

मिसिल स.- 8(60)/2018/डी.पी/एनपीपीए-डीवी-II

F. No. 8(60)/2018/DP/NPPA-Div. II

कार्यवाहीस. : 192/60/2018/F

Proceeding No : 192/60/2018/F

Minutes of the 192nd (overall) and 60th meeting of the Authority under DPCO, 2013 held on 29.10.2018 at 11:30 AM

The 192nd meeting of the Authority (overall), which is the 60th meeting under the DPCO, 2013, was held on 29th Oct., 2018 at 11:30 AM 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 B. Bandhopadhyay, Adviser, O/o Chief Adviser (Cost), Department of Expenditure.
- (iii) Dr. S. Eswara Reddy, Drugs Controller General (India)
- (iv) 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 Amarपाल Singh Sawhney, Director (Pricing)
- iii. Shri Rajesh Aggarwal, Joint Director (M&E)
- iv. Shri Baljit Singh, Asstt. Director (Pricing)
- v. 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 59th Meeting held on 08.08.2018.

1.1 The Authority confirmed the minutes of the 191st (overall) and the 59th Meeting under DPCO 2013 held on 08.08.2018.

2. Agenda item no. 2 - Action Taken Report

2.1 Noted.

3. Agenda item no. 3 - Price fixation of Ceiling Prices under NLEM, 2015.

3.1 Authority discussed the following cases of ceiling prices fixation/revision as presented in Agenda no. 3 falling under the purview of para 4 and 6 of DPCO, 2013 and approved the ceiling prices in following 5(five) cases:

S. NO.	NAME OF THE MEDICINE	DOSAGE FORM & STRENGTH	UNIT	APPROVED CEILING PRICE (Rs.)
(1)	(2)	(3)	(4)	(5)
1	Nitrous oxide	Inhalation	Cubic meter	219.29
2	Oxygen	Inhalation (Medicinal gas)	Cubic Meter	16.47
3	Dimercaprol	Injection 50 mg/ml	Per ml	187.85
4	Phytomenadione (Vitamin K1)	Tablet 10mg	Per tablet	13.63
5	Paracetamol	Oral Liquid 100 mg/ml (paediatric)	Per ml	1.52

4. Agenda item no. 4 – Status of New Drug applications.

4.1 Noted.

4.2 The Authority discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 4 [(i) to (lviii)] falling under the purview of para 2(u) of DPCO, 2013 and approved the retail prices in 55(fifty five) cases under para 5 and para 15 of the DPCO 2013(except cases at serial no 28 to30). 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.	Teneligliptin Hydrobromide + Metformin HCL (SR) Tablet	Each uncoated bilayer tablet contains: Teneligliptin Hydrobromide Hydrate eq to Teneligliptin 20 mg Metformin Hydrochloride IP 1000 mg (SR)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Anthem Biopharma Pvt. Ltd.	10.23
2.	Metformin HCL + Glimepiride Tablet (Semi Amaryl M)	Each uncoated bilayer tablet contains: Metformin Hydrochloride IP (in prolonged release form) 500 mg Glimepiride IP 0.5 mg	1 Tablet	M/s Windlass Biotech Pvt. Ltd. / M/s Sanofi India Ltd.	3.77
3.	Telmisartan + Cilnidipine + Chlorthalidone tablet	Each film coated tablet contains: Telmisartan IP 40 mg Chlorthalidone IP 6.25 mg Cilnidipine IP 10 mg	1 Tablet	M/s Windlass Biotech Pvt. Ltd / M/s Abbott Healthcare Pvt. Ltd	10.31
4.	Clarithromycin for Oral Suspension	Each 5ml (after reconstitution) contains: Clarithromycin IP 250mg, Titanium Dioxide IP (-).	1 ML	M/s Cipla Limited	5.49
5.	Telmisartan + Amlodipine +	Each film coated tablet contains: Telmisartan IP 40 mg	1 Tablet	M/s Akums Drugs & pharmaceuticals Ltd	8.91

