

मिसिलस - 8(39)/2016/डी पी /एनपीपीए- डीवी-II

F. No. 8(39)/2016/DP/NPPA-Div. II

कार्यवाहीस. : 171/39/2016/F

Proceeding No : 171/39/2016/F

Minutes of the 171st and 39th meeting of Authority under DPCO, 2013 held on 21.12.2016 at 11.00 AM.

- I. 1. The 171st overall meeting of the Authority, which is the 39th under the DPCO, 2013 was held on 21st, December, 2016 at 11.00 AM under the Chairmanship of Shri Bhupendra Singh, Chairman, NPPA. The following members of the NPPA were present:-

- (i) Dr. Sharmila Mary Joseph K, Member Secretary, NPPA.
- (ii) Sh. G.S. Negi, Adviser, Deptt. of Economic Affairs, Ministry of Finance.
- (iii) Shri Devendra Kumar, Adviser (Cost), Deptt. of Expenditure, Ministry of Finance.
- (iv) Shri R.Chandrashekhar, Deputy Drug Controller, Deptt. of Health & Family Welfare (representing DCGI).

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

- (i) Smt. Roshni Sohni, Director (M&E/Admn.)
- (ii) Shri A.K. Khurana, Director (Pricing/Ov.)
- (v) Shri Baljit Singh, Asstt. Director (Pricing)
- (vi) Shri Prasenjit Das, Asstt. Director (Pricing)

1.2 Chairman, NPPA welcomed all the members present in the meeting especially Sh. G.S. Negi, Adviser, Deptt. of Economic Affairs, Ministry of Finance who was attending the Authority meeting for the first time after his nomination.

II. Agenda Items

1. Agenda Item no. 1: Confirmation of Minutes of the 38th Meeting held on 9.11.2016.

The Authority confirmed the minutes of the overall 170th and the 38th Meeting under DPCO, 2013.

2. Agenda Item no. 2: Action Taken Report

2.1 Noted.

2.2 It was informed that ceiling prices of Paracetamol 80mg suppository, Paracetamol 160mg suppository, Paracetamol 125mg/5ml Oral Liquid and Paracetamol 120mg/5ml Oral Liquid were notified vide S.O. 3430(E) and S.O. 3431(E) dated 10th November, 2016, after the ceiling prices of these formulations were approved in the previous 37th as well as 38th meeting.

3. Agenda Item no. 3: Fixation of Ceiling Prices of Scheduled formulations in the revised Schedule-I of DPCO, 2013 (NLEM, 2015).

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3.1 The Authority discussed in detail the data and calculation sheets of 54 formulations at the meeting. The Authority approved the ceiling prices in respect of all the following 51 formulations.

