

मिसिलस.- 8(51)/2017/डी.पी/एनपीपीए-डीवी-II

F. No. 8(51)/2017/DP/NPPA-Div. II

कार्यवाहीस. : 183/51/2017/F
Proceeding No : 183/51/2017/F

Minutes of the 183rd and 51st meeting of Authority under DPCO, 2013 held on 15.12.2017 at 11.00 A.M.

I. The 183rd overall meeting of the Authority, which is the 51st under the DPCO, 2013 was held on 15th December, 2017 at 11.00 AM under the Chairmanship of Shri Bhupendra Singh, Chairman, NPPA. The following members of the NPPA were present:-

- (i) Shri Rakesh Ranjan, Member Secretary
- (ii) Shri Umesh Dongre, Adviser (Cost), Deptt. of Expenditure, Ministry of Finance.
- (iii) Shri Arun Kumar, Adviser, Deptt. of Economic Affairs, Ministry of Finance.
- (iv) Shri A. K. Pradhan, Deputy Drug Controller, Deptt. of Health & Family Welfare (representing DCG(I)).

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 A.P.S. Sawhney, Director (Pricing)
- (iii) Shri Arun Diwan, Dy. Director (O/C)
- (iv) Shri Baljit Singh, Asstt. Director (Pricing)
- (v) Shri Prasenjit Das, Asstt. Director (Pricing)

1.2 Chairman, NPPA welcomed all the members present in the meeting.

II. Agenda items

1. Agenda item no. 1 - Confirmation of Minutes of the 50th Meeting held on 22.11.2017.

1.1 The Authority confirmed the minutes of the overall 182nd and the 50th Meeting held on 22.11.2017 under DPCO, 2013.

2. Agenda item no. 2 - Action Taken Report

2.1 Noted.

2.2 The Authority discussed the matter in details and approved to issue a fresh notification to partially modify the SO. 3727(E) dated 23.11.2017 to give pre-GST retail price and post GST retail price.

3.1 Agenda item no. 3(i) - Fixation of Ceiling Prices under NLEM 2015.

3.1.1 The Authority discussed and approved the ceiling prices of Phenylephrine 5% drops based on institutional data under para 19 of DPCO, 2013 and Anti-D immunoglobulin 150 mcg vial based on para 6 of DPCO, 2013 under monopolistic condition as detailed below:


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S. NO.	UNIQUE NO. AS PER NLEM	NAME OF THE FORMULATION/ COMPOSITIONS	STRENGTH & Dosage Form	Unit for ceiling price	Approved ceiling price under NLEM, 2015 (Rs.)
A. Common Formulations					
1	25.5.3	Phenylephrine	Drops 5%	1 ml	3.38
B. New Formulation					
2	22.2.3	Anti-D immunoglobulin	150 mcg	Each vial	1509.69

4.1 Agenda item no. 4(i) - Price fixation of new drug under Para 5 of DPCO 2013

4.1.1 The Authority examined the retail price fixation of the companies in details. With a view to rationalize the prices of new drug, the Authority decided that wherever, the application has been received by NPPA for any new drug for which NPPA has already notified the price, the same price would be extended to subsequent applicants also. Accordingly, the Authority approved the retail price of 59 new drugs on the basis of retail price already notified after giving excise duty effect for post GST rates as detailed below:

