

मिसिल स.- 8(59)/2018/डी.पी/एनपीपीए-डीवी-II

F. No. 8(59)/2018/DP/NPPA-Div. II

कार्यवाहीस. : 191/59/2018/F

Proceeding No : 191/59/2018/F

Minutes of the 191st (overall) and 59th meeting of the Authority under DPCO, 2013 held on 08.08.2018 at 12:00 Noon

The 191st meeting of the Authority (overall), which is the 59th meeting under the DPCO, 2013, was held on 8th Aug, 2018 at 12:00 Noon under the Chairmanship of Dr. Rakesh Kumar Vats, Chairman, NPPA. The following members of the NPPA were present:

- (i) Ms. Ritu Dhillon, Member Secretary
- (ii) Shri Arun Kumar, Adviser, Department of Economic Affairs.
- (iii) Shri B. Bandhopadhyay, Adviser, O/o Chief Adviser (Cost), Department of Expenditure.
- (iv) Dr. S. Eswara Reddy, Drugs Controller General (India)
- (v) A.K.Pradhan, Deputy Drug Controller, Deptt. of Health & Family Welfare

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

- i. Shri Kalyan Nag, Adviser (Cost)
- ii. Shri Amarpal Singh Sawhney, Director (Pricing)
- iii. Shri Rajesh Aggarwal, Joint Director (M&E)
- iv. Shri Nihal Padric, Joint Director (Legal)
- v. Shri Baljit Singh, Asstt. Director (Pricing)
- vi. Shri Prasenjit Das, Asstt. Director (Pricing)

1.2 Chairman, NPPA welcomed all present in the meeting.

II. Agenda items

1. Agenda item no. 1 - Confirmation of Minutes of the 58th Meeting held on 28.06.2018.

1.1 The Authority confirmed the minutes of the 190th (overall) and the 58th Meeting under DPCO 2013 held on 28.06.2018.

2. Agenda item no. 2 - Action Taken Report

2.1 Noted.

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

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 (lxxii)] falling under the purview of para 2(u) of DPCO, 2013 and approved the retail prices in 72(Seventy two) cases under para 5 of the DPCO 2013. The following retail prices were approved:

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
1.	Rosuvastatin + Clopidogrel Capsule	Each film coated tablet contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg, Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg.	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Unimed Technologies Ltd.	11.70
2.	Amoxicillin + Clavulnic Acid Suspension	Each 5ml of reconstituted suspension contains: Amoxicillin Trihydrate IP eq. to Amoxicillin 400mg, Potassium Clavulante Diluted IP eq. to Clavulnic Acid 57mg In a Palatable suspension q.s. Color Approved colour used B One Ampoule Contain Sterile Water for Injection IP 30ml	1 ML	M/s Saitech Medicare Pvt. Ltd. / M/s Hegde & Hegde Pharmaceutical LLP	3.01
3.	Olmesartan +Amlodipine + Chlorthalidone Tablet	Each film coated tablet contains: Olmesartan Medoxomil IP 20mg, Amlodipine Besylate IP eq. to Amlodipine 5mg & Chlorthalidone IP 12.5mg	1 Tablet	M/s Synokem Pharmaceuticals Limited / M/s Zuventus Healthcare Limited	9.30
4.	Olmesartan +Amlodipine + Chlorthalidone Tablet	Each film coated tablet contains: Olmesartan Medoxomil IP 40mg, Amlodipine Besylate IP eq. to Amlodipine 5mg & Chlorthalidone IP 12.5mg	1 Tablet	M/s Synokem Pharmaceuticals / M/s Zuventus Healthcare Limited	16.19
5.	Misoprostol Tablet	Each uncoated tablets contains: Misoprostol IP 25mcg (As Misoprostol 1% Dispersion)	1 Tablet	M/s Synokem Pharmaceuticals Limited / M/s Zydus Healthcare Limited	4.37
6.	Misoprostol Tablet	Each uncoated tablets contains: Misoprostol IP 600mcg (As Misoprostol 1% Dispersion)	1 Tablet	M/s Synokem Pharmaceuticals Limited / M/s Zydus Healthcare Limited	56.93