	Chlorthalidone Tablet (Telmelife 3D)	Amlodipine Besylate IP eq to Amlodipine 5 mg Chlorthalidone IP 12.5 mg		/ M/s Neomac Pharmaceuticals Pvt. Ltd	
6.	Atorvastatin + Clopidogrel Capsule	Each hard gelatin capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin (As film coated tablet) 20 mg Clopidogrel Bisulphate IP eq. to Clopidogrel (as two film coated tablet each containing 37.5mg) 75 mg	1 Capsule	M/s Windlas Biotech Ltd. / M/s Abbott Healthcare Pvt. Ltd.	9.50
7.	Amoxicillin + Potassium Clavulante tablet (Clanoxy DT)	Each uncoated dispersible tablet contains: Amoxicillin Trihydrate eq to Amoxicillin 200mg Potassium Clavulante IP eq to Clavulanic Acid 28.5mg	1 Tablet	M/s Saitech Medicare Pvt. Ltd. / M/s Galpha Laboratories Ltd.	7.45
8.	Tramadol + Paracetamol Tablet (Trson-P)	Each film coated tablet contains: Tramadol Hydrochloride IP 37.5 mg Paracetamol IP 325 mg	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	2.49
9.	Voglibose + Metformin Tablet (Voglyson-M 0.3)	Each uncoated bilayered tablet contains: Voglibose IP 0.3 mg Metformin Hydrochloride IP 500 mg (as sustained release form)	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	3.86
10.	Rosuvastatin + Aspirin + Clopidogrel Capsules	Each hard gelatin capsules contains: Rosuvastatin Calcium IP eq to Rosuvastatin 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 Intas Pharmaceuticals Ltd.	11.62
11.	Mycophenolate Mofetil Oral Suspension IP	Each 5 ml of reconstituted suspension contains: Mycophenolate Mofetil IP 1 g (1 bottle with 110 gm powder for oral suspension containing 35 gm Mycophenolate Mofetil)	Each Pack	M/s Panacea Biotec Ltd.	5238.09
12.	Bisacodyl Suppository	Each Suppository contains: Bisacodyl IP 10 mg	1 Suppository	M/s Meridian Enterprises Pvt. Ltd.	18.63
13.	Telmisartan + Chlorthalidone Tablet (Telmelife CH 40)	Each film coated tablet contains: Telmisartan IP 40 mg Chlorthalidone IP 12.5 mg	1 Tablet	M/s Akum Drugs & Pharmaceuticals Ltd. / M/s Neomac Pharmaceuticals Pvt. Ltd.	8.00
14.	Cilnidipine + Telmisartan Tablet	Each film coated tablet contains: Telmisartan IP 80 mg Cilnidipine 10 mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Abbott Healthcare Pvt. Ltd.	10.60

15.	Divalproex Tablet (Diwok OD 750 mg)	Each film coated extended release tablet contains: Divalproex Sodium IP eq to Valproic Acid 750 mg	1 Tablet	M/s Swiss Garnier Biotech / M/s Wockhardt Ltd.	11.24
16.	Clotrimazole + Beclomethasone Dipropionate Cream	Cream contains: Clotrimazole IP 1.00% w/w Beclomethasone Dipropionate IP 0.025% w/w	1 GM	M/s Curetech Skincare / M/s Mankind Pharma Ltd.	4.46
17.	Telmisartan + Chlorthalidone Tablet (Cesar CT)	Each uncoated bilayered tablet contains: Telmisartan IP 40 mg Chlorthalidone IP 6.25 mg	1 Tablet	M/s Acme Formulations Pvt. Ltd. / M/s Cipla Ltd.	7.71
18.	Baclofen Oral Solution	Each 5 ml contains: Baclofen IP 5 mg	1 ML	M/s Sun Pharmaceutical Industries Ltd. / M/s Sun Pharma Laboratories Ltd.	1.42
19.	Glimepiride + Metformin Hydrochloride Tablet	Each uncoated bilayered tablet contains: Metformin Hydrochloride IP (as prolonged release) 500 mg Glimepiride IP 3 mg	1 Tablet	M/s Sun Pharma Laboratories Ltd.	6.99
20.	Glimepiride + Metformin Hydrochloride Tablet	Each uncoated bilayered tablet contains: Metformin Hydrochloride IP (as prolonged release) 500 mg Glimepiride IP 4 mg	1 Tablet	M/s Sun Pharma Laboratories Ltd.	8.58
21.	Glimepiride + Metformin Hydrochloride Tablet	Each uncoated bilayered tablet contains: Metformin Hydrochloride IP (as prolonged release) 1000mg Glimepiride IP 4 mg	1 Tablet	M/s Sun Pharma Laboratories Ltd.	9.78
22.	Metformin HCL + Gliclazide + Pioglitazone Tablets	Each uncoated bilayered tablet contains: Metformin Hydrochloride IP (sustained release) 500 mg Gliclazide IP (sustained release) 30 mg Pioglitazone HCL eq to Pioglitazone 15 mg	1 Tablet	M/s Eris Lifesciences Ltd.	5.78
23.	Metformin HCL + Gliclazide + Pioglitazone Tablets	Each uncoated bilayered tablet contains: Metformin Hydrochloride IP (sustained release) 500 mg Gliclazide IP (sustained release) 60 mg Pioglitazone HCL eq to Pioglitazone 15 mg	1 Tablet	M/s Eris Lifesciences Ltd.	8.29
24.	Chlorthalidone + Telmisartan Tablet (Telsar CH 40/6.25)	Each film coated tablet contains: Chlorthalidone IP 6.25 mg Telmisartan IP 40 mg	1 Tablet	M/s Gkm New Pharma / M/s Torrent Pharmaceuticals Ltd.	7.71
25.	Chlorthalidone + Telmisartan	Each film coated tablet contains: Chlorthalidone IP 12.5mg Telmisartan IP 40 mg	1 Tablet	M/s Gkm New Pharma / M/s Torrent	8.03

