

मिसिलस.- 8(54)/2017/डी.पी/एनपीपीए-डीवी-II

F. No. 8(54)/2017/DP/NPPA-Div. II

कार्यवाहीस. : 186/54/2017/F

Proceeding No : 186/54/2017/F

Minutes of the 186th (overall) and 54th meeting of the Authority under DPCO, 2013 held on 05.02.2018 at 11.00 A.M which was continued on 08.02.2018 at 3.00 P.M and on 12.02.2018 at 11.00 A.M

I. The 186th overall meeting of the Authority, which is the 54th meeting under the DPCO, 2013, was held on 5th February, 2018 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 Arun Kumar, Adviser, Deptt. of Economic Affairs, Ministry of Finance.
- (iii) Shri Umesh Dongre, Adviser (Cost), Deptt. of Expenditure, Ministry of Finance (attended only on 05.02.2018).
- (iv) Shri B. Bandyopadhyay, Adviser (Cost), Deptt. of Expenditure, Ministry of Finance.
- (v) Shri A.K.Pradhan, Deputy Drug Controller, Deptt. of Health & Family Welfare (representing DCG(I)) (attended on 05.02.2018).
- (vi) Dr. Ravi Kant Sharma, Asstt. Drug Controller, Deptt. of Health & Family Welfare (representing DCG(I)) (attended on 08.02.2018).
- (vii) Shri Aseem Sahu, Deputy Drug Controller, Deptt. of Health & Family Welfare (representing DCG(I)) (attended on 12.02.2018).

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 Rajesh K. Agrawal, Jt Director (M&E)
- (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 53rd Meeting held on 22.01.2018.

1.1 The Authority confirmed the minutes of the overall 185th and the 53rd Meeting held on 22.01.2018 under DPCO, 2013.

2. Agenda item no. 2 - Action Taken Report

2.1 The Authority noted the action taken report.

3. Agenda item no. 3 - Status of New Drug applications

3.1 Noted.

4. Agenda Item no. 4(i) to 4(xix): Fixation of retail price in respect of new drugs.

The Authority discussed the following 30 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:

Agenda item No.	Name of the Scheduled Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Proposed Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(7)
4(i).	Paracetamol + Dicyclomine Tablet (Pacimol Spas)	Each Uncoated tablet contains: Paracetamol IP 500mg, Dicyclomine Hydrochloride IP 20 mg	1 Tablet	M/s Akums Drugs and Pharmaceutical Ltd. / M/s IPCA Laboratories Ltd.	1.64
4(ii)	Amoxicillin Potassium Clavulanate Tablet (Clavam Forte DT)	Each uncoated dispersible tablet containing: Amoxicillin Trihydrate IP eq. to Amoxicillin 400mg, Potassium Clavulanate diluted IP eq. To Clavulanic acid 57 mg	1 Tablet	M/s Alkem laboratories Ltd.	16.35
4(iii)	Telmisartan + Chlorthalidone Tablet (Tigatel CH40)	Each film coated Tablet contains: Telmisartan IP 40mg, Chlorthalidone IP 12.5mg	1 Tablet	M/s Sun Pharma Laboratories Limited	7.64
4(iv)	Cilnidipine + Telmisartan tablet (Telvacil 80mg)	Each film coated Tablet contains: Cilnidipine 10mg, Telmisartan IP 80mg	1 Tablet	M/Pure and Cure Healthcare Pvt. Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	10.54
4(v)	Metoprolol Er Tablet	Each film coated extended release Tablet contains: Metoprolol Succinate IP 71.25mg eq. to Metoprolol Tartrate 75mg.	1 Tablet	M/s Intas Pharmaceuticals Limited	8.39
4(vi)	Paracetamol + Caffeine Tablete (Pacimol Active)	Each film coated Tablet contains: Paracetamol IP 650mg, Caffeine Anhydrous IP 50mg	1 Tablet	M/s Ipca Laboratories Limited	1.88
4(vii)	Doxycycline + Lactic Acid Bacillus capsules	Each hard Gelatin capsule contains: Doxycycline Hyclate eq. to Doxycycline 100mg, Lactic Acid Bacillus 5 Billion Spores	1 Capsule	M/s Mascot Health Series Pvt. Ltd. / M/s Zydus Healthcare Limited.	5.56
	Doxycycline + Lactic Acid Bacillus capsules	Each hard Gelatin capsule contains: Doxycycline Hyclate eq. to Doxycycline (Pellets) 100mg, Lactic Acid Bacillus (enteric coated Pellets) 5 Billion Spores	1 Capsule	M/s Bennet Pharmaceuticals Ltd.	5.56
4(viii)	Cilnidipine + Telmisartan Tablet	Each filmcoated tablet contains: Cilnidipine 10mg, Telmisartan IP 40mg	1 Tablet	M/s Saftab Life Science / M/s Lupin Limited	7.11
	Cilnidipine + Telmisartan Tablet	Each filmcoated tablet contains: Cilnidipine 10mg, Telmisartan IP 40mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	7.11