7.	Flunarizine + Propranolol tablet	Each uncoated bilayered tablet contains: Flunarizine Dihydrochloride BP eq. to Flunarizine 5mg, Propranolol Hydrochloride IP 40mg (As Sustained Release)	1 Tablet	M/s Akums Drugs and Pharmaceuticals Pvt. Ltd. / M/s Abbott Healthcare Pvt. Ltd.	5.39
8.	Flunarizine + Propranolol tablet	Each uncoated bilayered tablet contains: Flunarizine Dihydrochloride BP eq. to Flunarizine 10mg, Propranolol Hydrochloride IP 40mg (As Sustained Release)	1 Tablet	M/s Akums Drugs and Pharmaceuticals Pvt. Ltd. / M/s Abbott Healthcare Pvt. Ltd.	7.20
9.	Rosuvastatin + Clopidogrel capsule (Rozat CV)	Each hard Gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg (As film coated form tablet), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As film coated tablet form)	1 Capsule	M/s Akums Drugs and Pharmaceuticals Pvt. Ltd. and marketed by M/s Dr. Reddy's Laboratories Limited	13.10
10.	Cefixime + Clavulanic Acid suspension	Each 5ml of reconstituted Suspension contains: Cefixime Trihydrate IP eq. to Cefixime 50mg, Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 31.25mg Excipients. One Ampoule (FFS) of Sterile water for Injection IP 30ml	1 ML	M/s Twenty First Century Pharmaceuticals Pvt. Ltd. / M/s Glenmark Pharmaceuticals Ltd.	2.17
11.	Rabeprazole + Domperidone Capsule	Each hard gelatine capsule contains: Rabeprazole Sodium IP 40mg (As Reddish brown enteric coated pellets) Domperidone IP 30mg (As orange coloured sustained released pallets)	1 Capsule	M/s Windlas Biotech Ltd. / M/s Cadila Pharmaceuticals Limited	8.46
12.	Aceclofenac + Paracetamol Tablet (CLONET)	Each Uncoated tablet contains: Aceclofenac IP 100mg, Paracetamol IP 325mg	1 Tablet	M/s Burnet Pharmaceuticals Pvt. Ltd.	3.27
13.	Albendazole + Ivermectin Tablet (BEN +)	Each uncoated dispersible tablet contains: Albendazole IP 400mg, Ivermectin IP 6mg	1 Tablet	M/s Burnet Pharmaceuticals Pvt. Ltd.	17.48
14.	Cilnidipine + Metoprolol tablet	Each film coated bilayered tablet contains: Cilnidipine IP 10mg, Metoprolol Succinate IP eq. to Metoprolol Tartrate 50mg (In	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Mankind Pharma Ltd.	7.346

		extended release form)			
15.	Atorvastatin + Clopidogrel capsule (Jubicoad CV 10)	Each hard gelatine capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 10mg (As film coated tablets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As two film coated tablets)	1 Capsule	M/s Windlas Biotech Pvt. Ltd. / M/s Jubilant Life Sciences Limited	8.234
16.	Atorvastatin + Clopidogrel capsule (Jubicoad CV 20)	Each hard gelatine capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 20mg (As film coated tablets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As two film coated tablets)	1 Capsule	M/s Windlas Biotech Pvt. Ltd. / M/s Jubilant Life Sciences Limited	13.30
17.	Telmisartan + Chlorthalidone tablet (Telmijub CH 40)	Each Uncoated bilayer tablet contains: Telmisartan IP 40mg, Chlorthalidone IP 12.50mg Tablets	1 Tablet	M/s Hetero Labs Pvt. Ltd. / M/s Jubilant Life Sciences Limited	7.92
18.	Telmisartan + Chlorthalidone tablet (Telmijub CH 80)	Each Uncoated bilayer tablet contains: Telmisartan IP 80mg + Chlorthalidone IP 12.50mg Tablet	1 Tablet	M/s Hetero Labs Pvt. Ltd. / M/s Jubilant Life Sciences Limited	13.82
19.	Paracetamol + Phenylephrine + Caffeine + Diphenhydramine Tablet	Each uncoated tablet contains: Paracetamol IP 500mg Phenylephrine Hydrochloride IP 5mg, Caffeine (Anhydrous) IP 30mg, Diphenhydramine Hydrochloride IP 25mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Abbott Healthcare Pvt. Ltd.	3.06
20	Gliclazide + Metformin tablet	Each uncoated tablet contains: Gliclazide IP 60mg (in extended release form) Metformin Hydrochloride IP 500mg (in extended release form)	1 Tablet	M/s Mediforce Healthcare Pvt. Ltd. / M/s Mankind Pharma Limited	8.38
21.	Glimepiride + Metformin tablet	Each uncoated bilayered tablet contains: Glimepiride IP 0.5mg Metformin Hydrochloride IP 500mg (in sustained release form)	1 Tablet	M/s Mediforce Healthcare Pvt. Ltd. / M/s Mankind Pharma Limited	3.77