S. N O.	UNIQUE NO. AS PER NLEM	NAME OF THE FORMULATION/ COMPOSITIONS	STRENGTH	Dosage Form	Unit for Ceiling Price	Proposed ceiling price under NLEM, 2015 (Rs.)
A. Common Formulations						
Section 1-Anesthetic agents						
1.1-General Anesthetics and oxygen						
1	1.1.1	Halothane	Inhalation		Per ML	5.44
2	1.1.8	Thiopentone	Powder for Injection 0.5 g	Injection	Each Pack	37.79
1.3-Preoperative medication and sedation for short term procedures						
3	1.3.3	Midazolam	Injection 5mg/ml	Injection	Per ML	13.46
4	1.3.3	Midazolam	Injection 1mg/ml	Injection	Per ML	5.48
Section 2-Analgesics, antipyretics, non steroidal anti inflammatory medicines, medicines used to treat gout and disease modifying agents used in rheumatoid disorders.						
2.1- Non-opioid analgesics, antipyretics and nonsteroidal anti-inflammatory medicines						
5	2.1.2	Diclofenac	Injection 25 mg/ml	Injection	Per ML	1.35
6	2.1.3	Ibuprofen	Oral liquid 100 mg/5 ml	Oral Liquid	Per ML	0.17260
2.2-Opioid analgesics						
7	2.2.1	Fentanyl	Injection 50mcg/ml	Injection	Per ML	21.06
2.4-Disease modifying agents used in rheumatoid disorders						
Section 4-Antidotes and other substances used in poisoning						
4.2-Specific						
8	4.2.6	N-acetylcysteine	Injection 200 mg/ml	Injection	Per ML	20.79
Section 5-Anticonvulsants/ Antiepileptics						
9	5.3	Diazepam	Oral liquid 2 mg/5 ml	Oral Liquid	Per ML	2.54
10	5.9	Sodium Valporate	200mg/5ml Oral Liquid	Oral Liquid	Per ML	0.54
Section 6-Anti infective medicines						
6.2-Antibacterials						
6.2.1-Beta lactam medicines						
11	6.2.1.2	Amoxicillin (A) + Clavulanic acid (B)	Powder for Injection 500 mg (A) + 100 mg (B)	Injection	Each Pack	83.53
12	6.2.1.3	Ampicillin	Powder for Injection 500 mg	Injection	Each Pack	12.20
13	6.2.1.4	Benzathine benzylpenicillin	Powder for Injection 12 lac units	Injection	Each Pack	11.27
14	6.2.1.4	Benzathine benzylpenicillin	Powder for Injection 6 lac units	Injection	Each Pack	7.46
6.2.2-Other antibacterials						
15	6.2.2.1	Azithromycin	Powder for Injection 500 mg	Injection	Each Pack	176.90
16	6.2.2.9	Vancomycin	Powder for Injection 1 gm	Injection	Each Pack	423.48
17	6.2.2.9	Vancomycin	Powder for Injection 500 mg	Injection	Each Pack	254.72
6.4-Antiviral medicines						

6.4.1-Antiherpes medicines						
18	6.4.1.1	Acyclovir	Oral liquid 400 mg/5 ml	Oral Liquid	Per ML	1.18
19	6.4.1.1	Acyclovir	Powder for Injection 500 mg	Injection	Each Pack	425.80
20	6.4.1.1	Acyclovir	Powder for Injection 250 mg	Injection	Each Pack	329.68
6.4.3-Antiretroviral medicines						
6.4.3.1-Nucleoside reverse transcriptase inhibitors						
21	6.4.3.1.3	Lamivudine (A) + Nevirapine (B) + Stavudine (C)	150 mg (A) + 200 mg (B) + 30 mg (C)	Tablet	Per Tablet	14.47
6.4.3.2-Non-nucleoside reverse transcriptase inhibitors						
22	6.4.3.2.2	Nevirapine	Oral Liquid 50mg/5ml	Oral Liquid	Per ML	0.77
Section 6.5-Antiprotozoal Medicines						
6.5.3-Antimalarial medicines						
6.5.3.1-For curative treatment						
23	6.5.3.1.7	Quinine	Injection 300 mg/ml	Injection	Per ML	9.04
Section 8 -Antineoplastic/ Immunosuppressives and medicines used in palliative care						
8.1-Antineoplastic medicines						
24	8.1.1	5-Fluorouracil	Injection 250 mg/5 ml	Injection	Per ML	2.09
25	8.1.14	Cytosine arabinoside	Powder for Injection 500 mg	Injection	Each Pack	455.72
26	8.1.14	Cytosine arabinoside	Injection 100 mg/ ml	Injection	Each Pack	176.78
27	8.1.19	Etoposide	Injection 20 mg/ml	Injection	Per ML	33.26
28	8.1.27	Methotrexate	Injection 50 mg/ml	Injection	Per ML	35.65
Section 12-Cardiovascular medicines						
12.1-Medicines used in angina						
29	12.1.3	Diltiazem	Injection 5 mg/ml	Injection	Per ML	2.92
12.4-Medicines used in shock and heart failure						
30	12.4.2	Dobutamine	Injection 50mg/ml	Injection	Each Pack	34.79
31	12.4.3	Dopamine	Injection 40mg/ml	Injection	Per ML	5.02
Section 20-Gastrointestinal medicines						
20.1-Antiulcer medicines						
33	20.1.1	Omeprazole	Capsule 40mg	Capsule	Per Capsule	4.58
20.2-Antiemetics						
32	20.2.1	Domperidone	Oral Liquid 1mg/ml	Oral Liquid	Per ML	1.00
20.4-Antispasmodic medicines						
34	20.4.2	Hyoscine butylbromide	Injection 20 mg/ml	Injection	Per ML	9.67
Section 21-Hormones, other endocrine medicines and contraceptives						
21.3-Estrogens						
35	21.3.1	Ethinylestradiol	Tablet 0.05 mg	Tablet	Per Tablet	3.33
21.4-Medicines used in diabetes mellitus						
21.4.2-Medicines used to treat hypoglycemia						
36	21.4.2.1	Glucose	Injection 25 %	Injection	Per ML	0.15953
Section 23-Muscle relaxants and cholinesterase inhibitors						
37	23.1	Atracurium	Injection 10 mg/ml	Injection	Each Pack	48.63
38	23.3	Neostigmine	Tablet 15 mg	Tablet	Per Tablet	4.32