	Tablet (Telsar CH 40/12.5)			Pharmaceuticals Ltd.	
26.	Chlorthalidone + Telmisartan Tablet (Telsar CH 80/12.5)	Each film coated tablet contains: Chlorthalidone IP 12.5mg Telmisartan IP 80 mg	1 Tablet	M/s Gkm New Pharma / M/s Torrent Pharmaceuticals Ltd.	13.91
27.	Divalproex Tablet (Diwok OD 250 mg)	Each film coated extended release tablet contains: Divalproex Sodium IP eq. to Valproic Acid 250 mg	1 Tablet	M/s Swiss Garnier Biotech / M/s Wockhardt Ltd.	5.45
28.	Telmisartan + Amlodipine Tablet (Telmiride-AMH)	Each uncoated bilayered tablet contains: Telmisartan IP 40 mg Amlodipine Besylate IP eq. to Amlodipine 5mg Hydrochlorothiazide IP 12.5 mg	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	Deferred
29.	Telmisartan + Metoprolol Tablet (Telmiride-MT 25)	Each uncoated bilayered tablet contains: Telmisartan IP 40 mg Metoprolol Succinate IP 23.75 eq to Metoprolol Tartrate IP 25 mg (as extended release)	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	Deferred
30.	Telmisartan + Metoprolol Tablet (Telmiride-MT 50)	Each uncoated bilayered tablet contains: Telmisartan IP 40 mg Metoprolol Succinate IP 47.5 eq. to Metoprolol Tartrate IP 50mg (as extended release)	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	Deferred
31.	Voglibose + Metformin tablet	Each uncoated tablet contains: Voglibose IP 0.2 mg Metformin HCL IP 500 mg	1 Tablet	M/s Eris Lifesciences Ltd.	6.57
32.	Amoxycillin + Potassium Clavulnate Dry Syrup (Blumox-CA Forte)	Each combipack containing: a) Amoxycillin and Potassium Clavulanate Oral Suspension IP Each 5 ml suspension containing Amoxycillin Trihydrate IP eq to Amoxycillin 400 mg Potassium Clavulnate diluted IP eq to Clavulanic Acid 57 mg b) 1 vial sterile water for injection IP Each vial containing Sterile water for injection IP 30 ml	1 ML	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Blue Cross Laboratories Pvt. Ltd.	3.16
33.	Rosuvastatin + Aspirin + Clopidogrel Capsules	Each hard gelatin capsules contains: Rosuvastatin Calcium IP eq to Rosuvastatin 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 Emcure Pharmaceuticals Ltd.	17.88
34.	Rosuvastatin + Aspirin + Clopidogrel Capsules	Each hard gelatin capsules contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg (as pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Emcure	11.62

