मिसिल स.- 8(55)/2018/डी.पी/एनपीपीए-डीवी-II
F. No. 8(55)/2018/DP/NPPA-Div. II

कार्यवाहीस. : 187/55/2018/F
Proceeding No : 187/55/2018/F

Minutes of the 187th (overall) and 55th meeting of the Authority under DPCO, 2013 held on 26.02.2018 at 11.00 A.M

I. The 187th overall meeting of the Authority, which is the 55th meeting under the DPCO, 2013, was held on 26th 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 B. Bandyopadhyay, Adviser (Cost), Deptt. of Expenditure, Ministry of Finance
(iv) Shri A.K.Pradhan, 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 Baljit Singh, Asstt. Director (Pricing)
(iii) 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 54th Meeting held on 05.02.2018, which was continued on 08.02.2018 and 12.02.2018.

1.1 The Authority confirmed the minutes of theoverall 186thand the 54thMeeting held on 05.02.2018 and continued on 08.02.2018 and 12.02.2018under DPCO, 2013.

2. Agenda item no. 2 - Action Taken Report

2.1 The Authority noted the action taken report.

2.2 With regard to SO. 639(E) dated 12.02.2018, the Authority observed that in para 10 of the notification the Authority meeting was wrongly entered as 05th January 2018 instead

of 05th February 2018. Accordingly, the Authority directed to issue a corrigendum notification.

3. Agenda item no. 3 -Status of complaints of non-availability of drugs

3.1 Authority asked NPPA officers dealing with such cases to keep updated information on each case and also upload the same on the website fortnightly so that people can also see what action has been taken on their complaints. An application will be treated as disposed after the complainant receives the medicine.

4. Agenda item no. 4 - Status of price fixation for remaining scheduled drugs

4.1 Authority requested the pricing division to send letters to other hospitals to collect data and, if need be, inspect certain hospitals to collect the same if replies are not received in time.

5. Agenda item no. 5 - Request for discontinuation

5.1 Authority noted with satisfaction that old backlog is cleared. It also requested Chairman to request DoP to take quick decisions to decide the cases referred for auction under Para 3 of DPCO, 2013 to ensure availability.

6. Agenda item no. 6 - Update of Overcharging

6.1 Noted

7. Agenda item no. 7 - Status of New Drug applications

7.1 The Authority noted that Pharmacoeconomics cases and cases under Para 11(3) are pending for long and decided to request the DoP to reconstitute the committees at the earliest keeping in mind the concerns raised by NPPA.

8. **Agenda item no. 8 - New Drug cases**

8.1 The Authority discussed the following cases of retail price fixation of new drugs in Agenda no. 8(i) to 8(xv) falling under the purview of para 2(u) of DPCO, 2013 and approved the retail prices of 9(nine) cases following under para 5 of the DPCO 2013, as under:

