गोपनीय: Confidential

मिसिलस.- 8(21)/2015/डी.पी./एनपीपीए- डीवी-II

F. No. 8(21)/2015/DP/NPPA-Div. II

कार्यवाहीस. : 153/21/2015/F
Proceeding No : 153/21/2015/F

Minutes of the 153rd and 21st meeting of Authority under DPCO, 2013 held on 25th March, 2015 at 12.00 Noon

The 153rd overall meeting of the Authority, which is the 21st under the DPCO, 2013 was held on 25th March, 2015 at 12.00 Noon under the Chairmanship of Shri Injeti Srinivas, Chairman, NPPA. The following members of the NPPA were present:-

(i) Shri Amit Khare, Member Secretary, NPPA.

(ii) Shri L.M. Kaushal, Member (Ex-Officio), Director (Cost), Deptt. of Expenditure, Ministry of Finance.

(iii) Shri R. Chandrashekar, Deputy Drug Controller, Department of Health & Family Welfare (representing DCGI).

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

(i) Shri Kalyan Nag, Adviser (Cost)
(ii) Shri Jagdish Kumar, Director (M&E)
(iii) Shri A.K. Khurana, Director (Pricing & Admn.)
(iv) Shri Suneel Chopra, Dy. Director (Legal)
(v) Shri Naresh Arya, Dy. Director (Pricing)
(vi) Shri Rakesh Kakkar, Dy. Director (OC-I)
(vii) Shri S.S. Agrawal, Asstt. Director (M&E)
(viii) Smt. Babita Singh, Asstt. Director (M&E)
(ix) Shri T.R. Sathish Chandran, Asstt. Director (OC-II)

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

1. Agenda Item no. 1: Confirmation of Minutes of the 20th M eeting held on 05.02.2015

Members of the Authority who participated in the 152nd and the 20th Meeting under DPCO, 2013 confirmed the minutes of the meeting.

2. Agenda Item no. 2: Action Taken Report

Noted.

3. Agenda Item no. 3: Items of price fixation for Scheduled formulations under DPCO, 2013

The Authority considered, discussed and approved the price of one formulation pack for fixing/notifying the ceiling price under Para 4 and 6 of DPCO, 2013 based on the Monopoly conditions (i.e. where data in respect of only one company is available) and data furnished by company.

4. Agenda Item no. 4: Items of price fixation of the Scheduled formulations listed in NLEM, 2011 and included in the DPCO, 2013 as well as DPCO, 1995

4.1 The Authority discussed and considered the prices of 11 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. The ceiling prices under DPCO, 1995 of these formulations were fixed after 31st May, 2012 and thus, ceiling price fixation in DPCO, 2013 is to be carried out in April, 2015.

4.2 The Authority considered, discussed and approved the prices of the following 11 formulation packs for fixing/notifying the ceiling price under Para 4 of DPCO, 2013.

4.3 A Table showing the prices approved and applicable from 01.4.2015 in respect of each such medicine based on data of the IMS Health/Pharma Trac/Companies is given below:

Sl. No.	Medicines	Revised CP (incl. WPI but excl. local taxes) (Rs./unit) w.e.f. 01.4.2015
1	Chloroquine phosphate Injection 40 mg/ml (64.5mg = 40mg chloroquine)	1.24/ml
2	Chloroquine phosphate Syrup 50mg/5ml	0.27/ml
3	Erythromycin Estolate Syrup 125mg/5 ml	0.50/ml
4	Erythromycin Estolate Tablets 250mg	2.86/tablet
5	Erythromycin Estolate Tablets 500mg	5.56/tablet
6	Insulin Injection (Soluble) 40IU/ml	14.13/ml
7	Intermediate Acting (Lente/NPH Insulin) Injection 40IU/ml	
8	Premix Insulin 30:70 Injection 40IU/ml	
9	Metronidazole Injection 500mg/100ml	0.14/ml
10	Metronidazole Tablet 200mg	0.43/tablet
11	Metronidazole Tablet 400mg	0.78/tablet

5. Agenda Item no. 5: Price revision on the review application filed by M/s Cadila Healthcare Ltd. in respect of Ranitidine injection 25mg/ml.

The Authority discussed the proposal of price revision in respect of Ranitidine Injection 25mg/ml based on the review order dated 23.07.2014 received from the DOP and approved the revised ceiling price at Rs. 1.55/ml (without WPI applicable from date of notification to 31.3.2015) and Rs.1.61/ml (including WPI to be effective from 01.4.2015).