22.	Atorvastatin + 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)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Mankind Pharma Limited	8.394
23.	Atorvastatin + 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)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Mankind Pharma Limited	10.596
24.	Sofosbuvir + Velpatasvir tablet	Each film coated tablet contains: Sofosbuvir 400mg, Velpatasvir 100mg	28's Tablets	by M/s Natco Pharma Limited / M/s Abbott India Limited	15481.86
25.	Dicyclomine Hydrochloride Tablet	Each uncoated tablet contains: Dicyclomine Hydrochloride IP 20 mg	1 Tablet	M/s Kontest Chemicals Ltd.	0.85
26.	Trastuzumab 150mg	Each combi kit contains A) Each Lyophilized vial containing Trastuzumab IHS 150 mg, A,α trehalose dihydrate 136.2 mg, L-Histidine HCL 3.36 mg, L-Histidine 2.16 mg, Polysorbate 20 0.6 mg B) Each sterile WFI vial containing Sterile water for injection IP 10 ml	Per Pack	M/s Reliance Lifesciences Pvt. Ltd. / M/s Lupin Ltd,	18400.89
27.	Trastuzumab 150mg	Each combi kit contains A) Each Lyophilized vial containing Trastuzumab IHS 150 mg, A,α trehalose dihydrate 136.2 mg, L-Histidine HCL 3.36 mg, L-Histidine 2.16 mg, Polysorbate 20 0.6 mg B) Each sterile WFI vial containing Sterile water for injection IP 10 ml	Per Pack	Dr. Reddy's Laboratories Ltd.	18125.00
28.	Budesonide respules 0.5mg/2ml (suspension for nebulisation)	Each 2 ml respules contains: Budesonide IP 0.5 mg	2 ml Pack	M/s Sun Pharmaceutical Medicare Ltd. / M/s Sun Pharma Laboratories Ltd.	17.59

29.	Rosuvastatin + Aspirin + Clopidogrel Capsule (Sultatin Gold)	Each hard gelatin capsule containing Rosuvastatin Calcium eq to Rosuvastatin 10mg (as pellets) Aspirin IP 75 mg (as enteric coated pellets) Clopidogrel Bisulphate IP eq to Clopidogrel 75 mg (as pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Medopharm	11.53
30.	Ferrous Ascorbate + Folic acids drops (Trifer - XT)	Each ml drops contains: Ferrous Ascorbate eq to elemental iron 10mg Folic Acid IP 100mcg	1 ML	M/s Apex laboratories Pvt. Ltd.	3.58
31.	Trastuzumab 150mg	Each combi kit contains A) Each Lyophilized vial containing Trastuzumab IHS 150 mg, A, α trehalose dihydrate 136.2 mg, L-Histidine HCL 3.36 mg, L-Histidine 2.16 mg, Polysorbate 20 0.6 mg B) Each sterile WFI vial containing Sterile water for injection IP 10 ml	Per Pack	M/s Reliance Life Sciences Pvt. Ltd. / M/s RPG Life Sciences Ltd.	18125.00
32.	Formoterol + Budesonide Suspension (Fomtime 0.5)	Each 2 ml respules contains: Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate 20 mcg Budesonide IP 0.5 mg	2 ML Pack	M/s Sun Pharmaceutical Medicare Ltd. / M/s Sun Pharma Laboratories Ltd	35.04
33.	Formoterol + Budesonide Suspension (Fomtime 1)	Each 2 ml respules contains: Formoterol Fumarate Dihydrate IP eq to Formoterol Fumarate 20mcg Budesonide IP 1 mg	2 ML Pack	M/s Sun Pharmaceutical Medicare Ltd. / M/s Sun Pharma Laboratories Ltd	40.96
34.	Recombinant Human Chorionic Gonadotropin for Injection	Each PFS containing Recombinant Human Chorionic Gonadotropin for Injection 6500IU	Each Pack	M/s Bharat Serums and Vaccines Ltd.	1294.64
35.	Telmisartan + Amlodipine + Chlorthalidone Tablet (Tritelzar 80 HS)	Each film coated tablet contains: Telmisartan IP 80mg Amlodipine Besylate IP eq. to Amlodipine 5mg Chlorthalidone IP 12.50mg	1 Tablet	M/s GKM New Pharma / M/s Unichem Laboratories Limited.	13.76
36.	Olmesartan + Amlodipine + Chlorthalidone Tablet (Triolsar 20 HS)	Each film coated tablet contains: Olmesartan Medoxomil IP 20mg Amlodipine Besylate IP eq. to Amlodipine 5mg Chlorthalidone IP 12.50mg	1 Tablet	M/s GKM New Pharma / M/s Unichem Laboratories Limited.	9.25