Agenda Item No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Approved Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
8(i)	Atorvastatin + Aspirin Capsule (Atchol-ASP 150)	Each hard gelatin capsule contains: Atorvastatin Calcium eq. to Atorvastatin 10mg (as two film - coated tablets of 5 mg each) Aspirin 150mg (as two enteric coated tablets of 75mg each)	1 Capsule	M/s Aristo Pharmaceuticals Pvt. Ltd.	2.10
8(ii)	Nifedipine + Lidocaine Cream (LOXHEAL)	Each 30mg cream contains: Nifedipine IP 0.3 percent weight by weight, Lidocaine IP 1.5 percent weight by weight, Imidurea IP as Preservative 0.2percent weight by weight in Cream base	1 GM	M/s Uttaranchal Biotech Ltd. / M/s Neon Laboratories Ltd.	3.14
8(iii)	Pioglitazone + Gliclazide + Metformin Tablet (GLZ Total)	Each film coated tablet contains: Pioglitazone HCL IP eq. to Pioglitazone 15mg, Gliclazide IP 60mg (In modified release form) and Metformin HCL 500mg (extended release form)	1 Tablet	M/s M/s Mascot Health Seris Pvt. Ltd. / M/s Alembic Pharmaceuticals Limited	8.11
8(iv)	Ibuprofen + Paracetamol Tablet (Brufen Plus)	Each film coated tablet contains: Ibuprofen IP 400mg Paracetamol IP 325mg	1 Tablet	M/s Innova Captab Pvt. Ltd. / M/s Abbott Healthcare Pvt. Ltd.	1.04
8(v)	Misoprostol Tablet	Each uncoated tablet contains: Misoprostol IP 600mcg (As 1% Misoprostol dispersion)	1 Tablet	M/s Synokem Pharmaceuticals Limited / M/s Bharat Serums and Vaccines Limited	56.81
8(vi)	Glimepiride + Metformin Tablet	Each uncoated bilayered tablet contains: Glimepiride IP 3mg, Metformin Hydrochloride IP 850mg (in Sustained release form)	1 Tablet	M/s Windlas Biotech Ltd. / M/s Intas Pharmaceuticals Limited	7.05
8(vii)	Melphalan + Povidone Injection (Melphalan Injection IP 50mg)	Each vial contains: Melphalan HCL IP eq. to Melphalan 50mg, Povidone IP 20mg and Diluent For Melphalan Injection 10ml each vial contains Sodium Citrate IP 0.2g Proylene Glycol IP 6ml Ethanol (96%) IP 0.52ml water for Injection	Each Pack	M/s Natco Pharma Ltd	1767.38
8(viii)	Trastuzumab Injection	Each Lyophilized vial contains: Trastuzumab 150mg Injection	1 Vial	M/s Cadila Healthcare Limited / M/s Emcure Pharmaceuticals Ltd.	18125.79
8(xv)	Vitamin D3 (Cholecalciferol) (D-RISE SURE)	Each orally Disintegrating Strip contains: Vitamin D3 (Cholecalciferol) IP 60000 IU Orally Disintegrating Strip	1 Orally Disintegrating Strip	M/s Zim Laboratories Limited and Marketed by M/s USV Limited	24.76

8.2 Agenda item nos. 8(ix) to 8(xiv) are listed below:

Agenda Item No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Date of Launch/ Application
(1)	(2)	(3)	(4)	(5)	(6)
8(ix)	Chlorthalidone + Amlodipine + Telmisartan Tablet (TRITELSAR 80 HS)	Each film coated tablet contains: Chlorthalidone IP 12.5mg, Amlodipine Besylate IP eq. to Amlodipine 5mg, Telmisartan IP 80mg tablets	1 Tablet	M/s GKM New Pharma. / by M/s Unichem Laboratories Limited	**1.7.2013/ 14.12.2017**
8(x)	Olmesartan Medoxomil + Chlorthalidone + Amlodipine tablet (TRIOLSAR 20 HS)	Each film coated tablet contains: Olmesartan Medoxomil 20mg, Chlorthalidone IP 12.5mg, Amlodipine Besylate IP eq. to Amlodipine 5mg tablets	1 Tablet	M/s GKM New Pharma. / M/s Unichem Laboratories Limited	**1.7.2013/ 14.12.2017**
8(xi)	Olmesartan Medoxomil + Chlorthalidone + Amlodipine tablet (TRIOLSAR 40 HS)	Each film coated tablet contains: Olmesartan Medoxomil 40mg, Chlorthalidone IP 12.5mg, Amlodipine Besylate IP eq. to Amlodipine 5mg tablets	1 Tablet	M/s GKM New Pharma. / M/s Unichem Laboratories Limited	**1.12.2013/ 14.12.2017**
8(xii)	Chlorthalidone + Amlodipine + Telmisartan Tablet (TRITELSAR 40)	Each film coated tablet contains: Chlorthalidone IP 6.25mg, Amlodipine Besylate IP eq. to Amlodipine 5mg, Telmisartan IP 40mg tablets	1 Tablet	M/s GKM New Pharma / M/s Unichem Laboratories Limited	**1.7.2013/ 14.12.2017**
8(xiii)	Chlorthalidone + Amlodipine + Telmisartan Tablet (TRITELSAR 40 HS)	Each film coated tablet contains: Chlorthalidone IP 12.50mg, Amlodipine Besylate IP eq. to Amlodipine 5mg, Telmisartan IP 40mg tablets	1 Tablet	M/s GKM New Pharma / M/s Unichem Laboratories Limited	**1.7.2013/ 14.12.2017**
8(xiv)	Chlorthalidone + Amlodipine + Telmisartan Tablet (TRITELSAR 80)	Each film coated tablet contains: Chlorthalidone IP 6.25mg, Amlodipine Besylate IP eq. to Amlodipine 5mg, Telmisartan IP 80mg tablets	1 Tablet	M/s GKM New Pharma / M/s Unichem Laboratories Limited	**1.7.2013/ 14.12.2017**

