

मिसिलस.- 8(52)/2017/डी.पी/एनपीपीए-डीवी-II

F. No. 8(52)/2017/DP/NPPA-Div. II

कार्यवाहीस. : 184/52/2017/F

Proceeding No : 184/52/2017/F

Minutes of the 184th (overall) and 52nd meeting of the Authority under DPCO, 2013 held on 15.01.2018 at 11.00 A.M.

I. The 184th overall meeting of the Authority, which is the 52nd under the DPCO, 2013 was held on 15th January, 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 Umesh Dongre, Adviser (Cost), Deptt. of Expenditure, Ministry of Finance.
- (iii) Shri Arun Kumar, Adviser, Deptt. of Economic Affairs, Ministry of Finance.
- (iv) Shri Aseem Sahoo, 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 Rajesh K. Agrawal, Jt Director(M&E)
- (iv) Shri Arun Diwan, Dy. Director (O/C)
- (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.

II. Agenda items

1. Agenda item no. 1 - Confirmation of Minutes of the 51st Meeting under DPCO, 2013 held on 15.12.2017.

1.1 The Authority confirmed the minutes of the overall 183rd and the 51st Meeting held on 15.12.2017 under DPCO, 2013 except para 4.1.1, which has been modified as under:

“The Authority examined the retail price fixation of the companies in details. With a view to rationalize the prices of new drugs, the authority discussed and decided that wherever the application has been received by NPPA for any drug for which NPPA has already notified the price, the same would be extended to subsequent applicants also without any annual indexation since that has been nullified by Govt. New applications without any precedence

to be dealt under para 5 of DPCO, 2013. Authority re-confirmed the recommendation of NPPA for amendment of DPCO, 2013 to allow annual MRP increase in new drug cases as per W.P.I. as done in case of scheduled drugs. 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:”

2. Agenda item no. 2 - Action Taken Report

2.1 Noted.

3. Agenda item no. 3 - Fixation of Retail Prices as power delegated to Chairman as per decisions taken by in its 51st meeting held on 15.12.2017.

3.1 Noted.

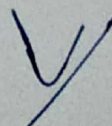
4 Agenda item no. 4 - Status of New Drug applications

4.1 Noted.

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

4.2 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	Retail Price (Rs.)
4 (i)	Glimepiride + Metformin Tablet	Each uncoated Bi- Layered tablet contains: Glimepiride IP 1mg, Metformin HCL IP 850mg (As sustained release form)	1 Tablet	M/s Windlas Biotech Ltd. / M/s Intas Pharmaceuticals Pvt. Ltd.	4.89
4 (ii)	Glimepiride + Metformin Tablet	Each uncoated Bi- Layered tablet contains: Glimepiride IP 2mg, Metformin HCL IP 850mg (As sustained release form)	1 Tablet		7.23
4 (iii)	Cilnidipine + Metoprolol Tablet	Each film coated Bi- Layered tablet contains: Cilnidipine 10mg, Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate 25mg (ER)	1 Tablet	M/s Safetab Life Science / M/s Intas Pharmaceuticals Pvt. Ltd.	6.98
4 (iv)	Escitalopram + Clonazepam Tablet (CENSPRAM MINI)	Each film coated tablet contains: Escitalopram Oxalate IP eq. to Escitalopram 5mg Clonazepam IP 0.5mg	1 Tablet	M/s Accent Pharma / M/s USV Limited	5.73
4 (v)	Ceftriaxone sodium & Tazobactam Sodium Injection for	Each combipack contains: Ceftriaxone sodium (sterile) eq. to anhydrous Ceftriaxone 500mg Tazobactam Sodium (sterile) eq. to anhydrous Tazobactam 62.5mg, And One FFS Ampoule containing Sterile water for injection 5ml	Each Pack	M/s Mankind Pharma Ltd.	76.69
4 (vi)	Rosuvastatin + Aspirin + Clopidogrel Capsule	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg (As Pellets),	1 Capsule	M/s GKM New Pharma/ M/s Unichem Laboratories Ltd.	



