गोपनीय : Confidential

मिसिल स.- 8(17)/2014 डी.पी./एन पी पी ए- डीवी-II

F. No. 8(17)/2014/DP/NPPA-Div. II

कार्यवाही स. : 149/17/2014/F
Proceeding No : 149/17/2014/F

Minutes of the 149th and 17th meeting of Authority under DPCO, 2013 held on 20th August, 2014 at 11.00 AM.

The 149th meeting of the Authority, which is the 17th under the DPCO, 2013 was held on 20th August, 2014 at 11.00 AM under the Chairmanship of Shri Injeti Srinivas, Chairman, NPPA. The following members of the NPPA were present:-

(i) Shri A.K. Gautam, Member Secretary Incharge, NPPA.
(ii) Dr. G.N. Singh, DCG(I), Member (Ex-Officio), represented by Shri R. Chandrashekar, Deputy Drug Controller, Department of Health.
(iii) Shri K.L. Prasad, Member (Ex-Officio), Adviser, Economic Division, Deptt. of Economic Affairs.
(iv) Shri L.M. Kaushal, Director (Cost), Member (Ex-Officio), Deptt. of Expenditure, Ministry of Finance.

The following officers also attended the meeting and assisted the Authority in its deliberations:-

(i) Shri Lal Sanglur, Director (Overcharging –II)
(ii) Shri Jagdish Kumar, Director (M&E)
(iii) Shri A.K. Khurana, Director (Pricing & Admin)
(iv) Smt. Manmohan Kaur, Dy. Director (Cost)
(v) Shri Naresh Arya, Dy. Director (Cost)
(vi) Shri Suneel Chopra, Dy. Director (Legal)
(vii) Smt. Babita Singh, Asstt. Director (Cost)

Chairman, NPPA welcomed all the members present in the meeting.

1. Agenda Item no. 1:

1.0 Members of the Authority who participated in the 148th and the 16th Meeting under DPCO, 2013 confirmed the minutes of the meeting. Chairman, also circulated a brief background note on Essential/Life Saving Drugs, Price Regulation and Related Issues, On which, NPPA is in the process of starting consultations with stakeholders.

2. Agenda Item no. 2: Action Taken Report:

2.0 Noted.

3. Agenda Item no. 3:

3.1 The Chairman, NPPA desired that the agenda may be circulated at least one week in advance prior to the Authority meeting. The Chairman also advised that besides the IMS data, data of the Pharma Trac may also be used as a secondary source, as they too provide comprehensive data base that may be utilized for the purpose of cross verification especially in case of huge data variation/data gaps. The Authority approved the recommendation made by the chairman.

3.2 The Authority discussed the status on the pricing of the 110 formulations which are pending due to non-availability of data inspite of sincere efforts made by NPPA. In a large number of cases, retail movement is not there, thus, data of retail channels is not available. In such cases, it is proposed that Institutional sales price particularly of Govt. of T.N., Rajasthan and other Central Departments may be considered for deriving/ working out PTRs. After receipt of data relating to Institutional sales, a formula may be devised to work out the ceiling price, after carrying out necessary analysis.

3.3 In case of formulation where strength/doses have not been specified in the NLEM, it was decided that all strengths/dosages may be considered for price fixation.

3.4 The Authority considered and discussed the prices of 11 formulation packs for fixing/notifying the ceiling price under para 6 of DPCO, 2013 based on the Monopoly conditions i.e. where data in respect of only one company is available. After due deliberations, the Authority approved the cases from Sr. no 5 to 11 (i.e. 7 cases). In

Case of Sr. no 1 to 4, the Authority deferred the cases due to non-availability of representative data.

3.5 The Authority considered and discussed the prices of the 3 formulation packs for fixing/notifying the ceiling price under para 4 of DPCO, 2013 based on the representations from the manufacturing/marketing company(ies) and clarifications/ revised data received from IMS Health. During the discussions, it was informed to the Authority that company wise price data considered is below the notified ceiling price. Therefore, these cases were approved.