Sl. No.	Name of the Scheduled Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
1.	Ferrous Ascorbate + Folic Acid + Cyanocobalamin + Zinc Sulphate Monohydrate tablet (Aurtrin - XT)	Each film coated tablet contains: Ferrous Ascorbate eq. to Elemental Iron 100mg, Folic Acid IP 1.5mg, Cyanocobalamin IP 15 mcg, Zinc Sulphate Monohydrate IP eq. to Elemental Zinc 22.5mg	1 Tablet	M/s Tirupati Medicare Limited / M/s Pfizer Limited	3.63
2.	Rosuvastatin + Clopidogrel Capsule (Roseday CV 10)	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin (As granules) 10mg, Clopidogrel Bisulphate IP eq. to Clopidogrel (As a film coated tablet) 75mg	1 Capsule	M/s Aeon Formulation Pvt. Ltd. / M/s USV Private Limited	13.37
3.	Teneligliptin + Metformin tablet (Ten20 M 1000)	Each uncoated bilayered tablets contains: Teneligliptin Hydrobromide hydrate eq. to Teneligliptin 20mg, Metformin HCL 1000mg (as extended release)	1 Tablet	M/s Glenamark Pharmaceuticals Ltd. / M/s Centaur Pharmaceuticals Pvt. Ltd.	10.87
4.	Clobetasol + Clotrimazole + Neomycin Sulphate Cream	Each gm contains: Clobetasol Propionate IP 0.05%w/w, Clotrimazole IP 1.00% w/w, Neomycin Sulphate IP 0.50%w/w	1 GM	M/s Mankind Pharma Ltd./ M/s Pharma Force Lab.	2.92
5.	Moxifloxacin + Cefixime Tablets (Moximac Plus)	Each Coated Sustained Release tablet contains: Moxifloxacin Hydrochloride BP eq. to Moxifloxacin 400mg, Cefixime IP (as trihydrate) eq. to Anhydrous Cefixime 400mg	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Macleods Pharmaceuticals Ltd.	33.05
6.	Moxifloxacin + Cefixime Tablets	Each Coated Sustained Release tablet contains: Moxifloxacin	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd.	33.05

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	(Macflo Plus)	Hydrochloride BP eq. to Moxifloxacin 400mg, Cefixime IP (as trihydrate) eq. to Anhydrous Cefixime 400mg		/ M/s Macleods Pharmaceuticals Ltd.	
7.	Tramadol + Paracetamol Tablet	Each Film Coated tablet contains: Tramadol Hydrochloride IP 37.5mg, Paracetamol IP 325mg	1 Tablet	M/s Anglo French Drugs & Industries Ltd.	5.57
8.	Rosuvastatin + Aspirin + Clopidogrel Tablet	Each film coated bilayered tablet contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg, Aspirin IP 75mg, Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg	1 Tablet	M/s Safetab Life Science / M/s Intas Pharmaceuticals Limited	9.97
9.	Teneligliptin + Metformin Tablet	Each uncoated bilayered tablets contains: Teneligliptin Hydrobromide hydrate eq. to Teneligliptin 20mg, Metformin HCL 500mg (as extended release)	1 Tablet	M/s Synokam Pharma limited/ M/s Cadila Pharmaceuticals Ltd.	9.62
10.	Teneligliptin + Metformin Tablet	Each uncoated bilayered tablets contains: Teneligliptin Hydrobromide hydrate eq. to Teneligliptin 20mg, Metformin HCL 1000mg (as extended release)	1 Tablet	M/s Synokam Pharma limited/ M/s Cadila Pharmaceuticals Ltd.	10.87
11.	Paracetamol + Caffeine + Phenylephrine + Diphenhydramine Tablet	Each uncoated tablet contains: Paracetamol IP 500mg, Caffeine (Anhydrous) IP 30mg, Phenylephrine Hydrochloride IP 5mg, Diphenhydramine Hydrochloride IP 25mg	1 Tablet	M/s Biochem Pharmaceutical Industries Ltd.	2.57
12.	Ramipril + Amlodipine Tablet	Each uncoated tablet contains: Ramipril IP 5mg, Amlodipine Besilate IP eq. to Amlodipine 5mg	1 Tablet	M/s Lupin Limited	4.11
13.	Teneligliptin + Metformin Tablet	Each Film uncoated bilayer tablet contains: Teneligliptin Hydrobromide Hydrate 20mg eq. to Teneligliptin 20mg, Metformin Hydrochloride IP 1000mg (In Sustained Release form)	1 tablet	M/s Lupin Limited / M/s Unichem Laboratories Ltd.	10.87
14.	Teneligliptin + Metformin Tablet	Each uncoated bilayer tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg, Metformin Hydrochloride IP 500mg	1 Tablet	M/s Lupin Limited / M/s Unichem Laboratories Ltd	9.62
15.	Rosuvastatin + Clopidogrel Capsule (Roistar CV 10/75)	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg (As Pellets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (as Pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Unichem Laboratories Ltd.	13.37
16.	Rosuvastatin + Clopidogrel Capsule (Roistar CV 20/75)	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (As Pellets), Clopidogrel Bisulphate IP eq. to	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Unichem Laboratories Ltd.	7.80



