

मिसिल स.- 8(61)/2018/डी.पी/एनपीपीए-डीवी-॥

F. No. 8(61)/2018/DP/NPPA-Div. II

कार्यवाहीस. : 193/61/2018/F

Proceeding No : 193/61/2018/F

**Minutes of the 193rd (overall) and 61st meeting of the Authority under DPCO, 2013 held on 19.12.2018 at 4:00 PM**

The 193rd meeting of the Authority (overall), which is the 61st meeting under the DPCO, 2013, was held on 19<sup>th</sup> Dec., 2018 at 4:00 PM under the Chairpersonship of Ms. Shubhra Singh, Chairperson, NPPA. The following members of the NPPA were present:

- (i) Ms. Ritu Dhillon, Member Secretary
- (ii) Dr. S. Eswara Reddy, Drugs Controller General (India)
- (iii) A.K.Pradhan, Deputy Drug Controller, Deptt. of Health & Family Welfare
- (iv) Shri Arun Kumar, Advisor, Dep't of Economic Affairs, Ministry of Finance

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 Baljit Singh, Asstt. Director (Pricing)
- iv. Shri Prasenjit Das, Asstt. Director (Pricing)

1.2 Chairperson, NPPA welcomed all present in the meeting.

**II. Agenda items**

**1. Agenda item no. 1 - Confirmation of Minutes of the 60<sup>th</sup> Meeting held on 29.10.2018**

1.1 The Authority confirmed the minutes of the 192<sup>nd</sup> (overall) and the 60<sup>th</sup> Meeting under DPCO 2013 held on 29.10.2018.

**2. Agenda item no. 2 – Action Taken Report**

2.1 Noted.

**3. Agenda item no. 3 – Status of New Drug application**

3.1 Noted.

3.2 With respect to the cases referred to DCGI, it has been informed by DCGI that an expert committee is in the process of examining these cases and will require another two month for giving its opinion. Chairperson requested DCGI to expedite the process of examination.

**4. Agenda item no. 4 – New Drug applications.**

1 The Authority discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 4 [(i) to (xxiii)] falling under the purview of para 2(u) of DPCO, 2013 and approved the retail prices in 23(twenty three) cases under para 5 and para 15 of the DPCO 2013. The following retail prices were approved:

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Recommended Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
1.	Omeprazole + Domperidone Capsule (OZSON-D)	Each hard gelatin capsule contains: Omeprazole 20mg (As enteric coated pellets) + Domperidone IP 10mg (As coated pellets) Capsule	1 Capsule	M/s Unison Pharmaceuticals Pvt. Ltd.	1.79
2.	Lamivudine + Tenofovir + Dolugetravir Tablets (Diltra)	Each film coated tablet contains: Lamivudine IP 300mg, Tenofovir Disoproxil Fumarate IP 300mg Dolugetravir Sodium eq. to Dolutegravir 50mg	1 Tablet	M/s Aurobindo Pharma Limited	114.06
3.	Metformin + Pioglitazone Tablet	Each uncoated tablet contains: Metformin Hydrochloride IP 1000mg (in sustained release form), Pioglitazone Hydrochloride IP eq. to Pioglitazone 15mg	1 Tablet	M/s Eris Lifesciences Ltd.	9.04
4.	Clinidipine + Metoprolol Tablet	Each Film coated bilayered tablet contains: Clinidipine IP 10mg, Metoprolol Succinate IP 23.75mg eq. to Metoprolol tartrate 25mg (In prolonged release form)	1 Tablet	M/s Safetab Life Science / M/s Ajanta Pharma Limited	6.79
5.	Clinidipine + Metoprolol Tablet	Each Film coated bilayered tablet contains: Clinidipine IP 10mg, Metoprolol Succinate IP 47.50mg eq. to Metoprolol tartrate 50mg (In prolonged release form)	1 Tablet	M/s Safetab Life Science / M/s Ajanta Pharma Limited	8.19
6.	Rosuvastatin + Aspirin + Clopidogrel Capsule	Each Hard Gelatine Capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg (As pellets) Aspirin IP 75mg (As enteric coated pellets) Clopidogrel Bisulphate IP eq.	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Micro Labs Limited	11.46