3.6 A Table showing the prices approved in respect of each such medicine is given below:

S.no	Particulars	Approved Revised Price (Price in Rs. including WPI)
A	**Cases based on Monopoly situations**	
5	Neomycin + Bacitracin Ointment 5mg + 500 IU/gm	0.90/gm
6	Phenylephrine Drops 5%	4.95/ml
7	Phenytoin Sodium Injection 25mg/ml	2.31/ml
8	Polygeline Injection 3.5%	0.53/ml
9	Pyridoxine Tablet 10mg	0.22/tablet
10	Sodium Meglumine Diatrizoate 60% Injection	4.92/ml
11	Sodium Meglumine Diatrizoate 76% Injection	5.84/ml
B	**Cases based on Representations of the company(ies)**	
1	Levodopa 100mg + Cabidopa 25mg	2.26/tablet
2	Levodopa 100mg + Cabidopa 10mg	1.61/tablet
3	Levodopa 250mg + Cabidopa 25mg	3.85/tablet

4. Agenda Item no. 4:

4.1 The Authority discussed and considered the prices of 9 formulation packs which are common in DPCO 2013 as well as in DPCO 1995. The Authority discussed the provisions of para 10(1) and 10(2) and 16 of DPCO 2013 regarding the fixation/revision of prices of scheduled medicines. It was informed that the para 10 deals with the pricing of the formulations covered under DPCO 1995 as well as included in the DPCO 2013. The para 16 deals with the revision of the ceiling prices of scheduled formulations under DPCO 2013 irrespective of their inclusion in DPCO 1995.

4.2 The cases at Sr. no 1 and 2 have been approved as their date of notification under DPCO, 1995 was 19.7.2012 and their prices remained frozen for one year i.e. upto 18.7.2013 and on 1st April of succeeding financial year i.e. 01.4.2014, their prices are to be revised (including WPI factor), accordingly, the Authority approved these two cases. The cases at Sr. no 3 to 9 have been deferred and decided to be notified on 01.4.2015 as per the provision of para 10(2) of the DPCO 2013, as their date of notification under DPCO, 1995 was after 01.4.2013.

4.3 A Table showing the prices approved in respect of each such medicine is given below:

S.no	Particulars	Approved ceiling Price (Price in Rs. including WPI)
1	Cefotaxime Injection 125mg	12.84/Injection
2	Chlorpromazine Hcl Tablet 25mg	0.29/tablet

5. Agenda Item no. 5:

5.0 The Authority discussed the proposal and approved the price revision in respect of the 36 cases based on the the revision of ceiling prices with inclusion of WPI in respect of common scheduled formulations included in DPCO, 2013 as well as DPCO, 1995. The details of these cases are as under:-

Sl. No.	Medicines	Route of Administration	Revised CP (incl. WPI but excl. local taxes)

			(Rs./unit)
1	Acetyl Salicylic Acid	Tablets	0.28
2	Benzathine Benzylpenicillin	Injection	11.77
3	Benzathine Benzylpenicillin	Injection	8.09
4	Betamethasone	Injection	4.04
5	Betamethasone Dipropionate	Cream / Ointment	0.55
6	Carbamazepine	Tablets	0.74
7	Carbamazepine	Tablet	1.46
8	Ciprofloxacin Hcl	Injection	0.17
9	Ciprofloxacin Hydrochloride	Ointment	1.13
10	Ciprofloxacin Hydrochloride	Drops	1.38
11	Co-Trimoxazole (Trimethoprim + Sulphamethoxazole)	Suspension	0.26
12	Co-Trimoxazole (Trimethoprim + Sulphamethoxazole)	Tablet	1.36
13	Dexamethasone	Tablet	0.20
14	Dexamethasone	Injection	2.67
15	Doxycycline	Tablet	1.00
16	Famotidine	Tablets	0.22
17	Gentamicin	Drops	0.95
18	Gentamicin	Injection	2.32
19	Griseofulvin	Tablet	1.54
20	Ibuprofen	Syrup	0.22
21	Levodopa+ Carbidopa	Tablets	1.61
22	Levodopa+ Carbidopa	Tablets	3.85
23	Levodopa+ Carbidopa	Tablets	2.26
24	Metronidazole	Syrup	0.17
25	Prednisolone	Tablet	1.83
26	Prednisolone	Tablet	0.58
27	Prednisolone	Tablet	0.98
28	Ranitidine	Injection	1.52
29	Salbutamol Sulphate	Tablet	0.18
30	Salbutamol Sulphate	Syrup	0.15
31	Salbutamol Sulphate	Inhalation	0.51
32	Salbutamol Sulphate	Tablet	0.15
33	Streptomycin Sulphate	Injection	10.28
34	Streptomycin Sulphate	Injection	8.41
35	Sulfadoxine + Pyrimethamine	Tablets	2.08
36	Sulfasalazine	Tablets	3.88

6. Agenda Item no. 6:

6.0 The Authority discussed the proposal and deferred due to data limitation/data gaps.

7. Agenda Item no.7:

7.0 The Authority discussed the cases of retail price fixation of new drug based on Form-I applications received from the following company(ies). In case of Sr. no 1, the Authority deferred the case and directed to seek clarification from the company regarding DCGI approval. The details of approved prices are as under:

S.No	Company name/Product name	Approved Price (Rs.)
7(ii)	M/s Tirupati Medicare Limited (Manufacturer) and M/s Ipca Laboratories Ltd (Marketing company) – Paracetamol 250 mg & Mefenamic Acid 100 mg Suspension Each 5 ml contains: Paracetamol IP 250 mg Mefenamic Acid IP 100 mg	0.59 per ml
7(iii)	M/s Nitin Lifesciences Limited (Manufacturer) and M/s Mankind Pharma Ltd (Marketing company) –Dicyclomine Hydrochloride 10 mg & Diclofenac Sodium 25 mg Injection Each ml contains: Dicyclomine Hydrochloride IP 10 mg Diclofenac Sodium IP 25 mg Benzalkonium Chloride Solution IP 0.05% w/v (As preservative) Water for Injection I.P. q.s.	8.06 per 2ml ampoule
7(iv)	M/s Safetab Life Science (Manufacturer) and M/s Lupin Ltd (Marketing company) –CLOPITAB CV 10 - Atorvastatin 10 mg & Clopidogrel 75mg Each hard gelatin capsule contains: Atorvastatin Calcium IP Eq. to Atorvastatin 10 mg (as film coated tablet) Clopidogrel Bisulphate IP Eq. to Clopidogrel 75mg	87.52 per 10 capsules
7(v)	M/s Cadila Healthcare Limited (Manufacturer as well as Marketing Company) –CYCLODROP - Cyclosporine 0.5 mg Each ml contains:	109.60 per ml

	Cyclosporine USP 0.5 mg Benzalkonium Chloride Solution IP 0.02% v/v (As Preservative)	
7(vi)	M/s Tee & Tee Healthcare (Manufacturer) and M/s Gujarat Terce Laboratories Limited (Marketing company)- MALARCE - Pyrimethamine IP 25 mg + Sulphamethoxypyridazine BP 500 mg Each uncoated tablet contains: Pyrimethamine IP 25 mg Sulphamethoxypyridazine BP 500 mg	1.93 per tablet
7(vii)	M/s Inventia Healthcare Private Limited (Manufacturer) and M/s Micro Labs Limited (Marketing company) –Metformin HCL + Gliclazide + Pioglitazone Tablet Each uncoated bilayered tablet contains: Metformin Hydrochloride IP 500 mg (In sustained release form) Gliclazide IP 60 mg (In sustained release form) Pioglitazone Hydrochloride IP Eq. to Pioglitazone 7.5 mg	3.65 per tablet
7(viii)	M/s SunGlow Pharmaceuticals (P) Ltd (Manufacturer) and M/s Ajanta Pharma Ltd (Marketing company) –Tramadol 50 mg and Diclofenac 75 mg SR Tablets Each film coated bilayered tablet contains: Tramadol HCL IP 50 mg Diclofenac Sodium IP 75 mg (as sustained release layer)	4.56 per tablet
7(ix)	M/s Res Sancta (Manufacturer) and Micro Labs Ltd. (Marketing company) – Cetirizine HCl + Paracetamol + Phenylepherin HCl suspension Cetirizine HCl + Paracetamol + Phenylepherin HCl suspension Composition: Each 5ml contains: Paracetamol 125mg Cetirizine HCl 2.5mg Phenylepherine HCl 2.5mg	0.35 per ml
7(x)	M/s Mankind Pharma Ltd. (Manufacturer as well as Marketing company)- Bisoprolol Fumarate 5mg & Amlodipine 5mg tablet Each film coated tablet contains: Bisoprolol Fumarate 5mg Amlodipine Besilate eq. to Amlodipine 5mg	2.41 per tablet
7(xi)	M/s Windlas Biotech Ltd. (Manufacturer) and M/s Torrent Pharmaceuticals (Marketing company)- Azulix 4 MF tablet - Glimepiride 4mg & Metformin HCl 500mg Each uncoated bilayered tablet contains:	6.60 per tablet

	Glimepiride 4mg Metformin HCl 500mg (in sustained release form)	
7(xii)	M/s Windlas Biotech Ltd. (Manufacturer) and M/s Torrent Pharmaceuticals (Marketing company)- Azulix 3 MF tablet- Glimepiride 3mg & Metformin HCl Each uncoated bilayered tablet contains: Glimepiride 3mg Metformin HCl 500mg (in sustained release form)	4.64 per tablet

8. Agenda Item no. 8:

8.0 Noted and directed to hold a meeting with the DCG(I)'s officials for discussing technical issues involved.

9. Agenda Item no. 9:

9.0 Noted and directed to hold a meeting with the DCG(I)'s officials for discussing technical issues involved.

10. Agenda Item no. 10:

10.0 Noted and directed to hold a meeting with the DCG(I)'s officials for discussing technical issues involved.

11. Agenda Item no. 11:

11.0 The Authority accorded ex-post facto approval for withdrawal of price notification in respect of Ciprofloxacin Injection 200mg/100mg.