		Clopidogrel 75mg (as Pellets)			
17.	Diclofenac Injection	Each ml contains: Diclofenac Sodium IP 75mg Injection	1 ML	M/s Cadila Healthcare Ltd.	13.71
18.	Teneligliptin + Metformin Tablet (EFIGLIN M)	Each uncoated Bilayered tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg, Metformin HCl 500mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s MedoPharm,	9.62
19.	Rosuvastatin + Clopidogrel Capsule	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (As granules), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (as to film coated tablets)	1 Capsule	M/s GKM New Pharma / M/s Cadila Healthcare Ltd.	7.80
20.	Rosuvastatin + Clopidogrel Capsule (Roseday CV 20)	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin (As Pellets) 20mg, Clopidogrel Bisulphate IP eq. to Clopidogrel (As Pellets) 75mg	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s USV Pvt. Ltd,	7.80
21.	Teneligliptin + Metformin Tablet	Each uncoated bilayer tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg, Metformin HCL 500mg (as sustained release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Emcure Pharmaceuticals Ltd.	9.62
22.	Teneligliptin + Metformin Tablet	Each uncoated bilayer tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg, Metformin HCL 1000mg (as sustained release)	1 Tablet	/s Synokem Pharmaceuticals Ltd. / M/s Emcure Pharmaceuticals Ltd.	10.87
23.	Metformin + Glimepiride + Voglibose Tablet	Each tablet contains: Metformin HCL 500mg (as sustained release form), Glimepiride 2mg, Voglibose 0.3mg	1 Tablet	M/s Sunglow Pharmaceuticals Pvt. Ltd. / M/s Intas Pharmaceuticals Ltd.	9.39
24.	Paracetamol Tablet	Each tablet contains: Paracetamol IP (as Immediate Release) 300mg, Paracetamol IP (as Sustained Release) 700mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Strassenburg Pharmaceuticals Ltd.	3.15
25.	Aceclofenac + Paracetamol Tablet	Each Tablet contains: Aceclofenac IP 100mg, Paracetamol IP 325mg	1 Tablet	M/s Rivpra Formulation Pvt. Ltd. / M/s Cadila Pharmaceuticals Ltd.	2.78
26.	Rosuvastatin + Clopidogrel Capsule	Each Hard gelatin capsule contains: Rosuvastatin 10mg, Clopidogrel 75mg	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Cadila Pharmaceuticals Ltd.	13.37
27.	Teneligliptin + Metformin Tablet (EFIGLIN M 1000)	Each uncoated Bilayered tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg, Metformin Hydrochloride IP 1000mg (as Sustained Release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s MedoPharm	10.87
28.	Olmesartan + Amlodipine Tablet	Each film coated tablet contains: Olmesartan Medoxomil IP 20mg,	1 Tablet	M/s Synokem Pharmaceuticals Ltd.	7.24