6. Agenda Item no. 6: Price revision on the review application of M/s Vins Bioproducts Ltd. in respect of Polyvalent Antisnake Venom 10ml Injection.

The Authority discussed the proposal of price revision in respect of Polyvalent Antisnake Venom 10ml injection based on the review order dated 20.01.2015 received from the DOP. The revised ceiling prices for Specific Antisnake Venom works out as under by also considering WPI of 3.849% for year 2014 to be effective from 01.4.2015:

Type	Revised Ceiling Price (From date of notification to 31.3.2015)	Revised Ceiling Price (w.e.f. 01.4.2015)
Injection Polyvalent Solution (**Liquid**)	Rs. 466.79	Rs. 484.76
Lyophilyzed Polyvalent Serum	Rs.566.85	Rs.588.67

7. Agenda Item no. 7: Price revision on the review application of M/s Bharat Serum and Vaccines Ltd. in respect of Rabies Immunoglobin Injection 150IU/ml.

The Authority discussed the proposal of price revision in respect of Rabies Immunoglobin Injection 150Iu/ml, based on the review order dated 20.01.2015 received from the DOP. The revised ceiling price works out to Rs. 3016.83/ml applicable from date of notification to 31.3.2015 and Rs. 3132.95/ml to be effective from 01.4.2015 after considering WPI of 3.849% for year 2014.

8. Agenda Item no. 8: Price revision on the review application of M/s Abbott Healthcare Pvt. Ltd. in respect of Co-Trimoxazole Suspension 40+200mg/5ml.

The Authority discussed the proposal of price revision in respect of Co-Trimoxazole Suspension 40+200mg/5ml, based on the review order dated 07.7.2014 received from the DOP. The revised ceiling price works out to Rs. 0.28/ml applicable from date of notification to 31.03.2015 and Rs. 0.29/ml to be effective from 01.4.2015 after considering WPI of 3.849% for year 2014.

9. A genda Item no. 9: Revision of ceiling prices of 16 common formulations pursuant to DOP order dated 05.02.2015 in respect of Sprionolactone 25mg Tablet of M/s RPG Life Sciences.

The Authority discussed the cases of 16 common formulations where prices were fixed by applying monopoly conditions and approved the revision after considering the MAT values involved in these 16 formulations. These ceiling prices are revised on the

basis of replies of companies/Pharma Trac data and considering the ceiling price of DPCO, 1995. The summary of ceiling prices is as under:

S.No.	Formulation	Strength	From date of notification to 31.3.2015	W.e.f. 01.4.2015
1	Acetyl Salicylic Acid Tablet	325 mg	0.72	0.75
2	Ascorbic Acid Tablet	100 mg	0.18	0.19
3	Carbamazepine Syrup	100 mg/ 5 ml	0.21	0.22
4	Chlorpromazine Injection	25 mg/ml	1.23	1.28
5	Cloxacillin Injection	250 mg	5.54	5.75
6	Co-Trimoxazole (Trimethoprim + Sulphamethoxazole) Tablet	80 mg +400 mg	0.62	0.64
7	Framycetin sulphate Cream	0.50%	0.79	0.82
8	Frusemide Tablet	40 mg	0.45	0.47
9	Pheniramine Maleate Injection	22.75 mg/ml	1.40	1.45
10	Rifampicin Tablet	150 mg	1.48	1.54
11	Spiranolactone Tablet	25 mg	1.87	1.94
12	Sulphadiazine Tablet	500 mg	1.14	1.18
13	Verapamil Tablet	40 mg	0.74	0.77

14	Verapamil Tablet	80 mg	1.38	1.43
15	Vitamin A Injection	50,000 IU/ml	1.75	1.82
16	Vitamin A Capsule	50000 IU	0.70	0.73

10. Agenda Item no. 10: Fixation of retail price in respect of new drug.

The Authority discussed the cases of retail price fixation of 25 new drugs in the light of decisions taken in 19th and 20th Authority Meeting in respect of permissions required from DCG(I)/SDCs. Moreover, the Authority directed to ensure that the retail price as proposed may not be more than the price charged by the same manufacturer for the same formulation sold to the company other than the applicant marketing company, as per the data furnished by the concerned company to NPPA. Accordingly, the retail prices for 25 formulations are fixed and approved as per para 5 and 6 of the DPCO 2013, as under:

S. No.	Company name/Product name	Approved Price (Rs.)
10(i)	M/s Theon Pharmaceuticals Ltd. (Manufacturer) and M/s IVA Healthcare Pvt. Ltd. (Marketing company) –Sterile Ceftriaxone sodium eq. to Ceftriaxone 250mg + Sterile Sulbactam sodium eq. to Sulbactam 125mg injection (Ceftriaxone & Sulbactam injection).	38.77/pack
10(ii)	M/s Alkem Lab. Ltd. (Manufacturer as well as Marketing company) –Ceftriaxone sodium eq. to Ceftriaxone 250mg + Sulbactam sodium eq. to sulbactam 125mg – (XONE SB 250mg injection).	38.77/pack
10(iii)	M/s Crescent Therapeuticas Ltd. (Manufacturer) and M/s Leeford Healthcare Ltd. (Marketing company) – Telmisartan 80mg + Hydrochlorothiazide 12.5mg (TELVILITE H tablet).	11.60/tablet
10(iv)	M/s Alkem Lab. Ltd. (Manufacturer as well as Marketing company) –Ceftriaxone sodium eq. to Ceftriaxone 1000mg + Sulbactam sodium eq. to sulbactam 500mg (XONE SB 1gm injection).	98.69/pack
10(v)	M/s Redicura Pharmaceuticals Pvt. Ltd. (Manufacturer as well as Marketing company) –Cefixime eq. to Anhydrous Cefixime 25mg – (Novafex Drops- Cefixime	3.70/ml

	Oral Suspension).	
10(vi)	M/s Theon Pharmaceuticals Ltd. (Manufacturer) and M/s IVA Healthcare Pvt. Ltd. (Marketing company) – Cefixime Trihydrate eq. to Anhydrous Cefixime 200mg + Azithromycin as Dihydrate eq. to Anhydrous Azithromycin 250mg – (Cefixime & Azithromycin tablet).	15.88/tablet
10(vii)	M/s Theon Pharmaceuticals Ltd. (Manufacturer) and M/s IVA Healthcare Pvt. Ltd. (Marketing company) – Cefixime Trihydrate eq. to Anhydrous Cefixime 200mg + Dicloxacillin (as extended release form) 500mg – (Cefixime & Dicloxacillin (ER) tablet).	13.99/tablet
10(viii)	M/s Theon Pharmaceuticals Ltd. (Manufacturer) and M/s IVA Healthcare Pvt. Ltd. (Marketing company) – Amoxycillin trihydrate eq. To Amoxycillin 250mg + Dicloxacillin sodium eq. to Dicloxacillin 250 – (Amoxycillin & Dicloxacillin capsule.	5.22/capsule
10(ix)	M/s Aristo Pharmceuticals Pvt. Ltd. (Manufacturer as well as Marketing company) – Telmisartan 80mg + Hydrochlorothiazide 12.5mg + Amlodipine besylate eq. to Amlodipine 5mg – (Telmisartan Hydrochlorothiazide + Amlodipine tablet).	122.86/10's tablet
10(x)	M/s Innova Captab Pvt. Ltd. (Manufacturer) and M/s Zuventus Healthcare Ltd. (Marketing company) – Cefixime Trihydrate eq. to Anhydrous Cefixime 50mg - (Trusten O Dry Syrup).	1.39/ml
10(xi)	M/s Biochem Pharmaceuticals Ind. Ltd. (Manufacturer as well as Marketing company) –Paracetamol 650mg (Paracetamol 650mg tablet).	1.62/tablet
10(xii)	M/s Indu Drugs Pvt. Ltd. (Manufacturer as well as marketing company) – Glimepiride 1mg + Metformin HCl 500mg SR– (GLYCIZ M1 tablet)	38.46/10's tablet
10(xiii)	M/s Indu Drugs Pvt. Ltd. (Manufacturer as well as marketing company) – Glimepiride 1mg + Metformin HCl 500mg SR– (GLYCIZ M2 tablet)	4.50/tablet
10(xiv)	M/s Indu Drugs Pvt. Ltd. (Manufacturer as well as marketing company) – Cefixime as trihydrate eq. to anhydrous cefixime 200mg + Ofloxacin 200mg – (ACCEF – O tablet).	9.86/tablet
10(xv)	M/s Associated Biotech (Manufactuerer) and M/s Zuventus Healthcare Ltd., (Marketing company) – Cefixime as trihydrate eq. to anhydrous cefixime 200mg + Ofloxacin 200mg – (TRUSTEN OF tablet).	9.86/tablet
10(xvi)	M/s Associated Biotech (Manufactuerer) and M/s Zuventus Healthcare Ltd. (Marketing company) –	9.86/tablet