		Aspirin IP 75mg (as enteric coated pellets) Clopidogrel Bisulphate IP eq to Clopidogrel 75mg (as pellets)		Pharmaceuticals Ltd.	
35.	Diclofenac + Virgin Linseed Oil + Methyl Salicylate + Menthol + Capsaicin Gel (Diclofam Hot)	Gel containing Diclofenac Diethylamine BP 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% Capsaicin USP 0.0255w/w	1 GM	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Abbott Healthcare Pvt. Ltd.	2.41
36.	Clotrimazole + Lignocaine Ear Drops (Triben)	Ear drops contains: Clotrimazole IP 1.0% w/v Lignocaine Hydrochloride IP 2.0% w/v	1 ML	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Jenburkt Pharmaceuticals Ltd.	5.27
37.	Timolol + Brinzolamide Eye Drops	Each ml contains Brinzolamide IP 1.0 w/v Timolol Maleate IP eq. to Timolol 0.5% w/v, Benzalkonium Chloride IP 0.01% w/v (as preservative)	5ML	M/s Ajanta Pharma Ltd.	283.25
38.	Diclofenac + Methyl + Menthol GEL (Volini Maxx Gel)	Contains: Diclofenac Diethylamine BP 2.32% w/w (eq. to Diclofenac Sodium 2% w/w), Methyl Salicylate IP 10% w/w & Menthol IP 5% w/w	Each Pack (20 gram)	M/s Sun Pharmaceutical Industries Ltd.	125.00
39.	Diclofenac + Methyl + Menthol GEL (Volini Maxx Gel)	Contains: Diclofenac Diethylamine BP 2.32% w/w (eq. to Diclofenac Sodium 2% w/w), Methyl Salicylate IP 10% w/w & Menthol IP 5% w/w	Each Pack (30 gram)	M/s Sun Pharmaceutical Industries Ltd.	187.50
40.	Olmesartan + Amlodipine + Chlorthalidone Tablet (TRIOLSAR 20)	Each film coated tablet contains: Olmesartan Medoxomil 20mg, Chlorthalidone IP 6.25mg, Amlodipine Besylate IP eq. to Amlodipine 5mg tablets	1 Tablet	M/s GKM New Pharma Ltd. / M/s Unichem Laboratories Limited	9.585
41.	Olmesartan + Amlodipine + Chlorthalidone Tablet (TRIOLSAR 40)	Each film coated tablet contains: Olmesartan Medoxomil 40mg, Chlorthalidone IP 6.25mg, Amlodipine Besylate IP eq. to Amlodipine 5mg tablets	1 Tablet	M/s GKM New Pharma Ltd. / M/s Unichem Laboratories Limited	15.61
42.	Losartan + Chlorthalidone + Amlodipine Tablet (TRILOSAR 6.25)	Each film coated tablet contains: Losartan Potassium IP 50mg, Chlorthalidone IP 6.25mg, Amlodipine Besylate IP eq. to Amlodipine 5mg tablets	1 Tablet	M/s GKM New Pharma Ltd. / M/s Unichem Laboratories Limited	6.36