4(ix)	Levetiracetam Tablet	Each film coated prolonged release tablet contains: Levetiracetam IP 1000mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Zydus Healthcare Limited	23.37
	Levetiracetam Tablet	Each film coated tablet contains: Levetiracetam IP 1000mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Emcure Pharmaceuticals Limited	23.37
4(x)	Phenylephrine + Chlorpheniramine Syrup	Each 5 ml Contains: Phenylephrine Hydrochloride IP 5mg, Chlorpheniramine Maleate IP 2mg	1 ML	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Lifestar Pharma Pvt. Ltd.	0.75
4(xi)	Sumatriptan + Naproxen Tablet (NAXCOM)	Each uncoated bilayer tablet contains: Sumatriptan Succinate IP eq. to Sumatriptan 85mg, Naproxen Sodium USP 500mg	1 Tablet	M/Sun Pharma Laboratories Limited.	30.82
4(xii)	Cilnidipine + Telmisartan + Chlorthalidone Tablet	Each film coated tablet contains: Cilnidipine 10mg, Telmisartan IP 40mg, Chlorthalidone IP 6.25mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Mankind Pharma Limited	9.79
4(xiii)	Telmisartan + Amlodipine + Chlorthalidone Tablet	Each film coated tablet contains: Telmisartan IP 40mg, Amlodipine Besylate IP eq. to Amlodipine 5mg, Chlorthalidone IP 12.5mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Abbott India Limited	8.75
	Telmisartan + Amlodipine + Chlorthalidone Tablet (Tigatel ACH 40)	Each film coated tablet contains: Telmisartan IP 40mg, Amlodipine Besylate IP eq. to Amlodipine 5mg, Chlorthalidone IP 12.5mg	1 Tablet	M/s Sun Pharma Laboratories Limited	8.75
4(xiv)	Telmisartan + Amlodipine + Chlorthalidone Tablet (Tigatel ACH 80)	Each uncoated tablet contains: Telmisartan IP 80mg, Amlodipine Besylate IP Eq. to Amlodipine 5mg & Chlorthalidone IP 12.5mg	1 Tablet	M/Sun Pharma Laboratories Ltd.	14.00
4(xv)	Human Insulin Injection	Insulin Biophasic Isophane Ph. Eur./ USP (30% as soluble Insulin Injection and 70% as Isophane Insulin Injection) Each ml contains: r-human Insulin (Regular) 100 IU/vial, m-Cresol USP - 0.16% w/v, Phenol IP 0.065% w/v	1 ML	M/s MJ Biopharma Pvt. Ltd. / M/s Koye Pharmaceuticals Pvt. Ltd.	63.66
4(xvi)	Human Insulin Injection	Insulin Biophasic Isophane Ph. Eur./ USP (50% as soluble Insulin Injection and 50% as Isophane Insulin Injection) Each ml contains: r-human Insulin (Regular) 100 IU/vial, m-Cresol USP - 0.16% w/v, Phenol IP 0.065% w/v	1 ML	M/s MJ Biopharma Pvt. Ltd. / M/s Koye Pharmaceuticals Pvt. Ltd.	63.66
4(xviii)	Human Insulin Injection	Soluble Insulin Ph. Eur./USP Each ml contains: r-human Insulin (Regular) 100IU/vial	1 ML	M/s MJ Biopharma Pvt. Ltd. / M/s Koye Pharmaceuticals Pvt. Ltd.	63.66
4(xix)	Docetaxel Injection (Docetaxel IP 120mg/3ml)	Each ml of concentrate contains: Docetaxel (as anhydrous) 40mg, Polysorbate 80 - 566mg, Ethanol Anhydrous 326mg, Citric Acid Monohydrate 2mg (for PH adjustment), water for injection	Each Pack (120mg/3ml)	M/s Venus Remedies Ltd. / M/s Cadila Healthcare Ltd.	10280.34
	Escitalopram + Clonazepam Tablet (Szetalo Plus 5)	Each film coated tablet contains: Escitalopram Oxalate IP eq. to Escitalopram 5mg, Clonazepam IP 0.5mg	1 Tablet	M/s Accent Pharma / M/s Abbott Healthcare Limited.	3.83