	Cefixime as trihydrate eq. to anhydrous cefixime 200mg + Ofloxacin 200mg – (C TAX OF tablet).	
10(xvii)	M/s Ajanta Pharma Ltd. (Manufacturer as well as Marketing company) – Ranitidine HCl eq. to Ranitidine 75mg (Ranitidine Oral Solution).	0.52/ml
10(xviii)	M/s Relax Pharmaceuticals Pvt. Ltd. (Manufacturer) and M/s Magnet Labs. Ltd. (Marketing company) – Ranitidine HCl eq. to Ranitidine 75mg (Ranitidine Oral Solution).	0.52/ml
10(xix)	M/s Meridian Enterprises Pvt. Ltd. (Manufacturer as well as Marketing company) – Diazepam 2.5mg Suppositories (SUPPAM 2.5mg).	3.90/suppository
10(xx)	M/s Ajanta Pharma Ltd. (Manufacturer as well as Marketing company) – Brimonidine tartrate 2mg + Timolol maleate eq. to timolol 5mg + Benzalkonium Chloride 0.005% w/v (Brimonidine tartrate + Timllol maleate Eye Drops).	108.40/5ml
10(xxi)	M/s Ajanta Pharma Ltd. (Manufacturer as well as marketing company) – Cyclosporine 1mg + Benzalkonium Chloride 0.01% w/v – (Cyclosporine Eye Drop 0.1%)	212.88/3ml
10(xxii)	M/s Theon Pharmaceuticals Ltd. (Manufacturer) and M/s Intas Pharmaceuticals Ltd. (Marketing company) – Ferrous Ascorbate eq. to elemental Iron 100mg + Adenosylcobalamin 15mcg + Zinc Sulphate monohydrate eq. to elemental Zinc 22.5mg + Folic Acid 1.5mg – (Ferrous Ascorbate + Adenosylcobalamin + Zinc Sulphate + Folic Acid Tablet).	3.79/tablet
10(xxiii)	M/s Micro Lab. (Manufacturer as well as marketing company) – Amlodipine besilate eq. to Amlodipine + Valsartan 80mg – (AMLONG-VL 80 tablet).	2.19/tablet
10(xxiv)	M/s Micro Lab. (Manufacturer as well as marketing company) – Amlodipine besilate eq. to Amlodipine + Valsartan 80mg – (AMLONG-VL 160 tablet).	3.38/tablet
10(xxv)	M/s IPCA Lab. Ltd. (Manufacturer as well as marketing company) – Chlorthalidone 12.5mg and Amlodipine Besilate eq. to Amlodipine 5mg - (CTD-AM 12.5/tablet).	2.33/tablet

11. Agenda Item no. 11: Ex-post facto approval of the Authority regarding reduction in Excise Duty notified vide no S.O. 776(E) dated 17.3.2015.

Noted and Approved.

12. Agenda Item no. 12: Ex-post facto approval of the Authority regarding revision of ceiling prices of 509 Scheduled formulations as per Wholesale Price Index (WPI) effective from 01.4.2015 notified vide S.O. 619(E) dated 26.02.2015.

Noted and Approved.

13. Agenda Item no. 13: Ex-post facto approval of the Authority in reference to the recommendations of NPPA on inclusion of Cancer treatment drugs in the National List of Essential Medicines-2011.

13.1 The Authority was informed that the NPPA has already forwarded its recommendation to the Department on 09.02.2015 based on a detailed study carried out for inclusion in the National List of Essential Medicines 2011 (NLEM 2011) on the request of Department of Pharmaceuticals vide their letter No. 31026/24/2010-PI.II dated 07.08.2014. As mentioned in the report, the recommendations relating to cancer treatment medicines were to be made based on a separate study already initiated by the NPPA for addition / deletion of cancer treatment drugs in the NLEM-2011.