	(Unistar Gold 10/75)	Aspirin IP 75mg (As enteric Coated Pellets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As Pellets)			
	Rosuvastatin + Aspirin + Clopidogrel Capsule (Zyrova Gold 10)	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg (As granules), Aspirin IP 75mg (As enteric Coated Tablets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As two film coated tablets)	1 Capsule	M/s GKM New Pharma /M/s Cadila Healthcare Ltd.	
	Rosuvastatin + Aspirin + Clopidogrel Capsule	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg (As granules), Aspirin IP 75mg (As enteric Coated Tablets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As two film coated tablets)	1 Capsule	M/s GKM New Pharma /M/s Zuventus Healthcare Limited	
	Rosuvastatin + Aspirin + Clopidogrel Capsule	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg (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 Zydus Healthcare Limited	
	Rosuvastatin + Aspirin + Clopidogrel Capsule	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg (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 Mankind Pharma Limited	
	Rosuvastatin + Aspirin + Clopidogrel Capsule	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg, Aspirin IP 75mg, Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg	1 Capsule	M/s Synokem Pharmaceuticals Ltd /M/s Cadila Pharmaceuticals Limited	
	Rosuvastatin + Aspirin + Clopidogrel Capsule	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg (As film coated tablet), Aspirin IP 75mg (As Gastro - resistant tablet), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As film coated tablet)	1 Capsule	M/s Pure and Cure Healthcare Pvt. Ltd. /M/s Jubilant Life Sciences Limited	
	Rosuvastatin + Aspirin + Clopidogrel Capsule	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg, Aspirin IP 75mg, Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg	1 Capsule	M/s Synokem Pharmaceuticals Ltd/ M/s Eris Lifesciences Ltd.	
4 (vii)	Rosuvastatin + Aspirin + Clopidogrel Capsule (Unistar Gold 20/75)	Each hard gelatin 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 GKM New Pharma /M/s Unichem Laboratories Ltd.	
	Rosuvastatin + Aspirin + Clopidogrel Capsule (Zyrova Gold 20)	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (As granules), Aspirin IP 75mg (As enteric Coated Tablets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As two film coated tablets)	1 Capsule	M/s GKM New Pharma /M/s Cadila Healthcare Ltd.	
	Rosuvastatin + Aspirin + Clopidogrel Capsule	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (As granules), Aspirin IP 75mg (As enteric Coated Tablets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As two film coated tablets)	1 Capsule	M/s GKM New Pharma /M/s Zuventus Healthcare Limited	
	Rosuvastatin + Aspirin + Clopidogrel Capsule	Each hard gelatin 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	1 Capsule	M/s Synokem Pharmaceuticals Ltd /M/s Zydus Healthcare Limited	