37.	Olmesartan + Amlodipine + Chlorthalidone Tablet (Triolsar 40 HS)	Each film coated tablet contains: Olmesartan Medoxomil IP 40mg Amlodipine Besylate IP eq. to Amlodipine 5mg Chlorthalidone IP12.50mg	1 Tablet	M/s GKM New Pharma / M/s Unichem Laboratories Limited.	16.70
38.	Telmisartan + Amlodipine + Chlorthalidone Tablet (Tritelsar 40)	Each film coated tablet contains: Telmisartan IP 40mg Amlodipine Besylate IP eq. to Amlodipine 5mg Chlorthalidone IP 6.25mg	1 Tablet	M/s GKM New Pharma / M/s Unichem Laboratories Limited.	8.35
39.	Telmisartan + Amlodipine + Chlorthalidone Tablet (Tritelsar 40 HS)	Each film coated tablet contains: Telmisartan IP 40mg Amlodipine Besylate IP eq. to Amlodipine 5mg Chlorthalidone IP 12.50mg	1 Tablet	M/s GKM New Pharma / M/s Unichem Laboratories Limited.	9.37
40.	Telmisartan + Amlodipine + Chlorthalidone Tablet (Tritelsar 80)	Each film coated tablet contains: Telmisartan IP 80mg Amlodipine Besylate IP eq. to Amlodipine 5mg Chlorthalidone IP 6.25mg	1 Tablet	M/s GKM New Pharma / M/s Unichem Laboratories Limited.	14.47
41.	Doxycycline + Lactic acid bacillus Capsules	Each hard gelatin capsules containing Doxycycline Hyclate IP eq to Doxycycline 100 mg Lactic Acid Bacillus 5 billion spores	1 Capsule	M/s GKM New Pharma / M/s Unichem Laboratories Limited.	4.96
42.	Rosuvastatin + Clopidogrel + Aspirin Capsules	Each hard gelatin capsule containing Rosuvastatin Calcium eq. to Rosuvastatin 10mg (as pellets) Aspirin IP 75 mg (as enteric coated pellets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75 mg (as pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Aprica Healthcare Pvt. Ltd.	11.53
43.	Rosuvastatin + Clopidogrel + Aspirin Capsules	Each hard gelatin capsule containing Rosuvastatin Calcium eq. to Rosuvastatin 20mg (as pellets) Aspirin IP 75 mg (as enteric coated pellets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75 mg (as pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Aprica Healthcare Pvt. Ltd.	17.88
44.	Memantine + Donepezil Tablet	Each film coated tablet containing Memantine Hydrochloride USP 5mg Donepezil Hydrochloride IP 5mg	1 Tablet	M/s Theon Pharmaceuticals Ltd. / M/s Emcure Pharmaceuticals Ltd.	9.93

45.	Memantine + Donepezil Tablet	Each film coated tablet containing Memantine Hydrochloride USP 10mg Donepezil Hydrochloride IP 5mg	1 Tablet	M/s Theon Pharmaceuticals Ltd. / M/s Emcure Pharmaceuticals Ltd.	12.56
46.	Cilnidipine + Telmisartan Tablet	Each film coated tablet containing Telmisartan IP 40mg Cilnidipine 10 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Abbott Healthcare Pvt. Ltd.	7.77
47.	Hyoscine Butyrbromide + Mefenamic Acid Tablet	Each film coated tablet containing Hyoscine Butyrbromide IP 10 mg Mefenamic Acid Tablet IP 250mg	1 Tablet	M/s Zydus Healthcare Ltd.	8.99
48.	Rosuvastatin + Aspirin + Clopidogrel Capsule (Rosulip Gold 10)	Each hard gelatin capsule containing Rosuvastatin Calcium eq. to Rosuvastatin 10mg (as pellets) Aspirin IP 75 mg (as enteric coated pellets) Clopidogrel Bisulphate IP e. to Clopidogrel 75 mg (as pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Cipla Ltd.	11.53
49.	Rosuvastatin + Aspirin + Clopidogrel Capsule (Rosulip Gold 20)	Each hard gelatin capsule containing Rosuvastatin Calcium eq. to Rosuvastatin 20mg (as pellets) Aspirin IP 75 mg (as enteric coated pellets) Clopidogrel Bisulphate IP e. to Clopidogrel 75 mg (as pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Cipla Ltd.	17.88
50.	Rosuvastatin + Aspirin + Clopidogrel Capsule (Unistar Gold 10/75)	Each hard gelatin capsule containing Rosuvastatin Calcium eq. to Rosuvastatin 10mg (as pellets) Aspirin IP 75 mg (as enteric coated pellets) Clopidogrel Bisulphate IP e. to Clopidogrel 75 mg (as pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Torrent Pharmaceuticals Ltd	11.53
51.	Rosuvastatin + Aspirin + Clopidogrel Capsule (Unistar Gold 20/75)	Each hard gelatin capsule containing Rosuvastatin Calcium eq. to Rosuvastatin 20mg (as pellets) Aspirin IP 75 mg (as enteric coated pellets) Clopidogrel Bisulphate IP e. to Clopidogrel 75 mg (as pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Torrent Pharmaceuticals Ltd	17.88