		to Clopidogrel 75mg (As pellets)			
7.	Rosuvastatin + Aspirin + Clopidogrel Capsule	Each Hard Gelatine Capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (As pellets) Aspirin IP 75mg (As enteric coated pellets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Micro Labs Limited	17.88
8.	Escitalopram + Clonazepam Tablet (Recita LD)	Each film coated tablet contains: Escitalopram Oxalate eq. to Escitalopram 5mg, Clonazepam IP 0.25mg	1 Tablet	M/s IPCA Laboratories Ltd.	5.88
9.	Glimepiride + Pioglitazone Tablet	Each uncoated tablet contains: Glimepiride IP 1mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15mg	1 Tablet	M/s Windlas Biotech Pvt. Ltd. / M/s Lupin Limited	6.38
10.	Glimepiride + Pioglitazone Tablet	Each uncoated tablet contains: Glimepiride IP 2mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15mg	1 Tablet	M/s Windlas Biotech Pvt. Ltd. / M/s Lupin Limited	8.20
11.	Diclofenac + Serratiopeptidase Tablets (Diclotal S)	Each enteric coated Tablet Contains: Diclofenac Sodium IP 50mg, Serratiopeptidase IP 10mg eq. to 20000 enzyme activity units of Serratiopeptidase.	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Blue Cross Laboratories Pvt. Ltd.	5.00
12	Paracetamol + Phenylephrine + Caffeine + Diphenhydramine Tablet (NEMO-KOLD-NF)	Each uncoated tablet contains: Paracetamol IP 500mg, Phenylephrine Hydrochloride IP 5mg, Caffeine (Anhydrous) IP 30mg, Diphenhydramine Hydrochloride IP 25mg	Tablet	M/s Samson Laboratories Pvt. Ltd. / M/s Galpha Laboratories Limited	2.70
13	Daclatasvir + Sofosbuvir Tablet	Each film coated tablet contains: Daclatasvir Dihydrochloride eq. to Daclatasvir 60mg, Sofosbuvir 400mg	1 Tablet	M/s Natco Pharma Ltd. / M/s Aprazer Healthcare Pvt. Ltd.	556.442
14	Telmisartan + Amlodipine + Hydrochlorthiazide Tablets (Telmiride – AMH)	Each film coated bilayered tablet contains: Telmisartan IP 40mg, Amlodipine Besylate IP eq. to Amlodipine 5mg, Hydrochlorthiazide IP	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	3.21

		12.50mg Tablets			
15	Telmisartan + Metoprolol Tablet (Telmiride – MT 25)	Each uncoated bilayered tablet contains: Telmisartan IP 40mg, Metoprolol Succinate IP 23.75mg, eq. to Metoprolol Tartrate IP 25mg (as Extended Release)	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	3.13
16.	Telmisartan + Metoprolol Tablet (Telmiride – MT 50)	Each uncoated bilayered tablet contains: Telmisartan IP 40mg, Metoprolol Succinate IP 47.50mg, eq. to Metoprolol Tartrate IP 50mg (as Extended Release)	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	3.57
17.	Amoxicillin + Clavulante acid Suspension	Each combipack contains: (a) One bottle of Amoxicillin & Potassium Clavunate Oral Suspension L.P. Each 5ml of reconstituted suspension contains: Amoxicillin Trihydrate IP eq. to Amoxicillin 400mg, Potassium Clavulante Diluted IP eq. to Clavulnic Acid 57mg (b) One vial of Sterile water for Injection IP Each vial contains: Sterile water for injection IP 30ml	1 ml	M/s Malik Life Sciences Ltd. / M/s Wockhardt Limited	3.28
18	Choline Salicylate Solution + Benzalkonium Chloride Solution + Lignocaine Hydrochloride Gel (ULFREE Gel)	Each film coated tablet contains: Choline Salicylate Solution B.P. eq. to Choline Salicylate 8.7% w/w, Benzalkonium Chloride Solution IP 0001% w/w, Lignocaine Hydrochloride IP 2.0% w/w	1 GM	M/s Group Pharmaceuticals Limited / M/s Hetero Healthcare Ltd.	4.29
19.	Bupivacaine + Fentanyl injection	Each ml Contains: Bupivacaine Hydrochloride IP 1.25mg eq. to anhydrous Bupivacaine Hydrochloride 1.185mg, Fentanyl Citrate IP eq. to Fentanyl 2.0mcg	20 ML Vial	M/s Troikaa Pharmaceuticals Ltd.	75.89
20.	Bupivacaine + Fentanyl injection	Each ml Contains: Bupivacaine Hydrochloride IP 1.00mg eq. to anhydrous Bupivacaine Hydrochloride 0.948mg, Fentanyl Citrate IP eq. to Fentanyl 2.0mcg	20 ML Vial	M/s Troikaa Pharmaceuticals Ltd.	71.43
21.	Diphtheria Toxoid +	Each pack contains:	0.5 ML	M/s Panacea	340.15