11.70

	Rosuvastatin + Aspirin + Clopidogrel Capsule	75mg (As Pellets) Each hard gelatin 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 Mankind Pharma Limited	18.00
	Rosuvastatin + Aspirin + Clopidogrel Capsule	Each hard gelatin 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 Lifestar Pharma Limited	
	Rosuvastatin + Aspirin + Clopidogrel Capsule (Jubira Gold 20)	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (As film coated tablet), Aspirin IP 75mg (As Gastro - resistant tablet), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As film coated tablet)	1 Capsule	M/s Pure and Cure Healthcare Pvt. Ltd. /M/s Jubilant Life Sciences Limited	
	Rosuvastatin + Aspirin + Clopidogrel Capsule	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg, Aspirin IP 75mg, Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg	1 Capsule	M/s Synokem Pharmaceuticals Ltd /M/s Eris Lifesciences Ltd.	
	Rosuvastatin + Aspirin + Clopidogrel Capsule	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (As film coated tablet), Aspirin IP 75mg (As enteric coated tablet), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As film coated tablet)	1 Capsule	M/s Safetab Lifescience M/s Lupin Limited	
4 (viii)	Olmesartan + Amlodipine Tablet (Tripinom 40)	Each uncoated tablet contains: Olmesartan Medoxomil 40mg, Amlodipine Besylate eq. to Amlodipine 5mg, Hydrochlorothizide 12.5mg	1 Tablet	M/s Accent Pharma / M/s Lupin Ltd.	12.29
4 (ix)	Rosuvastatin + Aspirin Capsule (Rozucorn Asp 20 Forte)	Each hard gelatine capsule contains: Rosuvastatin Calcium eq. to Rosuvastatin 20mg (As film coated tablet) Aspirin IP 150mg (as enteric coated tablet)	1 Capsule	M/s Torrent Pharmaceuticals Ltd.	8.78
4 (x)	Voglibose + Glimeperide + Metformin Tablet (Glimy MVI)	Each uncoated bilayer tablets contains: Voglibose IP 0.2mg, Glimeperide IP 1mg & Metformin Hydrochloride IP 500mg (SR)	1 Tablet	M/s ACME Generics / M/s Dr. Reddy's Laboratories Limited	6.786
	Voglibose + Glimeperide + Metformin Tablet (Glimy MV2)	Each uncoated bilayer tablets contains: Voglibose IP 0.2mg, Glimeperide IP 2mg & Metformin Hydrochloride IP 500mg (SR)	1 Tablet	M/s ACME Generics / M/s Dr. Reddy's Laboratories Limited	8.571
	Cefixime + Ofloxacin Tablet (Stancef-O Plus)	Each film coated tablet contains: Cefixime Trihydrate eq. to Cefixime Anhydrous IP 200mg, Ofloxacin IP 200mg	1 Tablet	M/s Theon Pharmaceuticals Limited a/ M/s Sun Pharmaceutical Industrial Limited	9.46
	Trypsin + Bromelain + Rutoside + Diclofenac Tablet (Volitra Enzo)	Each enteric coated tablet contains: Trypsin BP 48mg, Bromelain 90mg, Rutoside Trihydrate BP 100mg Diclofenac Sodium IP 50mg	1 Tablet	M/s Synokem Pharmaceuticals Limited / M/s Sun Pharmaceuticals Industries Limited	13.85
	Gliclazide + Metformin Tablet (GLZ MEX)	Each film coated tablet contains: Gliclazide IP 60mg (In modified release form), Metformin HCL 500mg (extended release form)	1 Tablet	M/s Mascot Health Seris Pvt. Ltd. / M/s Alembic Pharmaceuticals Limited	7.65
	Rosuvastatin + Clopidogrel Capsule (Turbovas C)	Each hard gelatine capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg (as film coated tablet), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (as 2 film coated tablet)	1 Capsule	M/s Micro Labs Limited	12.95

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

Review orders as per agenda 5(i) to 5(viii) are discussed and approved, ceiling price of formulations have been revised wherever applicable as detailed below:

Sl. No.	Review Order number and date	Petitioner Company	Formulation	Presently notified ceiling/retail price	Approved ceiling/retail price on the basis of review order	Remark
5 (i)	31015/41/2016.P.I.I dated 27.11.2017	M/s Alkem Laboratories Ltd.	Cholicalciferol 60K IU capsule, Cholicalciferol 1000 IU capsule, Cefixime Oral Liquid 100mg/5ml, Cefixime 50mg/5ml			DoP vide their review orders issued corrigendum to their earlier order in the same case and rejected the contention of the companies regarding applicability of WPI for fixing the ceiling price of formulations included first time in NLEM, 2015. Therefore, no revision.
5 (ii)	31015/39/2016.P.I.I dated 01.12.2017	M/s Reckitt Benckiser Healthcare Pvt. Ltd.	Clotrimazole 1% cream			
5 (iii)	31015/43/2016.P.I.I dated 01.12.2017	M/s Alkem Laboratories Ltd.	Cefotaxime 1 gm Injection			
5 (iv)	31015/60/2017-Pricing dated 14.11.2017	M/s Alembic Pharmaceuticals Ltd.	Erythromycin Esolate Tablets 250mg, Erythromycin Esolate Tablets 500mg and Erythromycin Esolate Syrup 125mg/5 ml			As directed vide review order, the notification to be set aside.
5 (v)	31015/7/2017-Pricing dated 24.7.2017	M/s Modi-Mundi Pharma Pvt. Ltd.	N-acetylcysteine 200mg sachet	Rs. 6.84 per gm	Rs. 8.16 per gm	
5 (vi)	31015/53/2017-Pricing dated 30.10.2017	M/s Pfizer Limited	Oxytocin Injection 10IU/ml	Re. 35.74 per ml	Re. 35.74 per ml	Company stated PTR is at the 2 nd highest count. PTR included in at the highest count. Hence, no change in price.
5 (vii)	31015/43/2017-Pricing dated 07.9.2017	M/s Mylan Pharmaceuticals Pvt. Ltd	Amphotericin B Powder for Injection 50 mg-Lipid/ Liposomal	Rs. 3394.25 per pack	Rs. 3402.55 per pack	
	31015/45/2017-Pricing dated 16.11.2017	M/s Sun Pharma Laboratories Ltd.				
5 (viii)	31015/48/2017-Pricing dated 01.12.2017	M/s Sun Pharmaceuticals Industries Limited	Gemcitabine 200mg Powder for Injection	Rs. 1045.77 per pack	Rs. 1063.15 per pack	

