

मिसिल स.- 8(68)/2019/डी.पी/एनपीपीए-डीवी-॥

F. No. 8(68)/2019/DP/NPPA-Div. II

कार्यवाहीस. : 200/68/2019/F

Proceeding No : 200/68/2019/F

Minutes of the 200th (overall) and 68th meeting of the Authority under DPCO, 2013 held on 25.06.2019 at 11:00 AM

The 200th meeting of the Authority (overall), which is the 68th meeting under the DPCO, 2013, was held on the 25th of June, 2019 at 11:00 AM under the Chairmanship of Ms. Shubhra Singh, Chairman, NPPA. The following members of the NPPA were present:

- (i) Ms. Ritu Dhillon, Member Secretary
- (ii) Shri Arun Kumar, Advisor, Dept of Economic Affairs, Ministry of Finance
- (iii) Shri B. Bandyopadhyay, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure

Shri A.K.Pradhan, Deputy Drug Controller, Deptt. of Health & Family Welfare was present as representative of DCGI.

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

- (i) Shri Kalyan Nag, Advisor
- (ii) Shri Amarpal Singh Sawhney, Director (Pricing)
- (iii) Shri Prasenjit Das, Asstt. Director (Pricing)
- (iv) Shri Prakash Hemani, Asstt. Director (Pricing)

Chairman, NPPA welcomed all present in the meeting.

II. Agenda items

1. Agenda item no. 1 - Confirmation of Minutes of the 67th Meeting held on 29.05.2019.

1.1 Noted.

2. Agenda item no. 2 – Action Taken Report on decisions taken by NPPA in its 67th meeting dated 29.05.2019

2.1 Noted.

3. Agenda item no. 3 – Ceiling Price fixation of Scheduled Drugs under NLEM, 2015

3.1 The Authority approved the ceiling price of Ibuprofen 200 mg soft gelatin capsule at Rs. 2.62 per capsule excluding GST and directed that the same be notified as soft gelatin capsule i.e. dosage form be specified.

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

4.1 Noted.

4.2 The representative of DCGI informed the Authority that DCGI had not given the approval for the formulation Methotrexate 100 mg injection even though the drug had been approved by State Drug Controller prior to 01.10.2012. Accordingly, the Authority decided to reject the Form-I application of M/s Cadila Healthcare Ltd relating to Methotrexate 100 mg injection.

5. Agenda item no. 5 - New Drug application

5.1 The Authority discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 5 (i) to 5(xxviii) (total 28 Form I applications) falling under the purview of para 2(u) of DPCO, 2013 and approved the retail prices in 23 (twenty three) cases [except five cases at sl no xiii, xiv, xxi, xxii and xxiii] under para 5 of the DPCO 2013, as detailed below:

A. Retail price fixed under para 5 of DPCO, 2013

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
1.	Tacrolimus Ointment (MYLIMUS 0.1% 10gm)	Each gm of Ointment contains: Tacrolimus IP 1mg (10gm pack)	1 gm	M/s Alina Healthcare Pvt. Ltd. / M/s Mylan Pharmaceuticals Private Limited	30.89
2.	Tacrolimus Ointment (MYLIMUS 0.1% 20gm)	Each gm of Ointment contains: Tacrolimus IP 1mg (20gm pack)	1 gm	M/s Alina Healthcare Pvt. Ltd. / M/s Mylan Pharmaceuticals Private Limited	30.89
3.	Amoxicillin + Potassium Clavulanate Suspension	Each 5ml of reconstituted suspension contains: Amoxicillin Trihydrate IP eq. to Amoxicillin 400mg, Potassium Clavulanate Diluted IP eq. to Clavulanic acid 57mg	1 ml	M/s Brooks Laboratories Ltd. / M/s Intas Pharmaceuticals Limited	3.28
4.	Metoprolol+ Amlodipine Tablet	Each film coated tablet contains: Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate 25mg, (as prolonged release form), Amlodipine Besylate IP eq. to Amlodipine 5mg.	1 Tablet	M/s Windlas Biotech Limited / M/s Abbott Healthcare Pvt. Ltd.	5.58
5.	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 Cipla Limited	16.73
6.	Atorvastatin + Vitamin D3 Tablet	Each film coated tablet contains: Atorvastatin Calcium IP eq. to	1 Tablet	M/s Sun Pharma Laboratories	9.18