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Section 25-Ophthalmological Medicines						
25.4-Miotics and antiglaucoma medicines						
39	25.4.3	Timolol	Drops 0.5%	Drops	Per ML	11.06
25.5-Mydriatics						
40	25.5.1	Atropine	Ointment 1%	Ointment	Per GM	3.36
Section 26-Oxytocics and Antioxytocics						
26.1-Oxytocics and abortifacient						
41	26.1.2	Methylergometrine	Injection 0.2 mg/ml	Injection	Per ML	13.24
42	26.1.5	Oxytocin	Injection 5IU/ml	Injection	Per ML	16.37
Section 28-Medicines acting on the respiratory tract						
28.1-Antiasthmatic medicines						
43	28.1.4	Ipratropium	Inhalation (MDI/DPI) 20 mcg/dose		Per MDI	0.57
44	28.1.5	Salbutamol	Oral liquid 2 mg/5 ml		Per ML	0.14389
Section 30-Vitamins and minerals						
45	30.8	Thiamine	Tablet 100 mg	Tablet	Per Tablet	3.47
B New Formulations						
Section 4-Antidotes and other substances used in poisoning						
4.2-Specific						
46	4.2.6	N-acetylcysteine	Sachet 200 mg	Sachet	Per GM	6.99
Section 21-Hormones, other endocrine medicines and contraceptives						
21.4-Medicines used in diabetes mellitus						
21.4.1-Insulins and other antidiabetic agents						
47	21.4.1.4	Metformin	Immediate Release 750 mg	Tablet	Per Tablet	2.82
48	21.4.1.4	Metformin	Controlled Release 750 mg	Tablet	Per Tablet	2.23
II	C. Common Formulations (Explanation to Schedule- I)					
26.2-Medicines used in pre term labour						
49	26.2.2	Nifedipine	10 mg	Capsule	Per Capsule	0.79
D. New Formulations (Explanation to Schedule-I)						
Section 2-Analgesics, antipyretics, non steroidal anti inflammatory medicines, medicines used to treat gout and disease modifying agents used in rheumatoid disorders.						
2.1- Non-opioid analgesics, antipyretics and nonsteroidal anti-inflammatory medicines						
50	2.1.4	Mefenamic acid	500 mg	Tablet	Per Tablet	2.27
51	2.1.4	Mefenamic acid	250 mg	Tablet	Per Tablet	1.78
2.2-Opioid analgesics						
52	2.2.3	Tramadol	50mg	Tablet	Per Tablet	7.48
Section 6-Anti infective medicines						
6.2-Antibacterials						
6.2.1-Beta lactam medicines						
53	6.2.1.8	Cefixime	400 mg	Capsule	Per Capsule	27.13
Section 20-Gastrointestinal medicines						
20.1-Antiulcer medicines						
54	20.1.1	Omeprazole	20 mg	Tablet	Per Tablet	4.57

