohydrate eq. to Dapagliflozin 5mg Metformin Hydrochloride IP 500mg (as Immediate release form)	1 Tablet	M/s Sun Pharma Laboratories Limited	6.25 <b>(Note 5)</b>
82.	Dapagliflozin & Metformin Hydrochloride Extended Release Tablets	<b>Each film coated tablet contains:</b> Metformin Hydrochloride...500mg (as extended release form) Dapagliflozin Propanediol Monohydrate eq to Dapagliflozin 5mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Cipla Ltd.	6.25 <b>(Note 5)</b>
83.	Dapagliflozin & Metformin Hydrochloride Extended Release Tablets	<b>Each film coated tablet contains:</b> Metformin Hydrochloride...1000mg (as extended release form) Dapagliflozin Propanediol Monohydrate eq to Dapagliflozin 5mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Cipla Ltd.	7.23 <b>(Note 5)</b>

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
84.	Dapagliflozin & Metformin Hydrochloride Extended Release Tablets	<b>Each film coated tablet contains:</b> Metformin Hydrochloride...500mg (as extended release form) Dapagliflozin Propanediol Monohydrate eq to Dapagliflozin 10mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Cipla Ltd.	9.21 <b>(Note 5)</b>
85.	Dapagliflozin & Metformin Hydrochloride Extended Release Tablets	<b>Each film coated tablet contains:</b> Metformin Hydrochloride...1000mg (as extended release form) Dapagliflozin Propanediol Monohydrate eq to Dapagliflozin 10mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Cipla Ltd.	10.69 <b>(Note 5)</b>

**Note 1.** The Authority noted that the retail price application of new drug is for Combipack and the retail price proposed is in per ml basis. The Authority deliberated upon the matter in detail and decided to approve the retail price as per Combipack which comes to Rs. 102.00 [Rs.3.40 X 30 ml]

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

**Note 3.** The Authority noted that the retail price of the new drug as per agenda 4(xxiii) and 4(xxx) is being fixed for the same company having the same formulation with only difference in 'film coated' and 'uncoated' and decided that there will be a single notification of the price indicating both the variants of the drug.

**Note 4.** The Authority deliberated upon the matter in detail and decided to approve the retail price in line with the decision as recorded in Note 7 of Para 4.1 of the Minutes of the 96<sup>th</sup> Authority meeting dated 24.03.2022.

**Note 5.** The Authority deliberated upon the matter in detail and decided to approve the retail price in line with the decision as recorded in Note 5 of Para 4.1 of the Minutes of the 96<sup>th</sup> Authority meeting dated 24.03.2022.

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

5.1 Noted.

**6. Agenda item no. 6 –Extension of revised price of Medical Oxygen**

6.1 The Authority noted that the price fixed for Liquid Medical Oxygen (LMO) and Oxygen Inhalation (Medicinal gas) in cylinder vide SO. 3322(E) dated 25.09.2020

applicable up to 31.03.2021 were extended upto 30.09.2021 vide SO. 1335(E) dated 25.03.2021, then upto 31.12.2021 vide SO. 3936(E) dated 23.09.2021, again upto 31.03.2022 vide SO. 5424(E) dated 28.12.2021 and then further extended upto 30.06.2022 or until further orders, whichever is earlier, vide SO. 1508(E) dated 30.03.2022.

6.2 The Authority further noted that the Department for Promotion of Industry & Internal Trade (DPIIT), Ministry of Commerce and Industry, Government of India vide its Office Memorandum dated 22.06.2022 stated as follows:

*"...the matter has been examined in this Department in consultation with Ministry of Health and Family Welfare vide OM. No. Z.20015/190/2021-ME-I dated 14.03.2022 and e-mail dated 20.06.2022 and it is recommended that the prices of above drugs may further be extended till 30.09.2022 keeping in view of the new variant of COVID i.e. Omicron, after which the issue may be reviewed again.*

6.3 The Authority deliberated upon the matter in detail and in view of continuing extraordinary circumstances due to the COVID pandemic decided that the revised price of Liquid Medical Oxygen (LMO) and Oxygen Inhalation (Medicinal gas) in cylinder fixed vide SO. 3322(E) dated 25.09.2020 and extended vide SO. 1335(E) dated 25.03.2021, SO. 3936(E) dated 23.09.2021, SO. 5424(E) dated 28.12.2021 and SO. 1508(E) dated 30.03.2022 be further extended up to 30.09.2022 or until further orders, whichever is earlier.