	Tetanus Toxoid + Inactivated w-B. pertussis bulk + Hib (PRP- TT) (Hib PRP Conjugated with carrier protein Tetanus Toxoid) + Aluminium content (A13+) (as Aluminium Phosphate Gel) + Thiomersal 0.025mg (easy four)	Diphtheria Toxoid 20Lf (30 IU), Tetanus Toxoid 7.5Lf (60 IU), Inactivated w-B. pertussis bulk 10 IOU (4 IU), Hib (PRP- TT) (Hib PRP Conjugated with carrier protein Tetanus Toxoid) 10 ug, Aluminium content (A13+) (as Aluminium Phosphate Gel) 0.25mg, Thiomersal 0.025mg,		Biotech Ltd.	
22.	Formoterol Fumarate + Budesonide Inhalation Suspension (Smartules)	Each 2ml Inhalation suspension contains: Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate 20mcg, Budesonide IP 0.5mg in an Isotonic Solution	2 ML	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Glenmark Pharmaceuticals Limited	36.04
23	Formoterol Fumarate + Budesonide Inhalation Suspension (Smartules)	Each 2ml Inhalation suspension contains: Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate 20mcg, Budesonide IP 1.0mg in an Isotonic Solution	2 ML	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Glenmark Pharmaceuticals Limited	42.12

4.2 The Authority further directed NPPA to monitor and ensure that the retail prices given by NPPA are being adhered to by the concerned Pharmaceutical companies.

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

**5.1 Agenda item no. 5(i) - Review order in respect of M/s Koye Pharmaceuticals Pvt. Limited against price fixation of Insulin Cartridges.**

5.1.1 The authority deliberated upon and accepted the recommendations of the multidisciplinary of experts that “There is no significant therapeutic advantage of insulin cartridges vis-a-vis insulin vials and hence no separate pricing be done for cartridges or vials” and decided to close the review order with no further action.

**5.2 Agenda item no. 5(ii) – Review order in respect of M/s Win-Medicare Pvt. Limited against price fixation of Povidone Iodine 10% solution.**

5.2.1 The authority deliberated upon the order and decided to revise the ceiling price of povidone iodine 10% solution to Rs. 0.87 per ml excluding GST as per the provisions of DPCO, 2013.

**5.3 Agenda item no. 5(iii) Review orders in respect Budesonide inhalation and its combinations and Tiotropium inhalations for M/s Glenmark Ltd, M/s Lupin Ltd and M/s Cipla Ltd**

5.3.1 The Authority deliberated the issue in detail and referred the case back to the multidisciplinary committee of experts to reconsider its decision and give specific advice on whether the difference in technology would have an implication on pricing.

**5.4 Agenda item no. 5(iv) – Status of review cases.**

5.4.1 Noted.

**6. Agenda item no. 6 – Upward revision of ceiling price of medicines under para 19 of the DPCO 2013**

6.1 This agenda was deferred.

**7. Agenda item no. 7 – Matters regarding discussion with DCGI.**

7.1 The proposal for greater synergy between NPPA and DCGI was welcomed by all. DCGI informed that they are regularly conducting statutory meetings with the State Drugs Controllers and would invite representatives of NPPA in such meeting where specific agenda pertaining to NPPA would be taken up. DCGI also informed that the office is developing various software programmes and would share the details with NPPA to explore areas of convergence.

**8. Agenda item no. 8 - Issue pertaining to notices given to M/s MSD.**

8.1 Noted. The Authority further directed NPPA to bring to the notice of the Authority the prices charged by the company post the date of notification i.e the 10<sup>th</sup> July, 2014.

**9. Agenda item no. 9 - Minutes of the 5<sup>th</sup> meeting of Multidisciplinary Committee of Experts held on 14.12.2018.**

9.1 Noted.

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

(Ritu Dhillon)  
Member Secretary