13.2 In this regard, the Authority noted that NPPA has completed the study based on inputs received from the Tata Memorial Centre (TMC), Mumbai, which is a Govt. of India organization working under the Department of Atomic Energy. The Authority further noted that NPPA issued a Public Notice dated 21.11.2014 inviting comments of all stakeholders on the recommendation received from TMC, Mumbai. After careful examination of the recommendations received from the Tata Memorial Centre, Mumbai; the comments received from the industry; and the MAT value, volume and price data with respect to these medications, NPPA had finalized the recommendations for inclusion / deletion of drugs formulations related to cancer treatment in the NLEM and accordingly, the recommendations in this regard, were sent to the Department vide its letter dated 27.02.15 for deletion of 3 medicines, viz. Busulphan, Raloxifiene and Danazol; from the First Schedule of the DPCO, 2013/NLEM, 2011, and inclusion of all strength and dosage form of ATRA (All Trans Retinoic Acid), Rituximab, Lenalidomide, Trastuzumab, Capecitabine, Temozolomide, Erlotinib, Zoledronic acid, Megestrol acetate and Letrozole". The Authority accorded its approval on the report on recommendation of NPPA on inclusion of Cancer treatment drugs in the NLEM-2011 forwarded to the Department of Pharmaceuticals on 27.02.2015.

14. Agenda Item no. 14: Non-application of provisions of DPCO, 2013 in respect Tolaz LA (Olanzapine Pamoate Prolonged Release Powder for suspension for IM Injection 210 mg/vial, 300mg/vial and 405mg/vial) of M/s. Torrent Pharmaceuticals Limited, as per para 32(iii) of DPCO, 2013.

The Authority discussed the agenda note circulated for its consideration in respect of non-application of provisions of DPCO, 2013 regarding Tolaz LA (Olanzapine Pamoate Prolonged Release Powder for suspension for IM Injection 210 mg/vial, 300 mg/vial and 405 mg/vial) of M/s Torrent Pharmaceuticals Limited under para 32 (iii) of the said order. The Authority also noted the recommendation of the 'Expert Committee' constituted for the said purpose that the said 'new drug' approved by the DCG(I) under Rule 122E of Drugs and Cosmetic Rules is eligible for exemption from price control for five years from the date of its market approval in India i.e. with effect from 14.10.2014. In this regard, it was also informed that Olanzapine Long Acting Injection (LAI) is given in Schizophrenia, characterized by hallucinations, disorganized behaviors and negative symptoms and which requires long term treatment to reduce symptomatic relapse. Olanzapine LAI has 2-4 weeks duration of action and useful addition for the maintenance therapy of schizophrenia. Comparative bioavailability of test of Olanzapine LAI developed by M/s Torrent in India has been carried out with Zypadhera of innovator company namely M/s Eli Lilly in Germany. Olanzapine LAI is a new drug to be launched in the country and the launch price indicated by the company Olanzapine LAI was significantly lower than the price of innovator's product abroad. The Authority after detailed deliberation and taking into account the recommendation of the 'Expert Committee' approved the new drug Tolaz LA (Olanzapine Pamoate Prolonged Release Powder for suspension for IM Injection 210 mg/vial, 300 mg/vial and 405 mg/vial) 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.

15. Agenda Item no. 15: A study on pricing of Cardiac Stents carried out in pursuance to Department of Pharmaceuticals letter no. 31026/53/2014-PI.I dated 11.12.2014.

15.1 The Authority was informed that NPPA has conducted a study on pricing of stents pursuant to Department of Pharmaceuticals letter no. 31026/ 53/ 2014-PI.I dated

11.12.2014. Also, there have been reports in certain sections of press regarding huge mark-up in prices of stents and feedback from the State Drugs Controllers regarding high prices, unreasonable margins to distributors on the sale of cardiac stents. The Authority was further informed that in a public interest litigation filed by Shri Birender Sangwan versus Union of India, through Ministry of Health & Family Welfare, and National Pharmaceutical Pricing Authority, New Delhi, (case of w.p.(c) 1772/2015) seeking directions of the court for inclusion of "Coronary Stents" in the National List of Essential Medicines (NLEM), the Hon'ble High Court, Delhi has passed an order on 25.02.2015 directing the respondents , "to treat this petition as a representation and pass an appropriate order in accordance with law within a period of 3 months from today."

15.2 The Authority deliberated on the recommendations made on the basis of available information and the study conducted by the National Health System Resource Centre (NHSRC) as contained in the report finalize by the NPPA on pricing of stents. The Authority further discussed the issues flagged and conclusion drawn in the report for appropriate action by the Ministry of Health & Family Welfare related to draft amendments in the Drugs and Cosmetics Act, 1940, and inclusion in the NLEM-2011 and the Department of Pharmaceuticals in so far as pricing of cardiac stents is concerned. The Authority endorsed the recommendations and decided that the same may be forwarded to the Department of Pharmaceuticals for an appropriate action at their end. A copy of the report may also be forwarded to Department of Health and Family Welfare for information and necessary action.

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

(Amit Khare)
Member Secretary