		Amlodipine Besylate IP eq. to Amlodipine 5mg		/ M/s Zuventus Healthcare Limited	
29.	Telmisartan + Metoprolol Tablet (Xstan-Beta 25mg)	Each film coated tablet contains: Telmisartan IP 40mg, Metoprolol Tartrate IP 25mg (ER)	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Blue Cross Laboratories Pvt. Ltd.	7.62
30.	Telmisartan + Metoprolol Tablet (Xstan-Beta 50mg)	Each film coated tablet contains: Telmisartan IP 40mg, Metoprolol Tartrate IP 50mg (ER)	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Blue Cross Laboratories Pvt. Ltd.	9.16
31.	Voglibose + Glimepride + Metformin Tablet	Each uncoated bilayered tablet contains: Voglibose IP 0.2mg, Glimepride IP 1mg, Metformin HCL IP 500mg (SR)	10 Tablets	M/s Windlas Biotech Pvt. Ltd. / M/s Zuventus Healthcare Limited	68.50
32.	Atorvastatin + Clopidogrel Capsules (Atchol CV 10mg)	Each hard gelatin capsule contains: Atorvastatin Calcium eq. to Atorvastatin (as pellets) 10mg, Clopidogrel (as pellets) 75mg.	10 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	83.94
33.	Voglibose + Glimepride + Metformin Tablet	Each uncoated bilayered tablet contains: Voglibose IP 0.2mg, Glimepride IP 2mg, Metformin Hydrochloride IP 500mg (SR)	1 Tablet	M/s Windlas Biotech Pvt. Ltd. / M/s Zuventus Healthcare Limited	8.68
34.	Teneligliptin + Metformin Tablet (Tenephron M)	Each uncoated bilayered tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg, Metformin Hydrochloride 500mg (SR)	1 Tablet	M/s Windlas Biotech Limited / M/s Abbott India Limited	9.62
35.	Teneligliptin + Metformin Tablet (Tenephron M Forte)	Each uncoated bilayered tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg, Metformin HCl 1000mg (SR)	1 Tablet	M/s Windlas Biotech Limited / M/s Abbott India Limited	10.87
36.	Teneligliptin + Metformin Tablet (TYTIN M)	Each uncoated bilayered tablet contains: Teneligliptin Hydrobromide hydrate eq. to Teneligliptin 20mg, Metformin Hydrochloride 500mg (as extended release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Wockhardt Ltd.	9.62
37.	Tacrolimus Capsule	Each Hard gelatin capsule contains: Tacrolimus IP 0.25mg	1 Capsule	M/s Emcure Pharmaceuticals Ltd,	10.82
38.	Telmisartan + Amlodipine Tablet	Each uncoated bilayer tablet Contains: Telmisartan IP 80mg, Amlodipine Besilate IP 5mg	10 Tablet	M/s J. K. Print Packs / M/s Mankind Pharma Ltd.	106.05
39.	Telmisartan + Amlodipine Tablet (Tigatel AM 40)	Each film coated tablet contains: Telmisartan IP 40mg, Amlodipine Besylate IP eq. to Amlodipine 5mg	1 Tablet	M/s Sun Pharma Laboratories Limited	6.90
40.	Cefixime + Ofloxacin Tablet (Ranixime Plus)	Each film coated tablet contains: Cefixime Trihydrate eq. to Cefixime Anhydrous IP 200mg, Ofloxacin IP 200mg	1 Tablet	M/s Theon Pharmaceuticals Limited / M/s Sun Pharmaceutical Industrial Limited	9.46
41.	Teneligliptin +	Each film coated tablet contains:	1 Tablet	M/s Precise	9.62