52.	Glimepiride + Metformin HCL tablet	Each uncoated bilayered tablet containing Glimepiride IP 0.5 mg Metformin Hydrochloride IP 500 mg (as prolonged released form)	1 Tablet	M/s Windlas Biotech Pvt. Ltd. / M/s Glenmark Pharmaceuticals Ltd.	3.77
53.	Telmisartan + Metoprolol Tablet (Telmiprime Beta 25)	Each sustain release tablet containing Telmisartan 40mg Metoprolol 25 mg	1 Tablet	M/s Bioaltus Pharmaceuticals Pvt. Ltd. / M/s Primus Remedies Pvt. Ltd.	7.58
54.	Telmisartan + Metoprolol Tablet (Telmiprime Beta 50)	Each sustain release tablet containing Telmisartan 40mg Metoprolol 50 mg	1 Tablet	M/s Bioaltus Pharmaceuticals Pvt. Ltd. / M/s Primus Remedies Pvt. Ltd.	9.10
55.	Atorvastatin + Clopidogrel + Aspirin Capsule	Each hard gelatin capsule containing Atorvastatin Calcium IP eq. to Atorvastatin 20 mg (as pellets) Aspirin IP 75 mg (as enteric coated pellets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75 mg (as pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Zydus Healthcare Ltd. and M/s Tristar Formulations Pvt. Ltd. / M/s Zydus Healthcare Ltd.	5.22
56.	Atorvastatin + Clopidogrel + Aspirin Capsule	Each hard gelatin capsule containing Atorvastatin Calcium IP eq. to Atorvastatin 10 mg (as pellets) Aspirin IP 75 mg (as enteric coated pellets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75 mg (as pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Zydus Healthcare Ltd. and M/s Tristar Formulations Pvt. Ltd. / M/s Zydus Healthcare Ltd.	3.86
57.	Methylcobalamin + Metformin Tablet (Glycomet 500 MC)	Each film coated tablet contains: Metformin Hydrochloride IP 500mg (As SR form) Methylcobalamin J.P. 750mcg	1 Tablet	M/s Aeon Formulations Pvt. Ltd. / M/s USV Pvt. Ltd.	5.45
58.	Methylcobalamin + Metformin Tablet (Glycomet 1000 MC)	Each film coated tablet contains: Metformin Hydrochloride IP 1000mg (As SR form) Methylcobalamin J.P. 750mcg	1 Tablet	M/s Aeon Formulations Pvt. Ltd. / M/s USV Pvt. Ltd.	7.97
59.	Ferrous Ascorbate + Folic Acid + Zinc Sulphate Tablet (Provikon-Fe)	Each film coated tablet contains: Ferrous Ascorbate eq. to elemental iron 100mg Folic Acid IP 1.5mg Zinc Sulphate Monohydrate eq. to elemental Zinc 22.5mg	1 Tablet	M/s Pharmafabrikon	6.22
60.	Ferrous Ascorbate + Folic Acid Suspension (Provikon-Fe)	Each 5ml contains: Ferrous Ascorbate eq. to elemental iron 30mg Folic Acid IP 550mcg	1 ML	M/s Pharmafabrikon	0.744

61.	Acelofenac + Paracetamol Tablet (Winace)	Each film coated tablet contains: Acelofenac IP 100 mg Paracetamol IP 325 mg	1 Tablet	M/s Windlas Biotech Pvt. Ltd. / M/s Win Medicare Pvt. Ltd.	3.34
62.	Diclofenac Sodium Injection	Each ml injection contains: Diclofenac Sodium IP 75 mg Benzyl Alcohol IP 4WV (as preservative) Water for injection Ip QS	1 ML Pack	M/s Bennet Pharmaceuticals Ltd.	20.00
63.	Telmisartan + Amlodipine + Chlorthalidone Tablet (CTD-Tam 6.25/40/5)	Each film coated tablet contains: Telmisartan IP 40 mg Amlodipine Besylate IP eq. to Amlodipine 5 mg Chlorthalidone IP 6.25 mg	1 Tablet	M/s Akum Drugs & pharmaceuticals Ltd. / M/s Ipca Laboratories Ltd.	8.62
64.	Telmisartan + Amlodipine + Chlorthalidone Tablet (CTD-Tam 12.5/40/5)	Each film coated tablet contains: Telmisartan IP 40 mg Amlodipine Besylate IP eq. to Amlodipine 5 mg Chlorthalidone IP 12.5 mg	1 Tablet	M/s Akum Drugs & pharmaceuticals Ltd. / M/s Ipca Laboratories Ltd.	8.75
65.	Telmisartan + Amlodipine + Chlorthalidone Tablet (CTD-Tam 6.25/80/5)	Each film coated tablet contains: Telmisartan IP 80 mg Amlodipine Besylate IP eq. to Amlodipine 5 mg Chlorthalidone IP 6.25 mg	1 Tablet	M/s Akum Drugs & pharmaceuticals Ltd. / M/s Ipca Laboratories Ltd.	14.40
66.	Telmisartan + Amlodipine + Chlorthalidone Tablet (CTD-Tam 12.5/80/5)	Each film coated tablet contains: Telmisartan IP 80 mg Amlodipine Besylate IP eq. to Amlodipine 5 mg Chlorthalidone IP 12.5 mg	1 Tablet	M/s Akum Drugs & pharmaceuticals Ltd. / M/s Ipca Laboratories Ltd.	14.00
67.	Telmisartan + Amlodipine + Chlorthalidone Tablet (Telvas 3D CT 80)	Each film coated tablet contains: Telmisartan IP 80 mg Amlodipine Besylate IP eq. to Amlodipine 5 mg Chlorthalidone IP 12.5 mg	1 Tablet	M/s Akum Drugs & pharmaceuticals Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	14.12
68.	Telmisartan + Amlodipine + Chlorthalidone Tablet (Telvas 3D CT 40)	Each film coated tablet contains: Telmisartan IP 40 mg Amlodipine Besylate IP eq. to Amlodipine 5 mg Chlorthalidone IP 12.5 mg	1 Tablet	M/s Akum Drugs & pharmaceuticals Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	8.91
69.	Telmisartan + Cilnidipine + Chlorthalidone Tablet (CTD-TC 6.25)	Each film coated tablet contains: Telmisartan IP 40 mg Cilnidipine IP 10 mg Chlorthalidone IP 6.25 mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Ipca Laboratories Ltd.	10.16
70.	PEG L-Asparaginase Injection	Each 5 ml vial injection contains: PEG L-Asparaginase Injection 750 IU/ml	5 ML/Vial	M/s Virchow Biotech Pvt. Ltd. / M/s Cadila Pharmaceuticals Ltd	38730.74
71.	PEG L-Asparaginase Injection	Each 5 ml vial injection contains: PEG L-Asparaginase Injection 750 IU/ml	5 ML/Vial	M/s Cadila Healthcare Ltd.	38730.74