**7. Agenda item no. 7 - Overcharging cases, where reduction in principal overcharging liability was observed based on CA/CMA certified data as compared to Pharmatrac data considered for issuance of SCN/Demand Notice-reg.**

7.1 Record note of discussion for private circulation.

**8. Agenda item no. 8 - Minutes of 42nd meeting of Multidisciplinary Committee of Experts held on 02.06.2022.**

8.1 Noted.

8.2 Record note of discussion for private circulation.

**9. Agenda item no. 9 - Form-IV intimation received from M/s Serum Institute of India Pvt Ltd in respect of 2 scheduled formulations (i) Tetanus Toxoid Injection 0.5ml and (ii) Tetanus Toxoid Injection 5 ml of M/s Serum Institute of India Pvt Ltd-reg.**

9.1 The Authority noted that Para 3 of DPCO 2013 which was applicable upto 22<sup>nd</sup> June, 2022 to M/s Serum Institute of India Pvt. Ltd for 2 scheduled formulations (i) Tetanus Toxoid Injection in 0.5ml pack and (ii) Tetanus Toxoid Injection in 5 ml pack was

extended further for six month i.e. upto 22.12.2022. The Authority deliberated upon the matter in detail and ratified the decision to invoke Para 3 of DPCO 2013 to M/s Serum Institute of India Pvt. Ltd for 2 scheduled formulations (i) Tetanus Toxoid Injection in 0.5ml pack and (ii) Tetanus Toxoid Injection in 5 ml pack for further six month i.e. upto 22.12.2022.

**10. Agenda item no. 10 - Price regulation of medical devices, namely, (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer & (v) Glucometer**

10.1 The Authority noted that the notification SO. No. 2808(E) dated 13.07.2021 relating to price regulation of Medical Devices, namely, (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer, and (v) Glucometer based on Trade Margin Rationalisation (TMR) approach applicable upto 31.01.2022 was further extended upto 31.07.2022 vide SO. 401(E) dated 31.01.2022.

10.2 The Authority deliberated upon the matter in detail and was of the opinion that as COVID pandemic is still a risk to public health; availability of Medical Devices, namely, (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer, and (v) Glucometer at affordable prices must be ensured. Hence, it was decided that the notification SO. 2808(E) dated 13.07.2021 be further extended up to 31<sup>st</sup> December, 2022 or until further orders, whichever is earlier.

10.3 The Authority also decided that the five medical devices as mentioned in the said notification be monitored as per the provisions of Paragraph 20(1) of the DPCO, 2013 subject to maintenance of trade margin.

**11. Agenda item no. 11 - Extension of validity of TMR notification pertaining to Oxygen Concentrators.**

11.1 The Authority noted that the price regulated for Oxygen Concentrators through Trade Margin Rationalization (TMR) approach vide SO. 2161(E) dated 03.06.2021 and valid upto 30.11.2021 was further extended upto 30.05.2022 vide SO. 4909(E) dated 30.11.2021 and again extended upto 30.06.2022 vide SO. 2465(E) dated 30.05.2022.

11.2 The Authority deliberated upon the matter in detail and was of the opinion that as COVID pandemic is still a risk to public health; availability of Oxygen Concentrators must be ensured. Hence, it was decided that the notification SO. 2161(E) dated 03.06.2021 be extended further upto 31<sup>st</sup> December, 2022 or until further orders, whichever is earlier.

11.3 The Authority also decided that the Oxygen Concentrators may be monitored as per the provisions of Paragraph 20(1) of the DPCO, 2013 subject to maintenance of trade margin.





**12. Agenda item no. 12 - Clarification sought by M/s Torrent Pharmaceuticals Ltd regarding the retail price of new drug "Chlorthalidone 12.5 mg + Telmisartan 40 mg tablet" given to M/s Torrent Pharmaceuticals Ltd vide SO. 5638(E) dated 02.11.2018 at Sl. No. 25**

12.1 The Authority noted that the retail price of the formulation "Chlorthalidone 12.5 mg + Telmisartan 40 mg tablet" with the brand name "Telsar CH 40/12.5" was notified vide SO. 5638(E) dated 02.11.2018 for M/s GKM New Pharma (manufacturer)/M/s Torrent Pharmaceuticals (marketing company) based on the decision taken in its 60<sup>th</sup> meeting dated 29.10.2018.