		Atorvastatin 10mg Vitamin D3 (Cholecalciferol) IP 1000 IU		Limited	
7.	Atorvastatin + Vitamin D3 Tablet	Each film coated tablet contains: Atorvastatin Calcium IP eq. to Atorvastatin 20mg Vitamin D3 (Cholecalciferol) IP 1000 IU	1 Tablet	M/s Sun Pharma Laboratories Limited	16.12
8.	Olmesartan Medoxomil + 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 Sun Pharma Laboratories Limited	9.65
9.	Olmesartan Medoxomil + 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 Sun Pharma Laboratories Limited	15.83
10.	Rosuvastatin + Aspirin + Clopidogrel Capsule	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg (As Film coated Tablet), Aspirin IP 75mg (As Aspirin Gastro – resistant Tablets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As film coated tablet)	1 Capsule	M/s Akums Drugs & Pharmaceuticals Limited / M/s Intas Pharmaceuticals Limited	11.15
11.	Rosuvastatin + Aspirin + Clopidogrel Capsule	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (As Film coated Tablet), Aspirin IP 75mg (As Aspirin Gastro – resistant Tablets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As film coated tablet)	1 Capsule	M/s Akums Drugs & Pharmaceuticals Limited / M/s Intas Pharmaceuticals Limited	16.82
12.	Paracetamol + Mefenamic Acid Suspension	Each 5ml Suspension contains: Paracetamol IP 250mg Mefenamic Acid IP 100mg	1 ml	M/s Tirupati Medicare Limited / M/s Intas Pharmaceuticals Limited	0.63
13.	Atorvastatin + Clopidogrel + Aspirin Capsule	Each hard gelatin capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 10mg (As Pellets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As Pellets) Aspirin IP 75mg (As enteric coated pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Cipla Limited	Rejected (Note 2)
14.	Atorvastatin + Clopidogrel + Aspirin Capsule	Each hard gelatin capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 20mg (As Pellets), Clopidogrel Bisulphate IP eq. to	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Cipla Limited	Rejected (Note 2)

		Clopidogrel 75mg (As Pellets) Aspirin IP 75mg (As enteric coated pellets)			
15.	Mefenamic acid + Paracetamol tablet	Each tablet contains: Mefenamic acid IP 500mg, Paracetamol IP 325mg	1 Tablet	M/s Cris Pharma (India) Ltd. / M/s Seagull Pharmaceuticals Pvt. Ltd.	2.76
16.	Mefenamic acid + Paracetamol Suspension	Each 5ml Suspension contains: Mefenamic acid IP 100mg, Paracetamol IP 250mg	1 ml	M/s Cris Pharma (India) Ltd. / M/s Seagull Pharmaceuticals Pvt. Ltd.	0.63
17.	Glimepiride + Metformin Tablet	Each uncoated bilayered tablet contains: Glimepiride IP 2mg Metformin Hydrochloride IP 1000mg (in prolonged release form)	1 Tablet	M/s Windlas Biotech Pvt. Ltd. / M/s Zuventus Healthcare Limited	8.75
18.	Glimepiride + Metformin tablet	Each uncoated bilayered tablet contains: Glimepiride IP 1mg Metformin Hydrochloride IP 500mg (in Sustain Release)	1 Tablet	M/s Swiss Garnier Biotech / M/s Zuventus Healthcare Limited	5.46
19.	Glimepiride + Metformin tablet	Each uncoated bilayered tablet contains: Glimepiride IP 2mg Metformin Hydrochloride IP 500mg (in Sustain Release)	1 Tablet	M/s Swiss Garnier Biotech / M/s Zuventus Healthcare Limited	7.96
20.	Escitalopram + Clonazepam tablet	Each film coated tablet contains: Escitalopram Oxalate IP eq. to Escitalopram 5mg, Clonazepam IP 0.5mg	1 Tablet	M/s Eris Lifesciences Ltd.	6.24
21.	Telmisartan + Amlodipine + Hydrochlorothiazide tablet	Each un coated tablet contains: Telmisartan IP 40mg, Amlodipine Besylate IP eq. to Amlodipine 5mg Hydrochlorothiazide IP 12.5mg	1 Tablet	M/s Sun Pharma Laboratories Limited / M/s Sun Pharmaceuticals Industries Limited	Deferred due to representation received from the company
22.	Telmisartan + Hydrochlorothiazide tablet	Each un coated tablet contains: Telmisartan IP 40mg, Hydrochlorothiazide IP 12.5mg	1 Tablet	M/s Sun Pharma Laboratories Limited / M/s Sun Pharmaceuticals Industries Limited	Deferred due to representation received from the company
23.	Telmisartan + Amlodipine tablet	Each uncoated tablet contains: Telmisartan IP 40mg, Amlodipine Besylate IP eq. to Amlodipine 5mg	1 Tablet	M/s Sun Pharma Laboratories Limited / M/s Sun Pharmaceuticals Industries Limited	Deferred due to representation received from the company
24.	Telmisartan + Chlorthalidone tablet	Each film coated tablet contains: Telmisartan IP 40mg, Chlorthalidone IP 12.5mg	1 Tablet	M/s Sun Pharma Laboratories Limited / M/s	8.21