72.	Ferrous Ascorbate + Folic Acid + Cyanocobalamin + Pyridoxine + Cholecalciferol tablet	Each film coated tablet containing Ferrous Ascorbate eq. to elemental iron 100mg Folic Acid IP 1.5 mg Cyanocobalamin (Vitamin B12) IP 7.5mcg Pyridoxine Hydrochloride (Vitamin B6) IP 1.5 mg Cholecalciferol (Vitamin D3) IP 1000IU	1 Tablet	M/s Tirupati Medicare Ltd. / M/s Cadila Healthcare Ltd.	9.44
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5. Agenda item no. 5 - Implementation of review orders

5.1 Agenda item no. 5(i) - Review order in respect of M/s Sun Pharmaceutical Industries Ltd against price fixation of Histac EVT 2's AI Strip and Fucibet Cream 15 gm AI Tube.

5.1.1 The authority deliberated upon and considered the review order issued by DoP and observed that the notification no. 579(E) dated 24.02.2016, issued in order to implement the review order under DPCO 1995 for price fixation of Fucibet cream which is presently applicable, shall continue and no further action is required as per the review order no. 31015/7/2013-PLI dated 18.05.2018 of DoP. It, therefore, decided to close the review order.

5.2 Agenda item no. 5(ii) - Review order in respect of M/s Unison Pharmaceuticals Pvt. Ltd for retail price fixation of (a) Glimepride 1 mg + Metformin HCL SR 500 mg + Pioglitazone 15 mg and (b) Glimepride 1 mg + Metformin HCL SR 500 mg + Pioglitazone 15 mg

5.2.1 The authority deliberated upon and considered the review order of DoP and noted that the company has started manufacturing of the subject formulations prior to DPCO, 2013 and therefore, subject formulations do not fall under the definition of 'new drug' as per the definitions of DPCO, 2013. It, therefore, decided that retail price notified for the subject formulations in respect of M/s Unison Pharmaceuticals Pvt. Ltd may be withdrawn.

5.3 Agenda item no. 5(iii) - Review order in respect of M/s Sun Pharma laboratories Ltd for retail price fixation of (i) Tigatel AM 40 tablet (ii) Tigatel H 40 tablet (iii) Tigatel H 80 tablet (iv) Tigatel AMH 40 tablet (v) Tigatel AMH 80 tablet.

5.3.1 The authority deliberated upon and considered the review order of DoP for working out the retail prices strictly as per para 5(i) of DPCO, 2013 and decided to revise the retail prices of Tigatel AM 40 tablet, Tigatel H 40 tablet, Tigatel H 80 tablet, Tigatel AMH 40 tablet and Tigatel AMH 80 tablet as Rs.7.74, Rs.8.36, Rs.13.35, Rs.8.33 and Rs.13.06 per tablet, respectively.

5.4 Agenda item no. 5(iv) - Review order in respect of M/s Sanofi-Synthelabo (India) Private Limited against price fixation of Amiodarone 50mg/ml Injection.