	Metformin Tablet (Glypte M)	Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg, Metformin Hydrochloride 500mg		Chemipharma Pvt. Ltd. / M/s Franco India Pharmaceuticals Private Limited	
42.	Teneligliptin + Metformin Tablet (Glypte M Forte)	Each film coated tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg, Metformin Hydrochloride 1000mg	1 Tablet	M/s Precise Chemipharma Pvt. Ltd. / M/s Franco India Pharmaceuticals Private Limited	10.87
43.	Glemipiride + Metformin Tablet (Ziglim - M1 Forte)	Each uncoated bilayered tablet contains: Glemipiride IP 1mg, Metformin Hydrochloride IP 1000mg (as SR form)	1 Tablet	M/s Inventia Healthcare Pvt. Ltd. / M/s FDC Limited	5.69
44.	Glemipiride + Metformin Tablet (Ziglim - M2 Forte)	Each uncoated bilayered tablet contains: Glimepiride IP 2mg, Metformin Hydrochloride IP 1000mg (as SR form)	1 tablet	M/s Inventia Healthcare Pvt. Ltd. / M/s FDC Limited	7.19
45.	Diclofenac Injection	Each ml contains: Diclofenac Sodium IP 75mg/ml	1 ml	M/s Zydus Healthcare Ltd.	13.71
46.	Doxorubicin (Pegylated Liposomal) Injection	Each ml contains: Doxorubicin HCL 2mg (Pegylated Liposomal) water for Injection	1 ml	M/s Natco Pharma Ltd.	694.29
47.	Telmisartan + Indapamide Tablet	Each uncoated bilayered tablet contains: Telmisartan IP 40mg Indapamide IP 1.5mg	1 Tablet	M/s Windlas Biotech Pvt. Ltd. / M/s Mankind Pharma Ltd.	8.48
48.	Paracetamol + Mefenamic Acid Injection (Zydol-P DS)	Each 5ml contains: Paracetamol 250mg Mefenamic Acid 100mg	1 ml	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Jenburkt Pharmaceuticals Ltd.	0.57
49.	Paracetamol + Phenylephrine + Chlorpheniramine + Sodium Citrate + Menthol Injection	Each 5ml contains: Paracetamol 125mg Phenylephrine Hydr,ochloride IP 5mg, Chlorpheniramine Maleate IP 0.5mg, Sodium Citrate IP 60mg, Menthol IP 1mg	1 ml	M/s Relax Pharmaceuticals Ltd. / M/s Magnet Labs Pvt. Ltd.	0.57
50.	Atorvastatin + Clopidogrel Capsule (Atacor CV)	Each hard gelatin capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 10mg (As film coated tablet), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As 2 film coated 37.5mg each tablet)	10 Capsule	M/s Windlas Biotech Pvt. Ltd. / M/s Dr. Reddy's Laboratories Ltd.	83.94
51.	Tacrolimus Capsule	Each hard gelatin capsule contains: Tacrolimus premix (20%) eq. to Tacrolimus IP 0.25mg	1 Capsule	M/s Intas Pharmaceuticals Ltd.	10.82
52.	Atorvastatin + Clopidogrel Capsule (Avas 10 Gold)	Each capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 10mg (As film coated tablet) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As 2 film coated 37.5mg each tablet)	10 Capsule	M/s Micro Lab. Ltd.	83.94
53.	Atorvastatin +	Each capsule contains:	10	M/s Micro Lab. Ltd.	83.94

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	Clopidogrel Capsule (Astin 10 Gold)	Atorvastatin Calcium IP eq. to Atorvastatin 10mg (As film coated tablet), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As 2 film coated 37.5mg each tablet)	Capsule		
54.	Glimepiride + Metformin Tablet (DIAPRIDE M 0.5)	Each uncoated bilayered tablet contains: Glimepiride IP 0.5mg, Metformin Hydrochloride IP 500mg (SR)	1 Tablet	M/s Micro Lab. Ltd.	2.22
55.	Telmisartan + Hydrochlorothiazide Tablet (Tigatel H 40)	Each uncoated tablet contains: Telmisartan IP 40mg, Hydrochlorothiazide IP 12.5mg	1 Tablet	M/Sun Pharma Laboratories Ltd.	7.16
56.	Telmisartan + Hydrochlorothiazide Tablet (Tigatel H 80)	Each uncoated tablet contains: Telmisartan IP 80mg, Hydrochlorothiazide IP 12.5mg	1 Tablet	M/Sun Pharma Laboratories Ltd.	11.12
57.	Telmisartan + Amlodipine Tablet (Tigatel AMH 40)	Each uncoated tablet contains: Telmisartan IP 40mg, Amlodipine Besylate IP Eq. to Amlodipine 5mg, Hydrochlorothiazide IP 12.5mg	1 Tablet	M/s Sun Pharma Laboratories Ltd.	7.48
58.	Telmisartan + Amlodipine Tablet (Tigatel AMH 80)	Each uncoated tablet contains: Telmisartan IP 80mg, Amlodipine Besylate IP Eq. to Amlodipine 5mg, Hydrochlorothiazide IP 12.5mg	10 Tablet	M/s Sun Pharma Laboratories Ltd.	117.83
59.	Sofosbuvir + Velpatasvir Tablet	Each film coated tablet contains: Sofosbuvir 400mg, Velpatasvir 100mg	28 tablets	M/s Hetro Lab Limited / M/s Emcure Pharmaceutical Limited	15625.00