Telmisartan + Amlodipine Tablet (Telmiduce AM)	Each uncoated tablet contains: Telmisartan IP 40mg, Amlodipine Besylate IP eq. to Amlodipine 5mg	1 Tablet	M/s Macleods Pharmaceuticals Ltd.	4.30
Telmisartan + Hydrochlorothiazide Tablet (Telmiduce H 40)	Each uncoated tablet contains: Telmisartan USP 40mg, Hydrochlorothiazide USP 12.50mg	1 Tablet	M/s Macleods Pharmaceuticals Ltd.	4.15
Rosuvastatin + Aspirin + Clopidogrel Capsule (Rozucor Gold 10)	Each Hard Gelatine Capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg (As pellets), Aspirin IP 75mg (As Gastro-resistant pellets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As pellets)	1 Capsule	M/s Synokem Pharmaceuticals Limited / M/s Torrent Pharmaceuticals Limited	9.97
Rosuvastatin + Aspirin + Clopidogrel Capsule (Rozucor Gold 20)	Each Hard Gelatine Capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (As pellets), Aspirin IP 75mg (As Gastro-resistant pellets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As pellets)	1 Capsule	M/s Synokem Pharmaceuticals Limited / M/s Torrent Pharmaceuticals Limited	18.00
Amoxicillin + Clavulante Suspension	Each combipack contains: (a) One bottle of Amoxicillin & Potassium Clavunate Oral Suspension I.P. Each 5ml of reconstituted suspension contains: Amoxicillin Trihydrate IP eq. to Amoxicillin 400mg, Potassium Clavulante Diluted IP eq. to Clavulnic Acid 57mg	1 ML	M/s Twenty First Century Pharmaceuticals Pvt. Ltd. / M/s Glenmark Pharmaceuticals Ltd.	2.91
Paracetamol + Mafenamic Suspension (Pacimol MF 125)	Each 5ml contains: Paracetamol IP 125mg, Mafenamic acid IP 50mg Flavoured Syrup base	1 ML	M/s Tirupati Medicare Limited / M/s IPCA Laboratories Pvt. Ltd.	0.48
Etomax P Tablet	Each film coated tablet contains: Etoricoxib IP 60mg, Paracetamol IP 325mg	1 Tablet	M/s Ravenbhel Healthcare (P) Limited / M/s IPCA Laboratories Pvt. Ltd.	5.14

5. Agenda Item No. 5: Review Orders on ceiling prices.

5.1 In view of paucity of time, review orders at agenda 5(vi), 5(viii), 5(ix), 5(xix), 5(xx), 5(xxii) and 5(xxiii) which require detailed discussions, were deferred. Review order at agenda 5(xvii) was discussed and Authority noted that response from DoP on clarification sought by NPPA has still not been received. The Authority decided to take up this case after receiving the clarification from DoP and directed NPPA to issue a reminder to DoP. Review orders as per agenda 5(xxi) was discussed and it was informed by Shri A.K.Pradhan, Dy. Drug Controller informed that the issue was referred to DCG(I) by Ministry of Health and Family Welfare (MoH&FW) and is under examination at their end. Accordingly, the Authority requested DCG(I) representative to expedite their response. Review orders at agenda 5 (i) to 5(v), 5(vii) and 5(x) to 5(xvi) and 5(xviii) are discussed and approved and ceiling price of formulations has been revised wherever applicable as detailed below:

Sl. No.	Review Order number and date	Petitioner Company	Formulation	Notified ceiling/retail price	Approved price on the basis of review	Remarks
(1)	(2)	(3)	(4)	(5)	(6)	(7)
5(i)	31015/33/2016-PII dated 19.9.2016	M/s Fresenius Kabi Pvt Ltd.	Paclitaxel 30mg/5 ml Injection	Rs. 202.51 per ml	---	Company's contention for pack-wise separate price was considered and rejected by CoE under para 11(3&4) of DPCO, 2013. As regard nano-based formulation, based on the recommendation of the CoE under para 11(3&4) of DPCO, 2013, the matter was referred to Core Committee of NLEM on 11.08.2017. No response has been received so far. The Authority deliberated on the issue and decided that since there is no separate specific entry for nano-based formulation, no separate pricing can be agreed to. Hence, the Authority rejected the company's contention and decided to close the review order.
5(ii)	31015/7/2013-PII dated 21.7.2017	M/s Sun Pharmaceutical Industries Ltd	Fucibet Cream 15 gm AL Tube	Rs. 46.22	---	Fucibet Cream is non-scheduled formulation under NLEM, 2011 as well as NLEM, 2015. Its price was fixed under DPCO 1995, against which the company had filed a review. NPPA fixed the price of this formulation in compliance of the review order no. 31015/7/2013-PII dated 07.10.2015. Against this order, the company went for review and as per the review order, NPPA was directed to fix the price as per the provisions applicable for non-scheduled formulation under DPCO, 2013. DOP was requested, vide letter dated 1.1.2018, to clarify on provisions applicable to non-scheduled formulation. Authority deliberated the issue and noted that there is no provision under DPCO, 2013 to fix the price of non-scheduled formulation. Accordingly, the Authority decided to close the review order without any further action.
5(iii)	31015/36/2017-Pricing dated 24.8.2017	M/s Abbott India Ltd	Clomiphene 50 mg tablet	Rs. 6.76 per tablet	Rs. 7.56 per tablet	Authority approved the change of ceiling price as per column 6
			Clomiphene 100 mg tablet	Rs. 10.62 per tablet	Rs. 11.08 per tablet	Authority approved the change of ceiling price as per column 6
5(iv)	31015/12/2017-Pricing dated 28.9.2017	M/s Neon Laboratories Ltd	Sodium Bicarbonate Injection - 8.4%	Rs. 1.17 per ml	No Change	Pharmatrac confirmed that PTR claimed by the company is not reflected in August 2015 and PTR reported by Pharmatrac is as per the highest count. Accordingly, the Authority approved no change in price.
			Lignocaine-2% + Adrenaline-	Rs. 0.83 per ml	No Change	