6. Agenda item no. 6: Status of review orders issued by DoP for implementation by NPPA

6.1 Noted.

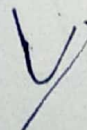
7. Agenda item no. 7: Draft amendment in existing guideline on overcharging cases.

7.1 After deliberation the Authority approved proposed amendments in existing guideline on overcharging cases.

8. Agenda item no. 8: Deliberation to deal overcharging cases where neither Pharmatrac data are available nor the concerned pharmaceutical companies have submitted batch-wise production and sales details.

8.1 After intensive deliberation the Authority advised NPPA office to prepare a list of all such cases of DPCO, 2013 and first try to obtain said data from IMS-Health (Data provider vendor) within a schedule time frame of 45 days. If NPPA is able to get the data regarding the brands under consideration in the overcharging case from IMS-Health, then the show cause notice will be issued to the company quantifying the amount and rest of the provisions of internal guidelines will be followed. If, however, no alternative data are available implying that MAT of the company is on lower side, the following two options may be considered:

- a. If number of brands available in pharmatrac for the formulation under consideration is more than 5, average of the MAT volume of lowest 3 (three) traded brands of that formulation may be taken as the MAT volume of the brand under question. A show cause notice may be issued based on the quantification which may be arrived at by multiplying the MAT volume calculated above and the price differential i.e the price charged above the ceiling price. The calculation may cover the period from date of notification till the month for which the Pharmatrac data is available just before issue of show cause notice or till the formulation continues to be scheduled, whichever is earlier.
- b. If number of brands available in pharmatrac for the formulation under consideration is less than 5, MAT volume of the lowest traded brand of that formulation may be taken as the MAT volume of the brand under question. A show cause notice may be issued based on the quantification which may be arrived at by multiplying the MAT volume calculated above and the price differential i.e the price charged above the ceiling price. The calculation may cover the period from date of notification till the month for which the Pharmatrac data is available just before issue of show cause notice or till the formulation continues to be scheduled, whichever is earlier.



8.2 A draft OM on the above lines should be uploaded on the website inviting comments from the stakeholders within 10 working days from the date of website publication and to be put up to Authority again for confirmation with comments from industrial associations.

9. Agenda item no. 9: Status of IPDMS

9.1 Noted.

10 Agenda item no. 10: Status regarding launch of drugs Without Price Approval (WPA)

10.1 Noted.

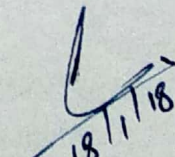
11. Agenda item no. 11: request of M/s Allergan India Private Limited for discontinuation of scheduled formulation Pred Forte (Prednisolone 1% Eye Drops) under para 21(2) of DPCO, 2013.

11.1 Considering the high market share of the formulation and “negative margins” & non-recovery of the cost of production” given by the Company as reason for discontinuation, it was decided to ask the Company to apply for Price fixation under para 19 of DPCO, 2013. DoP may also be requested to invoke Para 3 of DPCO, 2013 till a decision on above referred request of the Company for Price fixation under para 19 of DPCO, 2013.

12 Agenda item no. 12: Request of M/s GlaxoSmithKline Private Limited for discontinuation of scheduled formulation OTRIVIN (Xylometazoline Hydrochloride Nasal Solution IP 0.1% w/v) under para 21(2) of DPCO, 2013.

12.1 Considering the high market share of the formulation and “economically un-viability to market the product” given by the Company as reason for discontinuation, it was decided to ask the Company to apply for Price fixation under para 19 of DPCO, 2013. It was also decided to request DoP may also be requested to invoke Para 3 of DPCO, 2013 till a decision on above referred request of the Company for Price fixation under para 19 of DPCO, 2013.

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


18/1/18
(Rakesh Ranjan)
Member Secretary