5.4.1 The authority deliberated upon and considered the review order of DoP for working out the ceiling price after considering MAT value and PTR of M/s Sanofi (India) Pvt. Ltd's product 'Cardarone' and decided to revise the ceiling price of Amiodarone 50mg/ml Injection to Rs. 20.94 per ml.

5.5 Agenda item no. 5(v) - Review order in respect of M/s Torrent Pharmaceuticals Ltd for retail price fixation of Rozucor Gold 10 capsule (Rosuvastatin 10m + Aspirin 75 mg + Clopidogrel 75 mg).

5.5.1 The authority deliberated upon and considered the review order for working out the retail price strictly as per para 5(i) of DPCO, 2013 and decided to revise the retail price of Rozucor Gold 10 capsule (Rosuvastatin 10m + Aspirin 75 mg + Clopidogrel 75 mg) to Rs. 11.70 per capsule.

5.6 Agenda item no. 5(vi) - Review order in respect of M/s Mylan Pharmaceuticals Pvt Ltd against price fixation of Amphotericin B Lipid/Liposomal PFI 50 mg.

5.6.1 The authority deliberated upon and considered the review order for working out the ceiling price by taking the revised PTR of 'Amphomul' and decided to revise the ceiling price of Amphotericin B Lipid/Liposomal PFI 50 mg to Rs. 3844.83 per pack.

5.7 Agenda item no. 5(vii) - Review order in respect of M/s Lupin Ltd for retail price fixation of Ramipril 5 mg + Amlodipine 5 mg tablet.

5.7.1 The authority deferred the case and decided that it be taken up in the next meeting.

5.8 Agenda item no. 5(viii) - Review order in respect of M/s J.B. Chemicals & Pharmaceuticals Limited against price fixation of Ranitidine Oral liquid 75mg/5ml, Metronidazole 200mg Tablet and Metronidazole 400 mg tablet.

5.8.1 The authority deliberated upon and considered the review order for working out the ceiling prices based on corrected data and decided to revise the ceiling prices of Ranitidine Oral liquid 75mg/5ml, Metronidazole 200mg Tablet and Metronidazole 400 mg tablet to Rs. 0.68 per ml, Rs. 0.43 per tablet and Rs.0.80 per tablet respectively.

5.9 Agenda item no. 5(ix) - Review order in respect of M/s IPCA Laboratories Ltd against price fixation of Methotrexate 2.5 mg, 7.5 mg and 10 mg tablet.

5.9.1 The authority deliberated upon and considered the review order and noted that the review order directed re-fixation of the ceiling prices of methotrexate 2.5 mg, 7.5 mg and 10 mg tablet by considering only the brands and generic versions of the medicine having market share more or equal to 1%. It noted that as the same had already been considered while implementing the review order dated 05.04.2018, therefore, no further action was required.

5.10 Agenda item no. 5(x) - Review order in respect of M/s Sun Pharmaceutical Industries Ltd for retail price fixation of (i) Stanocef-O Plus Tablet (ii) Volitra Enzo tablet.

5.10.1 The authority deliberated upon and considered the review order for working out the retail prices strictly as per para 5(i) of DPCO, 2013 and decided to revise the retail prices of Stanocef-O Plus Tablet and Volitra Enzo tablet to Rs. 10.59 and Rs.14.10 per tablet respectively.

5.11 Agenda item no. 5(xi) - Review order in respect of M/s IPCA Laboratories Limited against price fixation of Pacimol Spas Tablets and Pacimol Active tablet.

5.11.1 The authority deliberated upon and considered the review order for working out the retail prices based on corrected data and decided to revise the retail prices of Pacimol Spas Tablets and Pacimol Active tablet to Rs. 1.78 and Rs.2.36 per tablet respectively.

5.12 & 5.13 Agenda item no. 5(xii) and 5 (xiii) - Review order of Sevoflurane Inhalation in respect of M/s Piramol Enterprises Ltd and M/s Abbott India Ltd.

5.12.1 and 5.13.1 The authority deliberated upon and considered the review order for working out the ceiling price after considering PTR and MAT value of M/s Piramol Enterprises Ltd's product 'Sevoflurane' and decided to revise the ceiling price of Sevoflurane Inhalation to Rs. 28.07 per ml.

5.14 Agenda item no. 5(xiv) - Review order of Autrin-XT film coated tablet containing Ferrous Ascorbate eq to elemental iron 100 mg + Folic acid 1.5 mg + Cyanocobalamin IP 15 mcg + Zinc Sulphate Monohydrate IP eq to elemental zinc 22.5 mg in respect of M/s Pfizer Ltd.

5.14.1 The authority deferred the case and decided that it be taken up in the next meeting.

5.15 Agenda item no. 5(xv) - Review order in respect of M/s Sun Pharma Laboratories Limited against price fixation of Oxaliplatin 50 mg injection.