11.1 The Authority ratified the withdrawal of notifications S.O. 1755(E) dated 10.07.2014 regarding Heparin Sodium injection 25000 IU/ml and partial withdrawal of S.O. No. 1750(E) dated 10.07.2014 regarding Enalapril 5 mg Tablets by notifications subsequently issued vide S.O. No. 1904(E) and 1903(E) respectively both dated 25.07.2014. The Authority also granted post- facto approval in respect of notification issued vide S.O. No. 1884 (E) on 22.07.2014 to cover all left out companies not covered vide S.O. Nos. 1730(E) to 1779(E) issued on 10.07.2014 who are selling at a price higher than the notified price, not mentioned in paragraph 12 of the above said orders issued under para 19 of DPCO, 2013.

12 **Agenda Item no. 12:**

12.0 The Authority discussed the agenda note circulated for its consideration in respect of non-application of provisions of DPCO, 2013 regarding Fixed Dose Combination (FDC) of Prasugrel Hydrochloride 10mg (as film coated) of M/s Torrent Pharmaceuticals Limited under para 32(iii) of the said order. The Authority was informed the Expert Committee constituted for the said purpose has recommended the said 'new drugs' approved by the DCG(I) under Rule 122E of Drugs and Cosmetic Rules for exemption from price control for five years from the date of its market approval in India i.e. with effect from 15.01.2014. The Authority after detailed discussions and also taking into account the recommendation of the Expert Committee approved the FDC of Prasugrel Hydrochloride 10mg (as film coated) of M/s Torrent Pharmaceuticals Limited for exemption from the provisions of the DPCO, 2013 for a period of five years as provided under para 32(iii) of the said order.

13. Agenda Item no. 13:

13.0 The Authority noted the status of development of software on E-filing system by NIC for the purpose of effective monitoring and pricing of medicines under DPCO, 2013.

14. Agenda Item no. 14:

14.0 The Authority discussed the 2nd Internal Guideline prepared by the NPPA for dealing with cases of price revision of scheduled formulations under para 19 of DPCO, 2013. After due deliberations, the Authority decided that guidelines be placed on NPPA's website as 'Draft Guidelines' for seeking comments of different stakeholders/industry associations within a period of 21 days from the date of placing the same on website.

15. Agenda Item no. 15:

15.0 The Authority was informed that the exercise for price fixation of anti cancer non-scheduled formulations as per 1st internal guideline under para 19 of the DPCO, 2013 has been carried out based on the available market data provided by the IMS-Health. The Authority also noted the position with regard to writ petitions filed by the two Industry Associations namely IPA and OPPI in the Mumbai and Delhi High Court respectively. It

noted that no stay order has been granted in either of the cases and the price notifications remain valid. The Authority then took up the exercise of price fixation of anti cancer drugs carried out by NPPA based on the internal guidelines under para 19 of the DPCO, 2013. The Authority deliberated on the entire exercise and observed that it did not cover entire market in terms of MAT value and also certain medicines not specifically used for treatment of cancer like Mycophenolic Acid, Sirolimus, Tacrolimus etc. are included in the exercise. The Authority discussed the same in detail and directed that the data as available with NPPA should be cross checked with Pharma Trac data to make the exercise more extensive so as to avoid the apparent anomalies.

Other Items:

16. A brief presentation on the draft Central Sector Scheme of Assistance for setting up Price Monitoring and Enforcement Units (PMEUs) at the States/ UTs broadly covering the various aspects of the proposed scheme viz. need for bringing out a new scheme, purpose and objectives of setting up PMEUs at the States/ UTs level, categorisation of States/ UTs for the purpose of staffing and providing requisite infrastructure, administrative structure of the PMEU, items for which Non-Recurring and Recurring grants would be provided, expected time frame for implementation, total outlay proposed and continuation of the scheme in the succeeding five years plans. A copy of the draft Scheme was also circulated to all the members.

After detailed deliberations, it was felt that the draft scheme should be circulated to DCGI and all the State Governments/UT Administrations for their views and comments. Based on the comments and suggestions received, the revised/ modified scheme should be sent for approval of the Government.

17. This issues with the approval of Chairman, NPPA.

(A.K. Gautam)
Member Secretary Incharge
20/8/14