4. Agenda Item no. 4: Fixation of retail price in respect of new drugs.

4.1 The Authority discussed the following 28 cases of retail price fixation of new drugs falling under the purview of para 2(u) of DPCO, 2013 and approved the retail prices of the following under para 5 of the DPCO 2013, as under:

S. No.	Company name/Product name	Approved Retail Price (Rs.)
4(i)	(1) M/s Aurochem Lab. (I) Pvt. Ltd. (Manufacturer) and M/s Glenmark Pharmaceuticals Ltd. (Marketing company) - Clobetasol Propionate 0.05% w/w, Clotrimazole 1.00% w/w, Neomycin sulphate 0.5% w/w and Chlorocresol (as preservative) 0.10% w/w cream - (Candid 3D Cream).	Rs. 3.04 per Gm
4(ii)	M/s Pharma Force Lab. (Manufacturer) and M/s Gem Mankind (Marketing company) - Clobetasol Propionate 0.05% w/w, Clotrimazole 1% w/w, Neomycin Sulphate 0.50% w/w and Chlorocresol (as preservative) 0.10% w/w cream - (Fungikind Cream).	Rs. 3.04 per Gm
4(iii)	M/s SPB Lab. (Manufacturer) and M/s Alkem Lab. Ltd. (Marketing company) - Adaplene 0.1% w/w and Hydrous Benzoyl Peroxide eq. to Benzoyl Peroxide 2.5% w/w - (Oxtiv AP Gel).	Rs. 18.10 per Gm
4(iv)	M/s Cadila Healthcare Ltd. (Manufacturer as well as Marketing company) - Adaplene 0.1% w/w and Hydrous Benzoyl Peroxide eq. to Benzoyl Peroxide 2.5% w/w - (Adapalene and Benzoyl Peroxide Gel).	Rs. 18.10 per Gm
4(v)	M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) and M/s Sun Pharmaceuticals Ind. Ltd. (Marketing company) - Trypsin 48mg, Bromelain 90mg, Rutoside Trihydrate 100mg and Diclofenac Sodium 50mg - (Volitra Enzo Tablet).	Rs. 14.44 per Tablet
4(vi)	M/s Windlas Biotech Ltd. (Manufacturer as well as Marketing company) - Aceclofenac 100mg and Paracetamol 325mg (Aceclofenac & Paracetamol Tablet).	Rs. 2.90 per Tablet
4(vii)	M/s Windlas Biotech Ltd. (Manufacturer as well as Marketing company) - Rabepazole sodium 20mg and Domperidone SR 30mg- (Rabepazole sodium & Domperidone SR Capsule).	Rs. 6.87 per Capsule
4(viii)	M/s Windlas Biotech Ltd. (Manufacturer as well as Marketing company) - Pantoprazole sodium 40mg and Domperidone SR 30mg- (Pantoprazole sodium + Domperidone SR Capsule).	Rs. 7.95 per Capsule
4(ix)	M/s Inventia Healthcare P. Ltd. (Manufacturer) and M/s Curatas Pharmaceuticals LLP (Marketing company) - Metformin HCl SR 500mg, Voglibose 0.2mg and Glimepiride 2mg tablet - (Metformin HCl SR, Glimepiride and Voglibose Tablet).	Rs. 90.48 per 10 Tablets
4(x)	M/s Inventia Healthcare P. Ltd. (Manufacturer) and M/s Curatas Pharmaceuticals LLP (Marketing company) - Metformin HCl SR 500mg, Voglibose 0.2mg and Glimepiride 1mg tablet - (Metformin HCl SR, Glimepiride and Voglibose Tablet).	Rs. 71.43 per 10 Tablets
4(xi)	M/s Synkem Pharmaceuticals Ltd. (Manufacturer) and M/s Ajanta Pharma Ltd. (Marketing company) - Metformin HCl (SR) 500mg and Voglibose 0.2mg - (Voglibose + Metformin HCl SR Tablet).	Rs. 4.84 per Tablet
4(xii)	M/s Unichem Lab. Ltd. (Manufacturer as well as Marketing company) - A moxycillin trihydrate eq. to Amoxycillin 400mg and Potassium Clavulante diluted eq. to Clavulanic acid 57mg - (Ampoxin CV Forte/Myclav Dry Syrup 457mg/5ml).	Rs. 3.03 per ML
4(xiii)	M/s Infutec Healthcare Ltd. (Manufacturer as well as Marketing company) - Sterile water for irrigation 1000ml.	Rs. 70.83 per 1000ml pack
4(xiv)	M/s Infutec Healthcare Ltd. (Manufacturer as well as Marketing company) - Sterile water for irrigation 3000ml.	Rs. 170.38 per 3000ml pack