12.2 The Authority further noted that M/s Torrent Pharmaceuticals Ltd mentioned that due to unavoidable circumstances, they need to get the same formulation manufactured from another manufacturer i.e. M/s Hetero Labs Ltd under the existing brand and submitted (a) the copy of license of CDSCO and State Licensing Authority of M/S Hetero Labs Ltd to manufacture the subject formulation; and (b) the copy of joint agreement between Hetero Labs Ltd and Torrent Pharmaceuticals.

12.3 The Authority observed that Para 15(2) of DPCO, 2013 provides for application for retail price of new drugs by the applicant company prior to its launch. M/s Torrent Pharmaceuticals Ltd had already launched the subject formulation after taking retail price approval from NPPA and presently the company only intends to switch the manufacturer.

12.4 The matter was discussed by the Authority and its attention was also drawn to O.M. dated 24.11.2017 regarding guidelines for examination of cases of launch of 'New Drugs' by pharma companies. The Authority opined that as per para 15(2) of DPCO, 2013 it is not a new launch of the formulation as the company had already obtained the retail price approval in 2018 prior to its launch and also launched the formulation. The Authority deliberated upon the matter in detail and decided that since the applicant marketing company wishes to change the manufacturer of a branded formulation, already launched, for which retail price has been notified, it may be allowed to continue marketing the formulation while keeping the same brand name with the changed manufacturer at the price not exceeding the present applicable retail price. Hence, the Authority decided to allow M/s Torrent Pharmaceuticals to market the formulation "Chlorthalidone 12.5 mg + Telmisartan 40 mg tablet" having the same brand name "Telsar CH 40/12.5" with the new manufacturer M/s Hetero Labs Ltd at the price not exceeding the present applicable retail price.

**13. Agenda item no. 13 Form-IV Intimation by M/s Neon Laboratories Limited in respect of scheduled formulation Tropine 1ml Injection (Atropine Sulphate Injection 0.6mg/ml) under para 21(2) of DPCO, 2013.**



13.1 The Authority deliberated upon the matter in detail and decided that Para 3 of DPCO 2013 be invoked in relation to M/s Neon Laboratories Ltd for the scheduled formulation Atropine Injection 0.6mg/ml for further period of six month i.e. upto 05.02.2023.


**14. Agenda item no. 14 - Revision of retail price of Each hard gelatin capsule contains Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate 12 mcg + Budesonide IP 400 mcg for M/s. Biodeal Pharmaceuticals Pvt. Ltd. (manufacturer) and M/s. Mankind Pharma Ltd. (marketer) (F.No. 2489).**

14.1 The Authority noted that the based on the retail price application being filed by M/s Mankind Pharma Ltd for the formulation "Each hard gelatin capsule contains Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate 12 mcg + Budesonide IP 400 mcg" the retail price was calculated as per the provisions of DPCO 2013 based on Pharmatrac data for capsule only and the draft working sheet was uploaded on NPPA website. The Authority further noted the representation made by M/s Mankind Pharma Ltd. was with respect to the data considered for price fixation by NPPA and that M/S Mankind Pharma Ltd. quoted the data from 'IQVIA' database which is not considered by NPPA as per current practice. Accordingly, the retail price of the subject formulation for M/s Mankind Pharma Ltd (marketer)/M/s Biodeal Pharmaceuticals Pvt. Ltd (manufacturer) was approved in the 93<sup>rd</sup> Authority meeting dated 15.11.2021 at Rs. 7.10 per capsule excluding GST and notified vide SO. 4884(E) dated 26.11.2021.

14.2 The Authority also noted that M/s Mankind Pharma Ltd had again represented against the notified retail price of the formulation to Department of Pharmaceuticals (DoP), which was forwarded to NPPA by DoP for necessary action. Accordingly, clarification was sought from M/s Pharmatrac based on the representation made by M/s Mankind Pharma Ltd. It was clarified by M/s Pharmatrac that Transcap, Rotacap and Respicap are also capsules and based on the clarification , the retail price of "Each hard gelatin capsule contains Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate 12 mcg + Budesonide IP 400 mcg" was recalculated at Rs. 9.35 per capsule excluding GST.

14.3 The Authority deliberated upon the matter in detail and decided to approve the revised retail price of each hard gelatin capsule contains Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate 12 mcg + Budesonide IP 400 mcg" for M/s Mankind Pharma Ltd (marketer)/M/s Biodeal Pharmaceuticals Pvt. Ltd (manufacturer) at Rs. Rs. 9.35 per capsule excluding GST.

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

  
(Dr. Vinod Kotwal)  
Member Secretary