4.2 Agenda item no. 4(ii)- Price fixation of new drug under Para 5 of DPCO 2013 - Methylprednisolone sodium Succinate Injection 1000mg for M/s Claris Injectables Limited.

4.2.1 The Authority examined the matter in details and approved the retail price of Methylprednisolone sodium Succinate Injection 1000mg for M/s Claris Injectables Limited at Rs. 782.78 per vial excluding GST.

4.3 Agenda Item no. 4(iii)- Price fixation of new drug under Para 5 of DPCO 2013 - Methylprednisolone sodium Succinate Injection 500mg for M/s Claris Injectables Limited.

4.3.1 The Authority examined the matter in details and approved the retail price of Methylprednisolone sodium Succinate Injection 500mg for M/s Claris Injectables Limited at Rs. 469.76 per vial excluding GST.

4.4 Agenda item no. 4(iv)- Price fixation of new drug under Para 5 of DPCO 2013 - Methylprednisolone sodium Succinate Injection 125 mg for M/s Claris Injectables Limited.

4.4.1 The Authority examined the matter in details and approved the retail price of Methylprednisolone sodium Succinate Injection 125 mg for M/s Claris Injectables Limited at Rs. 228.44 per vial excluding GST.

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4.5 Agenda item no. 4(v)- Price fixation of new drug under Para 5 of DPCO 2013 - BortiRel 3.5mg for M/s Reliance Life Science Pvt. Ltd.

4.5.1 The Authority examined the matter in details and approved the retail price of **BortiRel 3.5mg** for M/s Reliance Life Science Pvt. Ltd at Rs. 12500 per vial excluding GST.

5. Agenda item no. 5 - Status of Monitoring of Prices of Medical Devices.

5.1 Noted. As regards the trade margins involved in medical devices, one RTI application has been received seeking details of trade margin in respect of intra ocular lenses, cochlear implants, balloon catheters and heart valves. The Authority decided to upload in the public domain of NPPA, the details of trade margins of these medical devices whose trade margin analysis have been completed as a part of information dissemination.

6. Agenda item no. 6 - Discontinuation of scheduled formulation Inj NS 0.45% 500ml (Inj. 0.45% Sodium Chloride 500ml) by M/s Baxter (India) Pvt. Ltd. Under para 21 (2) of DPCO, 2013.

6.1 The Authority confirmed the earlier decision to approve the discontinuation request of the Company as the same is not a critical drug and alternatives with somewhat different strength/pack size would be available

7. Agenda item no. 7 – Status of filing in IPDMS by Pharma Companies

7.1 Noted.

8. Agenda item no. 8 – Status regarding launch of drugs Without Price Approval (WPA)

8.1 Noted.

9. Agenda item no. 9 - Status regarding reports on the treatment of Late Miss Adya Singh diagnosed with dengue at Fortis Memorial Research Institute, Gurgaon

9.1 The issue has been deliberated in details and it was decided that the issue will be further discussed and deliberated in the continuation meeting to be held on 20.12.2017 at 11:00 AM in the conference Hall of NPPA.

10. Agenda item no. 10 – Request of M/s India Medtronic Pvt Ltd for discontinuation of Endeavor Sprint RX Zotarolimus Eluting Coronary System under para 21(2) of DPCO, 2013

10.1 Noted.

11. The meeting was adjourned with a vote of thanks to the Chair, to meet again on 20.12.2017 at 11:00 AM for Agenda No. 9 and supplementary agenda, if any.


(Rakesh Ranjan)
Member Secretary