43.	Losartan + Chlorthalidone + Amlodipine Tablet (TRILOSAR 12.50)	Each film coated tablet contains: Losartan Potassium IP 50mg, Chlorthalidone IP 12.50mg, Amlodipine Besylate IP eq. to Amlodipine 5mg tablets	1 Tablet	M/s GKM New Pharma Ltd. / M/s Unichem Laboratories Limited	6.41
44.	Darunavir + Ritonavir tablet	Each film coated tablet contains: Darunavir Ethanolate eq. to Darunavir 600mg and Ritonavir IP 100mg tablet	1 Tablet	M/s Emcure Pharmaceuticals Limited	172.52
45.	Telmisartan + Amlodipine + Chlorthalidone Tablet (Tazloc AC 12.5)	Each uncoated bilayered tablet contains: Telmisartan IP 40 mg Amlodipine Besylate IP eq. to Amlodipine 5 mg Chlorthalidone IP 12.5 mg	1 Tablet	M/s Aeon Formulations Pvt. Ltd. / M/s USV Pvt. Ltd.	8.91
46.	Darunavir + Ritonavir tablet (Durart - R 450)	Each film coated tablet Contains: Darunavir 400mg & Ritonavir 50mg Tablets	1 Tablet	M/s Mylan Laboratories Pvt. Ltd. / M/s Mylan Pharmaceuticals Pvt. Ltd.	123.71
47.	Diclofenac + Methyl + Menthol Gel (Diclotal MR Gel)	Contains: Diclofenac Diethylamine BP 1.16%w/w (eq. to Diclofenac Sodium 1%), Methyl Salicylate IP 5% w/w, Mephenesin IP 85 5%w/w, Menthol IP 2% w/w, Turpentine Oil BP 3%w/w	1 GM	M/s The Madras Pharmaceuticals / M/s Blue Cross Laboratories Pvt. Ltd.	2.46
48.	Lamivudine + Tenofovir + Dolugetravir tablet	Each uncoated tablet contains: Lamivudine IP 300mg, Tenofovir Disoproxil Fumarate IP 300mg eq. to Tenofovir Disoproxil 245mg, Dolugetravir Sodium eq. to Dolutegravir 50mg.	1 Tablet	M/s Emcure Pharmaceuticals Limited	114.06
49.	Darunavir + Ritonavir tablet (Danavir R)	Each film coated tablet contains: Darunavir Ethanolate eq. to Darunavir 800mg, Ritonavir 100mg Tablet	1 Tablet	M/s Hetero Labs Limited / M/s Hetero Healthcare Limited	212.91
50.	Lamivudine + Tenofovir + Dolugetravir tablet (ACRIPTEGA)	Each uncoated tablet contains: Lamivudine IP 300mg, Tenofovir Disoproxil Fumarate IP 300mg, Dolugetravir Sodium eq. to Dolutegravir 50mg.	1 Tablet	M/s Mylan Laboratories Limited / M/s Mylan Pharmaceuticals Private Limited	114.06
51.	Daclatasvir + Sofosbuvir tablet (HEPCINAT PLUS)	Each film coated tablet contains: Daclatasvir Dihydrochloride eq. to Daclatasvir 60mg, Sofosbuvir 400mg	1 Tablet	M/s Natco Pharma Limited	556.442

52.	Daclatasvir + Sofosbuvir tablet	Each film coated tablet contains: Daclatasvir Dihydrochloride eq. to Daclatasvir 60mg, Sofosbuvir 400mg	1 Tablet	M/s Natco Pharma Limited / M/s Cadila Healthcare Limited	556.442
53.	Daclatasvir + Sofosbuvir tablet (MYHEP DVIR)	Each film coated tablet contains: Daclatasvir Dihydrochloride eq. to Daclatasvir 60mg, Sofosbuvir 400mg	1 Tablet	M/s Mylan Laboratories Pvt. Ltd. / M/s Mylan Pharmaceuticals Pvt. Ltd.	556.442
54.	Diclofenac + Methyl + Menthol GEL (Volini Maxx Gel)	Contains: Diclofenac Diethylamine BP 2.32% w/w (eq. to Diclofenac Sodium 2% w/w), Methyl Salicylate IP 10% w/w & Menthol IP 5% w/w	Each Pack (15 gram)	M/s Sun Pharmaceutical Industries Ltd.	93.75
55.	Diclofenac + Methyl + Menthol GEL (Volini Maxx Gel)	Contains: Diclofenac Diethylamine BP 2.32% w/w (eq. to Diclofenac Sodium 2% w/w), Methyl Salicylate IP 10% w/w & Menthol IP 5% w/w	Each Pack (10 gram)	M/s Sun Pharmaceutical Industries Ltd.	62.50
56.	Ceftriaxone 1 gm plus Tazobactam 125 mg injection	Each injection vial contains: Ceftriaxone Sodium IP eq. to Ceftriaxone 1 gm Tazobactam Sodium eq. to Tazobactam 125 mg	1 Vial	M/s Innova Captab Pvt. Ltd. / M/s Emcure Pharmaceuticals Ltd	136.11
57.	Cefpodoxime + Potassium Dry Syrup (Cefoprox CV)	Each 5 ml of the reconstituted suspension Cefpodoxime Proxetil IP eq. to Cefpodoxime 50 mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 31.25 mg	1 ML	M/s Hetero Labs Ltd / M/s Cipla Limited	2.40
58.	Cefpodoxime + Potassium Dry Syrup (Cefoprox CV)	Each 5 ml of the reconstituted suspension Cefpodoxime Proxetil IP eq. to Cefpodoxime 100 mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 62.50 mg	1 ML	M/s Hetero Labs Ltd / M/s Cipla Limited	3.72