5.15.1 The authority deliberated upon and considered the review order for working out the ceiling price after considering PTR and MAT value of M/s Sun Pharma Ltd product 'Oxidach 50mg' and decided to revise the ceiling price of Oxaliplatin 50 mg injection to Rs. 2439.44 per pack.

5.16 Agenda item no. 5(xvi) - Review order in respect of M/s Sun Pharma Laboratories Limited against price fixation of Tigatel ACH-40 tablet.

5.16.1 The authority deliberated upon and considered the review order for working out the retail price strictly as per para 5(i) of DPCO, 2013 and decided to revise the retail price of Tigatel ACH-40 tablet to Rs. 9.00 per tablet.

5.17 Agenda item no. 5(xvii) - Review order in respect of M/s Serum Institute of India Pvt. Ltd Tetanus Toxoid Injection.

5.17.1 The authority deliberated upon and considered the review order. It decided that the stay order passed by Hon'ble Delhi High Court and its implication be examined and the case be resubmitted in the next Authority meeting.

5.18 Agenda item no. 5(xviii) - Review order in respect of M/s Glenmark Pharmaceuticals Ltd against price fixation of Clotrimazole 1% cream (Review order no. 31015/19/2017-Pricing dated 10.01.2018).

5.18.1 The authority deliberated upon and considered the review order for working out the ceiling price after considering the revised MAT value of the product of M/s Midas care Pharmaceuticals and decided to revise the ceiling price of Clotrimazole 1% cream to Rs. 2.73 per gm.

5.19 Agenda item no. 5(xix) - Representation of M/s Bharat Serum and Vaccines Ltd against price fixation of Anti-Tetanus Immunoglobulin.

5.19.1 The authority deferred the case and decided that it be taken up in the next meeting.

5.20 Agenda item no. 5(xx) - Directions in the review application 31015/108/2017-Pricing dated 19-April-2018 in respect of M/s Acculife Healthcare Ltd against price fixation of Dextran 40 Injection.

5.20.1 The authority deliberated upon and considered the review order for working out the ceiling price on the basis of MAT value and PTR of the products of M/s Acculife Healthcare Ltd, M/s Otsuka Pharmaceuticals Ltd and M/s Shreya Lifescience Ltd and decided to revise the ceiling price of Dextran 40 Injection to Rs. 0.80 per ml.

6. Agenda item no. 6 - Fixation of retail price of a new drug for existing manufacturers of scheduled formulations in the event of the new drug not available in domestic market.

6.1 The Authority deliberated upon the issue in detail and directed that existing practice may be continued.

7. Agenda item no. 7 - Report on Price Fixation of Methyldopa 500mg tablet of M/s Wockhardt Ltd.

7.1 The Authority deliberated upon and approved the recommendations made by the Committee.

8. Agenda item no. 8 - Agenda note on Form-IV applications of M/s. Medopharm for discontinuation of 12 scheduled formulations under Para 21 (2) of DPCO, 2013.

8.1 Approved.

9. Agenda item no. 9 - Agenda note on Form-IV application submitted by M/s. GlaxoSmithKline Consumer Private Limited for discontinuation of scheduled formulation Otrivin (Xylometazoline Hydrochloride Nasal Solution IP 0.1% w/v).

9.1 The Authority deliberated upon the issue and directed NPPA to recommend to DoP to consider invoking para 3 of DPCO, 2013.

10. Agenda item no. 10 - Agenda for Authority Meeting to be held on 06.08.2018 on registration of various products as “Cosmetics” instead of “Drugs” under Drugs and Cosmetics Act, 1940.

10.1 Noted.

11. Agenda item no. 11 - Ceiling prices fixed on the basis of Procurement prices of Institutions.

11.1 The Authority deliberated upon the agenda and approved the agenda for withdrawal of notification w.r.t Ferrous salt (A) + Folic Acid (B) - 20 MG (A) + 100 mcg (B) /ml (IFA Syrup) and Ferrous salt (A) + Folic Acid (B) - Tablet 45 MG (A) + 400 mcg (B) tablet formulations.

12. Agenda item no. 12 - Price Revision of Human normal Immunoglobulin.

12.1 The Authority directed NPPA to collect additional data in respect of 10% Human normal Immunoglobulin, if available, and resubmit the case in the next meeting of the Authority.

13. Agenda item no. 13 - Representation for the ceiling price of DPT vaccine under DPCO 2013.

13.1 Deferred.

14. Agenda item no. 14 - Revision of the ceiling price of BCG vaccine under DPCO 2013 by M/s Serum Institute of India.

14.1 Deferred.

15. Agenda item no. 15 - Ceiling price of Orthopedic knee implants.

15.1 The Authority reviewed the ceiling price of Orthopedic knee implants and decided to extend the price notification so no. 2668 (E) dated 16.08.2017 for another one year i.e upto 15.08.2019.

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

(Ritu Dhillon)
Member Secretary