				Sun Pharmaceuticals Industries Limited	
25.	Glimepiride + Metformin Tablet	Each uncoated bilayered tablet contains: Glimepiride IP 1mg Metformin Hydrochloride IP 1000mg (in prolonged release form)	1 Tablet	M/s Windlas Biotech Pvt. Ltd. / M/s Zuventus Healthcare Limited	6.57
26.	Gliclazide + Metformin Tablet	Each un coated tablet contains: Gliclazide IP 80mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Anphar Organics Pvt. Ltd. / M/s Lupin Limited	6.65
27.	Clopidogrel + Aspirin Tablet	Each film coated tablet contains: Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg Aspirin IP (As enteric coated) 75mg	1 Tablet	M/s Sun Pharma Laboratories Limited	3.48
28.	Clopidogrel + Aspirin Tablet	Each film coated tablet contains: Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg Aspirin IP (As enteric coated) 150mg	1 Tablet	M/s Sun Pharma Laboratories Limited	3.55

Note 1. The retail price are to be notified after 10 days of uploading the draft working sheet.

Note 2. The representative of DCGI informed the Authority that DCGI approval had not been granted for the said formulation even though the concerned company had applied for the same. Therefore, the Authority decided to reject the Form-I application of the applicant company.

6. Agenda item no. 6 – Status of implementation of Review Cases

6.1 Noted.

6.1.1 Agenda item no. 6(i) - Review application against ceiling price fixation of Ringer lactate Injection fixed vide S.O. 2401(E) dated 28.07.2017 filed by (i) M/s Albert David Ltd (ii) M/s Aculife healthcare Pvt. Ltd (iii) M/s B. Braun Medical (india) Pvt. Ltd (iv) M/s Fresenius Kabi India Pvt. Ltd (v) M/s Ostuka Pharmaceuticals India Pvt. Ltd.

6.1.1.1 The Authority deliberated upon the matter in detail and directed that since the companies are seeking a separate price based on special features of the product, the matter may be referred to DCGI for examining the license of these products. Since the matter pertains to a review order issued by Department of Pharmaceuticals, DCGI may be requested to examine the claim expeditiously and inform the Authority in the next meeting.

6.1.1.2 Agenda item no. 6(ii) - Review Order No. 31015/46/2018-Pricing dated 19.03.2019 for M/s Biological E. Ltd in respect of ceiling price fixation of Tetanus Toxoid Injection vide S.O. 5727(E) dated 13.11.2018.

6.1.1.2 The Authority deliberated upon the matter in detail and decided to accept the request of the applicant as a special case and approve the ceiling price of Tetanus Toxoid injection at Rs. 10.61 per 0.5 ml pack excluding GST and Tetanus Toxoid injection at Rs. 22.94 per 5 ml pack excluding GST towards implementation of the review order no. 31015/46/2018-Pricing dated 19.03.2019.

7. Agenda item no. 7 - Agenda for discussion for upward revision of ceiling prices of 19 scheduled formulations under para 19 of DPCO, 2013.

7.1 Record of discussion for members being circulated separately.

8. Agenda item no. 8 – Intimation of Minutes of 11th meeting of Multidisciplinary Committee of Experts held on 24.06.2019

8.1 Noted.

9. Agenda item no. 9 – Ceiling price notified by the NPPA for Oxygen Gas is being supplied to the various hospitals through composite contract – reg.

9.1 The issue was discussed at length. It was directed to place the matter in the next meeting with a detailed agenda.

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

Sd/-
(Ritu Dhillon)
Member Secretary