5. Agenda item no. 5 - Implementation of review orders

5.1 Agenda item no. 5(i) - Review order in respect of M/s Lupin ltd for retail price of Ramipril 5 mg + Amlodipine 5 mg tablet.

5.1.1 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 Ramipril 5 mg + Amlodipine 5 mg tablet to Rs. 12.04 per tablet.

5.2 Agenda item no. 5(ii) – Review order of Aurtin – XT coated tablet containing Ferrous Ascorbate eq. to element iron 100 mg + folic acid 1.4 mg + Cyanolobalamine IP 15 mcg + Zinc Sulphate Monohydrate IP eq elemental Zinc 22.5 mg in respect of Pfizer Ltd.

5.2.1 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 Aurtin – XT coated tablet to Rs. 8.01 per tablet.

5.3 Agenda item no. 5(iii) - Review order in respect of M/s Sun Pharma Laboratories Limited against price fixation of Sodium Valproate Oral Liquid 200mg/5 ml and Timolol Drops 0.5%.

5.3.1 The authority deliberated upon the review order w.r.t formulation Sodium Valproate Oral Liquid 200mg/ 5 ml to consider only those medicines having MAT value of more than 1% market share and observed that the ceiling price was already worked out and notified, considering only those medicines having MAT value of more than 1% market share and hence there is no change in ceiling price. In view of the above, the review order relating to Sodium Valproate Oral Liquid 200mg/ 5ml shall be treated as closed. In respect of Timolol Drops 0.5%, the Authority agreed with the view of the Expert Committee that the formulation is not covered in para 11(3) of DPCO, 2013. Hence, the Authority decided to close the review order of Timolol 0.5% with no change in the ceiling price.

5.4 Agenda item no. 5(iv) - Review order in respect of M/s Sun Pharmaceutical Industries Limited against price fixation of Ciprofloxacin 250 mg and 500 mg tablet.

5.4.1 The authority deliberated upon the review order w.r.t formulation Ciprofloxacin 250 mg tablet to verify the MAT and PTR data for CIFRAN 250 mg Tablet and revise the ceiling price. After considering the documents submitted by the company and the confirmation from the Pharmatrac, it was noted that PTR of Rs. 16.76 considered by NPPA while working out the ceiling price has the maximum count as per pharmatrac in August 2015. Therefore, the PTR considered by NPPA for working out ceiling price is correct. Hence, there is no change in ceiling price. In respect of Ciprofloxacin 500 mg tablet the Authority agreed with the view of the Expert Committee that is not covered in para 11(3) of DPCO, 2013. Hence, the Authority decided to close the review order of ciprofloxacin 500 mg tablet with no change in the ceiling price.

5.5 Agenda item no. 5(v) - Review order in respect of M/s Alembic Pharmaceuticals Limited against price fixation of Valembic 80AM and Valembic 160AM tablet.

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 Valembic 80AM and Valembic 160AM tablet to Rs. 5.56 and Rs.8.56 per tablet respectively.

5.6 Review against retail price fixation of Triolmezest CH 20 tablet & Triolmezest CH 40 tablet (for M/s Sun Pharma Laboratories Ltd) and Rosuvas CV 10 tablet (for M/s Sun Pharmaceutical industries Ltd).

5.6.1 The authority deliberated upon and considered the review order for working out the retail price and decided to revise the retail price of Triolmezest CH 20 tablet, Triolmezest CH 40 tablet and Rosuvas CV 10 tablet to Rs. 9.15, Rs.16.19 and Rs.11.43 per tablet respectively.

5.7 Agenda item no. 5(vii) – Representation of M/s Bharat Serum and Vaccines Ltd against price fixation of Anti Tetanus Immunoglobulin.