The Authority observed that M/s Unichem Laboratories Ltd has commenced production of the above mentioned new drugs more than 4(four) years **before applying for the price fixation.** This is in gross violation of the provisions of DPCO 2013. In the normal course, prices prevailing 6 months prior to the date of application for the new drugs should be taken. If the manufacturer/ marketing company has already launched the new drug at a price higher than the retail price, it is liable to deposit the overcharged amount along with interest from the date of overcharge, in addition to the penalty. In this case, considering the long-time gap between the launch of the drug and the date of application, retail price fixed on the basis of 2017 prices will not be a true indicator of the retail price in 2013. The

Authority deliberated the issue in detail and, considering the extraordinary circumstances, it was decided that the prices prevailing six months before the date of launch should be taken as the basis. It was also noted that two of the components in these new drugs are scheduled drugs and, therefore, for the purpose of calculation of overcharged amount, indexing should be done on the 1st April of every year using WPI. Accordingly, the Authority directed to put up the draft revised calculation of Agenda item nos. 8(ix) to 8(xiv) in the next Authority meeting based on the above decision.

The Authority also noted that there are only marginal variations in the composition of these "new drugs", as shown in the tables below, and, after detailed deliberations, decided to refer the matter to DCGI to give its views on the therapeutic rationale of these new drugs.

Sl. No.	Name of New Drug ➡ Composition ⬇	Tritelsar 40	Tritelsar 40 HS	Tritelsar 80	Tritelsar 80 HS
1.	Telmisartan	40	40	80	80
2.	Amlodipine	5	5	5	5
3.	Chlorthalidone	6.25	12.5	6.25	12.5

Sl. No.	Name of New Drug ➡ Composition ⬇	Triolsar 20 HS	Triolsar 40 HS
1.	Olmesartan	20	40
2.	Amlodipine	5	5
3.	Chlorthalidone	12.5	12.5

8.3 While discussing the retail price fixation of new drugs, it was noted that if there is an existing manufacturer of any "new drug", as per the procedure prescribed in the DPCO, 2013, i.e. averaging of PTRs of existing manufacturers of that formulation, price of the existing manufacturer is in effect extended to the applicant company. Thus, if a manufacturer has monopoly and launched the drug at a very high price, its "price advantage" is automatically extended to the applicant company.

8.4 The Authority noted the retail price fixation of 14 (fourteen) cases in which prices fixed earlier have been extended to the applicant company, as stated in agenda item no. 8(xvi), based on the power delegated to Chairman as per decision taken in its 51st meeting held on 15.12.2017

9. Agenda Item No. 9 - Implementation of review orders

9.1 The Authority deliberated the review cases and approved revision of ceiling prices of formulations, wherever applicable, as detailed below:

Agenda item 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)
9(i)	31015/19/2017-Pricing dated 24.8.2017	M/s Sanofi India Ltd	Furosemide 10mg/ml Injection	Rs. 0.99 per ml	Rs. 1.50 per ml	Authority approved the change of ceiling price as per column 6.
9(ii)	31015/56/2017-Pricing dated 30.10.2017	M/s Biological E. Ltd	Snake Venom antiserum-Soluble/ Liquid Polyvalent	Rs. 337.05 per 10 ml pack	Rs. 392.64 per 10 ml pack	Pharmatrac could not confirm about the PTR of the product of Biological E. Ltd. Based on the summary of invoice for the month of August 2015 submitted by the company, the Authority observed that the maximum count of PTR is Rs. 366.37. The PTR claimed by the company has appeared once. The Authority deliberated the issue in details and decided to approve the change of ceiling price as per column 6 by taking the PTR of Rs. 366.37.
9(iii)	31015/10/2017-Pricing dated 30.10.2017	M/s Neon Laboratories Ltd	Midazolam 1mg/ml Injection	Rs. 5.36/ml	no change	The Authority deliberated the matter in detail. Pharmatrac in its reply stated that since it is a hospital product the price capture might not be proper and Neon Laboratories sales distribution is different as they are mainly into hospital products. Further, the petitioner company has not furnished all the documents as per OM dated 13.4.2017. Accordingly, the Authority could not verify the claim of the petitioner company and decided to close the review order without any change.
			Midazolam 5mg/ml Injection	Rs. 13.17/ml	no change	

9(iv)	31015/19/2017-Pricing dated 10.01.2018	M/s Glenmark Pharmaceuticals Ltd	Clotrimazole 1% cream	Rs. 2.46/gm	no change	The Authoritynoticed that previously MAT of Midas pharmaceuticals wasconsidered as per the Pharmatrac data only. There is no sufficient ground or evidence provided by either Pharmatrac or the company regarding the change in MAT. Hence, further change in MAT could not be considered. Accordingly, Authority decided to close the review order without any change.
9(v)	31015/46/2017-Pricing dated 22.01.2018	M/s Wockhardt Ltd	Methyldopa 500 mg tablet	Rs. 4.24 per tablet	--	It was discussed in great detail and the decision of the authority is recorded in the note below this table.
9(vi)	31015/33/2017-Pricing dated 24.8.2017 31015/37/2017-Pricing dated 28-Sep-2017	Cadila Healthcare Ltd M/s Abbott Healthcare Ltd.	Co-trimoxazole [Sulphamethoxazole (A) + Trimethoprim (B)] Tablet 800 mg (A) + 160 mg (B)	Rs. 0.96 per tablet	no change	The petitioner company has not furnished all the documents as per OM dated 13.4.2017. In the absence of adequate information, it was decided to close the case.
9(vii)	31015/27/2016-PI.I dated 14-sep-2016 31015/52/2017-Pricing dated 30.10.2017	M/s Cipla Ltd M/s Glenmark Pharmaceuticals Ltd (Inhalers)	Budesonide 100 mcg/Dose	Rs. 1.19 /dose	----	The authority deliberated the matter in the light of the order, recommendation of the committee of experts and litigation in the court. It is noticed that the manufacturer has not submitted the requisite information like summary of invoices, sample of the product claimed as DPI and invoices as per OM dated 13.4.2017.Accordingly, the Authority decided to give 10 days time to get requisite information from the companies. Matter will be placed in the next meeting of the Authority.
			Budesonide 200 mcg/Dose	Rs. 1.40 /dose	----	
			Budesonide 400 mcg + Formoterol 6mcg/Dose	Rs. 2.68 /dose	----	
			Budesonide 200mcg + Formoterol 6mcg/Dose	Rs. 2.4 /dose	----	
			Budesonide 100mcg + Formoterol 6mcg/Dose	Rs. 1.70 /dose	----	
			Tiotropium 9 mcg/dose	Rs. 2.11 /dose	----	
			Tiotropium 18 mcg/dose	Rs. 2.14 /dose	----	
9(viii)	31015/30/2016-PI.I dated 14.9.2016 31015/82/2016-PI.I dated 05.4.2017	M/s FDC Ltd M/s Wallace Pharmaceuticals Private Limited	Oral Rehyderation Salt	Rs. 0.72 per gm	----	Considering that the matter referred to the MoHFW, the decision on this is deferred.