			1:20000 (5mcg/ ml) Injection			
			Adenosine 3mg/ml Injection	Rs 80.92 per ml	Rs. 89.34 per ml	M/s Neon Laboratories Ltd did not submit any requisite documents as required in OM dated 13.4.2017. Accordingly, the claim of Neon Laboratories Ltd could not be considered. Claim of M/s Sun Pharma Laboratories Ltd for the same formulation was considered based on evidence submitted by them and the Authority approved the new ceiling price under col. 6. Both the review orders containing the same formulation were thus considered together and the price under col. 6 was approved by the Authority.
5(v)	31015/39/ 2017- Pricing dated 24.8.2017	M/s Sun Pharma Laboratori es Ltd	Adenosine 3mg/ml Injection	Rs. 80.92 per ml		
			Isosorbide 5- mononitrate 10 mg tablet	Rs. 1.78 per tablet	No Change	
			Isosorbide 5- mononitrate 20 mg tablet	Rs. 2.78 per tablet	No Change	Pharmatrac confirmed that PTR claimed by the company was not the highest count and PTR reported by Pharmatrac is as per the highest count. The Authority approved no change in price.
5(vii)	31015/20/ 2017- Pricing dated 28.9.2017	M/s Wockhard t Ltd	Povidone Iodine 10% solution	Rs. 0.64 per ml	Rs. 0.76 per ml	Authority approved the change of ceiling price as per column 6
	31015/34/ 2017- Pricing dated 28.9.2017	M/s Win Medicare Pvt Ltd				
5(x)	31015/26/ 2017- Pricing dated 30.10.2017	M/s Pfizer ltd	Methylpredni solone 40 mg/ml injection	Rs. 43.55 per ml	Rs. 48.97 per ml	Authority approved the change of ceiling price as per column 6
5(xi)	31015/69/ 2017- Pricing dated 28.11.2017	M/s Sun Pharma Laboratori es Ltd	Sodium Valproate CR tablet 300 mg	Rs. 5.50 per tablet	Rs. 5.71 per tablet	Authority approved the change of ceiling price as per column 6
	31015/68/ 2017- Pricing dated 28.11.2017	M/s Abbott Healthcar e Pvt Ltd	Sodium Valproate CR tablet 500 mg	Rs. 8.46 per tablet	Rs. 8.85 per tablet	Authority approved the change of ceiling price as per column 6
5(xii)	31015/31/ 2017- Pricing dated 28.11.2017	M/s IPCA Laboratori es Ltd	Isosorbide 5 mononitrate 20 mg tablet	Rs. 2.78 per tablet	Rs. 2.98 per tablet	Authority approved the change of ceiling price as per column 6
5(xiii)	31015/44/ 2017- Pricing dated	M/s Neon Laboratori es Ltd	Lignocaine Topical Forms 2-5%	Rs. 0.95 per gm/ml	Rs. 0.98 per gm/ml	Authority approved the change of ceiling price as per column 6

	28.11.17					
5(xiv)	31015/65/ 2017- Pricing dated 01.01.2018	M/s Parental Drugs (india) Ltd	Glucose 10% Injection 1000 ml pack	Rs. 23.43 per 1000ml pack	No change	The petitioner did not submit any supporting documents as per OM dtd 13.4.2017. Further, Pharmatrac could not verify the claim of the company on the data issue. Accordingly, the Authority could not verify the claim of the petitioner company and decided to close the review order.
5(xv)	31015/89/ 2017- Pricing dated 10.01.2018	M/s Sun Pharma Laboratori es Ltd	Sumatriptan 25 mg tablet	Rs. 30.21 per tablet	No Change	Pharmatrac confirmed that PTR claimed by the company was not highest count and PTR reported by Pharmatrac is as per the highest count. Accordingly, the Authority approved no change in price.
			Sumatriptan 25 mg tablet	Rs. 46.76 per tablet	No Change	
5(xvi)	31015/67/ 2017- Pricing dated 10.01.2018	M/s RPG Lifescienc es Ltd	Spiroinolacton 50 mg tablet	Rs. 3.45 per tablet	No change	Pharmatrac confirmed that PTR claimed by the company was not the highest count and PTR reported by Pharmatrac is as per the highest count. Accordingly, the Authority approved no change in price.
5(xvi ii)	31015/91/ 2016-PI.I dated 22.01.2018	M/s Sun Pharmace utical Industries Ltd	Nitrofurantoi n 100 mg capsule	Rs. 7.13 per capsule	No change	Earlier review order was implemented except consideration of WPI impact. As per this corrigendum review order, DoP rejected the contention of the petitioner w.r.t WPI. Hence, Authority decided to close the review order.

6. Agenda item no. 6: Stakeholder meeting for revisiting the ceiling price of coronary stents trade margin of other medical devices.

6.1 Minutes have been issued separately.

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


 (Rakesh Ranjan)
 Member Secretary