5.7.1 The authority deliberated upon and considered the representation of the company as directed by DoP and decided to consider the representation against ceiling price earlier fixed under para 19 on the basis of institutional procurement price of Anti Tetanus Immunoglobulin 250 IU and revised the ceiling price to Rs. 1043.05 per pack under para 4(1) considering relevant market data.

5.8 Agenda item no. 5(viii) - Review order in respect of M/s Serum Institute of India Pvt Ltd. Tetanus Toxoid injection.

5.8.1 The authority deliberated upon and considered the review order for working out the ceiling price and decided to revise the ceiling price of Tetanus Toxoid injection to Rs. 9.95 and Rs.21.43 for 0.5 ml pack and 5 ml pack respectively.

5.9 Agenda item no. 5(ix) - Ceiling prices fixed on the basis of Procurement prices of Institutions

5.9.1 The Authority deliberated upon the agenda and approved the agenda for withdrawal of notification w.r.t Vitamin A oral liquid 100000 IU/ml. The Authority further discussed that Vitamin A oral liquid 100000 IU/ml is procured by the State Government Agencies for NHM programme, therefore, state government agencies may be advised to procure Vitamin A oral liquid 100000 IU/ml through competitive tender process. In addition to the above, it has also been decided that NPPA may re-fix the ceiling price of Vitamin A oral liquid 100000 IU/ml, whenever, the market price data of this formulation is available.

6. Agenda item no. 6 – Status of applications under para 32 of DPCO, 2013.

The Authority deliberated upon the applications w.r.t exemption under para 32 of DPCO, 2013.

6.1 The brief history of the application of MeRes100 of M/s Meril Lifesciences Pvt Ltd. (including previous application under para 32(iii)) was also circulated in the authority meeting. The authority deliberated upon the case of 'Sirolimus Eluting BioResorbable vascular scaffold system(MeRes100) of M/s Meril Lifesciences Pvt Ltd' directed that it be referred to Department of Pharmaceuticals with full facts.

6.2. In the case of 'Ready to use infusion bags Gemcitabine Hydrochloride injection 10mg/ml of M/s Sun Pharmaceuticals Industries Ltd.', the authority was informed that the company claims that the product is advantageous over the currently available products. It is a ready to use infusion bag containing Gemcitabine Hydrochloride Injection. The firm claims that this ready to use injection is advantageous as it avoids the inconvenience of diluting a concentrated Gemcitabine Hydrochloride injection, as well as, eliminates the risks of microbiological contamination and any potential calculation or dilution error. However, the authority noted that no substantial scientific and documentary evidence has been submitted by the firm to support this claim. Therefore, this is not covered under para 32 of DPCO for exemption.

6.3. In the case of Silver Sulfadiazine (Nanonized) 0.5% w/w and Chlorhexidine gluconate 0.2% w/w topical cream of M/s Sun Pharmaceutical Industries Ltd., the firm claims that the topical preparation containing Silver Sulfadiazine cream is advantageous over the currently available products in having improved efficacy thereby leading to dose reduction, as well as, faster wound healing as a result of quicker absorption of fine sized particles having increased surface area. However, the authority noted that no documentary evidence substantiating the above claim has been submitted by the firm. Therefore, the Authority considered that it may not be covered under para 32 of the DPCO for exemption.

6.4. In the case of Diclofenac 4% Topical Solution of M/s Sun Pharmaceutical Industries Ltd, the company claims that the product is manufactured by Sun Pharmaceuticals Industries Ltd. It has entered into a licensing agreement with M/s Troikka Pharmaceuticals Limited to co-market the formulation. The firm claims that this product is advantageous due to the fact that it has a higher penetration of Diclofenac through the skin and the product is significantly superior in therapeutic performance over the currently available topical gel formulations. It was significantly observed by the authority that various topical formulations of Diclofenac were currently available in the market. Although the firm has submitted certain documents to support their product Diclofenac Topical gel, no specific documents to support the superiority of this product over the presently available topical formulations of Diclofenac have been submitted. Therefore, the Authority considered that it may not be covered under para 32 of giving exemption of DPCO.

7. Agenda item no. 7 – Minutes of 4th meeting of Multidisciplinary Committee of Expert held on 27.09.2018.

7.1 Noted.

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

(Ritu Dhillon)
Member Secretary