9(ix)	31015/37/2017-Pricing dated 28-Sep-2017	M/s Abbott Healthcare Ltd.	Phenobarbitone Oral liquid 20 mg/5 ml	Rs. 0.35 per ml	Rs. 0.40 per ml	Based on the documentary evidence submitted by the company, the Authority approved the change of ceiling price as per column 6.

Note on deliberation and decision of Agenda no. 9(v): As per NLEM 2011, Methyldopa 250 mg tablet was a scheduled medicine and its ceiling price was fixed which was revised to Rs. 2.48 per tablet vide SO. 1204(E) dated 06.5.2015 towards implementation of a review order. A complaint was received on 16.2.2015 that M/s Wockhardt ltd had stopped distributing Methyldopa 250 mg tablet and instead had launched Methyldopa 500 mg tablet at a much higher MRP of Rs 16.0 per tablet. Considering it as a WPA case, retail price of Methyldopa 500 mg tablet for M/s Wockhardt Ltd/ M/s Medibios Lab Ltd was fixed at Rs. 4.46 per tablet vide SO. 1253(E) dated 29.3.2016.

M/s Wockhardt Ltd went for review against this order as, in the meantime, Methyldopa 500 mg tablet had become a scheduled formulation vide SO. 701(E) dated 10.3.2016. DoP vide its order dated 05.1.2017 directed NPPA to fix the ceiling price of Methyldopa 500 mg tablet as per para 4(1) and para 6 of DPCO, 2013.

The fixation of ceiling price of Methyldopa 500 mg tablet was proposed in the 42nd Authority meeting dated 09.3.2017. The Authority decided to consider the same retail price fixed earlier as ceiling price of this formulation which, after adjustment of WPI, came to Rs. 4.33 per tablet per tablet notified vide SO. 787(E) dated 10.3.2017. The present review order is against this notification.

The Authority discussed the matter in detail and noted that M/s Wockhardt Ltd has denied that it ever manufactured the Methyldopa 250 mg and that it was not an "existing" manufacturer of the formulation within the meaning of DPCO 2013 and, therefore, Methyldopa 500 mg was not a "new drug". Some evidences available with NPPA show that M/s Wockhardt Ltd was the manufacturer of Methyldopa 250 mg. During the period from January 2012 to December 2017, for which data are available with NPPA, a total of 1.71 crore strips (of 10 tabs each) worth Rs 31.49 crore was sold in the market. Over a period of 4 years from December 2013 to December 2017, the MAT volume of Methyldopa 250 mg has reduced from 48.65 lakh strips of 10 tablets to just 32,445 strips and the MAT value has gone down from Rs 8.77 cr to just Rs 5.60 lakh, clearly indicating that the drug has been withdrawn from the market.

The Authority was of the view that this kind of total denial by M/s Wockhardt Ltd gives rise to strong suspicions. It was decided that the matter needs to be enquired into in detail and the matter needs to be referred to an appropriate agency of the Government of India dealing with such economic offences.

If M/s Wockhardt Ltd was a manufacturer of Methyldopa 250 mg then extending the retail price Methyldopa 500 mg as its ceiling price is logical. However, if it was not an existing manufacturer of Methyldopa 250 mg then the fixation of ceiling price of Methyldopa 500 mg may be re-examined once it is proved in an expert investigation.

9.2 The Authority noted the status of review cases as per agenda item no. 9(x).

10. Agenda Item No. 10 - Status of analysis of trade margin and price fixation of Medical Devices.

10.1 Noted.

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

(Rakesh Ranjan)
Member Secretary