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4(xv)	M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) and M/s Apex Lab. Pvt. Ltd. (Marketing company) – Mefenamic Acid 50mg and Paracetamol 125mg – (Paracetamol and Mefenamic Acid oral Suspension).	Rs. 0.50 per ML
4(xvi)	M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) and M/s Lupin Ltd (Marketing company) – Diclofenac sodium 75mg – (Defenac Injection 75mg/1ml).	Rs. 14.30 per ML
4(xvii)	M/s Accent Pharma (Manufacturer) and M/s Blue Cross Lab. Pvt. Ltd. (Marketing company) - Telmisartan 40mg, Hydrochlorothiazide 12.5mg and Amlodipine 5mg (Xstan-AMH Tablets).	Rs. 6.00 per Tablet
4(xviii)	M/s Synokem Pharmaceuticals Ltd. (Manufacturer) and M/s Emcure Pharmaceuticals Ltd. (Marketing company) - Rosuvastatin calcium eq. to Rosuvastatin 5mg (as pellets) & Clopidogrel Bisulphate eq. to Clopidogrel 75mg (as pellets) capsule – (Rosuvastatin calcium IP 5mg and Clopidogrel Bisulphate 75mg Capsule).	Rs. 10.35 per Capsule
4(xix)	M/s Synokem Pharmaceuticals Ltd. (Manufacturer) and M/s Emcure Pharmaceuticals Ltd. (Marketing company) - Rosuvastatin calcium eq. to Rosuvastatin 10mg (as pellets) & Clopidogrel Bisulphate eq. to Clopidogrel 75mg (as pellets) capsule – (Rosuvastatin calcium IP 10mg and Clopidogrel Bisulphate 75mg Capsule).	Rs. 13.94 per Capsule
4(xx)	M/s Emcure Pharmaceuticals Ltd. (Manufacturer as well as Marketing company) – Nevirapine 400mg – (Nevirapine extended release tablet).	Rs. 21.22 per Tablet
4(xxi)	M/s Sanzyme (P) Ltd. (Manufacturer) and M/s Sandoz Pvt. Ltd. (Marketing company) - Human Chorionic Gonadotrophin (hcg) 2000 IU, Reconstitue with 1ml of sodium chloride injection (0.9% w/v) – (Chorionic Gonadotrophin Injection).	Rs. 260.80 per vial
4(xxii)	M/s Sanzyme (P) Ltd. (Manufacturer) and M/s Sandoz Pvt. Ltd. (Marketing company) - Human Chorionic Gonadotrophin (hcg) 10000 IU, Reconstitue with 1ml of sodium chloride injection (0.9% w/v) - (Chorionic Gonadotrophin Injection).	Rs. 550.00 per vial
4(xxiii)	M/s Indu Drugs Pvt. Ltd. (Manufacturer) and M/s Kardian Pharma India Pvt. Ltd. (Marketing company) – Olmesartan Medoxomil 40mg and Hydrochlorothiazide 12.5mg – (Olmetab H Tablet).	Rs. 12.60 per Tablet
4(xxiv)	M/s Indu Drugs Pvt. Ltd. (Manufacturer) and M/s Nutrinova Life Sciences Pvt. Ltd. (Marketing company) - Ferrous Ascorbate 100mg, Folic Acid 1500mcg and Zinc sulphate 22.5mg – (Zyofer XT Tablet).	Rs. 71.17 per 10 Tablets
4(xxv)	M/s Bymaa Lab. Pvt. Ltd. (Manufacturer) and M/s Medo Pharm (Marketing company) - Metformin HCl SR 500mg + Glimepiride 1mg – (Glylim Forte 1 Tablet).	Rs. 4.00 per Tablet
4(xxvi)	M/s Intas Pharmaceuticals Ltd. (Manufacturer as well as Marketing company) – Gemcitabine HCl eq. to Gemcitabine 1.4gm – (Gemcitabine injection 1.4gm).	Rs. 6362.52 per Vial
4(xxvii)	M/s Aristo Lab. Pvt. Ltd. (Manufacturer) and M/s Aristo Pharmaceuticals Pvt. Ltd. (Marketing company) – Ceftriaxone sodium eq. to Ceftriaxone 500mg and Sultactam sodium eq. to Sulbactam 250mg – (Monocef-SB 500mg Injection).	Rs. 69.50 per vial
4(xxviii)	M/s Bymaa Lab. Pvt. Ltd. (Manufacturer) and M/s Medo Pharm (Marketing company) – Metformin HCl SR 500mg and Voglibose 0.3mg – (Emvose M 0.3 Tablet).	Rs. 57.62 per 10 Tablets

5. Agenda Item no. 5: Review order of Department of Pharmaceuticals (DoP) in respect of retail price fixation of Paracetamol 325 mg + Hyoscine Butylbromide 10 mg tablet (Buscogast Plus Tablet) for M/s Boehringer Ingelheim India Pvt. Ltd against S.O. 583 (E) dated 24.02.2016 under DPCO, 2013.

5.1 This case was discussed in detail and the Authority approved the revised retail price of Paracetamol 325 mg + Hyoscine Butylbromide 10 mg tablet (Buscogast Plus Tablet) at Rs. 4.32 per tablet.

6. **Agenda Item no. 6: Review order of Department of Pharmaceuticals (DoP) and Representation from M/s Abbott Healthcare Pvt. Ltd against ceiling price of Ascorbic Acid (Vitamin C) Tablet 500mg notified vide S.O. 1351 (E) dated 02.6.2016.**

6.1 This case was discussed in detail and the Authority approved the revised ceiling price of Ascorbic Acid (Vitamin C) Tablet 500mg at Rs 0.84 per tablet

7. **Agenda Item No. 7: Discontinuation of Clindatime 150 Capsule (Clindamycin) under para 21(2) of DPCO, 2013 by M/s Mankind Pvt. Ltd.**

7.1 The matter was deferred for the next Authority Meeting.

Additional agenda items circulated during the meeting:-

8. **Guidelines regarding discontinuation of scheduled formulations under Para 21(2) of DPCO 2013.**

8.1 A draft proposal for modified guidelines for discontinuation was circulated to the Authority members. The members were requested to examine and offer their comments by 23rd December, 2016 or it will be taken as deemed approved.

9. **Signing of MOU between NPPA and different web-based Pharma Platforms for dissemination of information on ceiling price of medicines/NPPA mobile app and public grievances**

9.1 A draft MOU between NPPA and different web-based Pharma Platforms for dissemination of information on ceiling price of medicines/NPPA mobile app and public grievances was circulated to the Authority members. The members were requested to examine and offer their comments by 23rd December, 2016 failing which it shall be taken as approved.

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


(Dr. Sharmila Mary Joseph K)
Member Secretary