

मिसिल स.- 8(22)/2015/डी.पी./एनपीपीए- डीवी-II

F. No. 8(22)/2015/DP/NPPA-Div. II

कार्यवाहीस. : 154/22/2015/F
Proceeding No : 154/22/2015/F

Minutes of the 154th and 22nd meeting of Authority under DPCO, 2013 held on 06th May, 2015 at 12.30 P.M.

The 154th overall meeting of the Authority, which is the 22nd under the DPCO, 2013 was held on 06th May, 2015 at 12.30 P.M. under the Chairmanship of Shri Injeti Srinivas, Chairman, NPPA. The following members of the NPPA were present:-

- (i) Dr. Sharmila Mary Joseph K, Member Secretary, NPPA.
- (ii) Dr. K.L. Prasad, Member (Ex-Officio), Adviser, Economic Division, Deptt. of Economic Affairs.
- (iii) Shri Devendra Kumar, Adviser (Cost), Deptt. of Expenditure, Ministry of Finance.
- (iv) Shri L.M. Kaushal, Member (Ex-Officio), Director (Cost), Deptt. of Expenditure, Ministry of Finance.
- (v) Shri S. Dey, 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 Lal Sanglur, Director (Overcharging-II)
- (iii) Shri Jagdish Kumar, Director (M&E)
- (iv) Shri A.K. Khurana, Director (Pricing & Admn.)
- (v) Shri Suneel Chopra, Dy. Director (Legal)
- (vi) Shri Naresh Arya, Dy. Director (Pricing)
- (vii) Shri Rakesh Kakkar, Dy. Director (OC-I)
- (viii) Shri S.S. Agrawal, Asstt. Director (M&E)
- (ix) Smt. Babita Singh, Asstt. Director (M&E)



- (x) Shri T.R. Sathish Chandran, Asstt. Director (OC-II)
- (xi) Shri Baljit Singh, Asstt. Director (OC-II)

Chairman, NPPA welcomed all the members present in the meeting and introduced Dr. Sharmila Mary Joseph K, who joined NPPA recently as Member Secretary and also welcomed Sh. Devendra Kumar, Adviser (Cost).

1. Agenda Item no. 1: Confirmation of Minutes of the 21st Meeting held on 25.3.2015

Members of the Authority who participated in the 153rd and the 21st 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 of the Scheduled formulations listed in NLEM, 2011 and included in the DPCO, 2013 as well as DPCO, 1995

3.1 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 Para 10 deals with the pricing of the formulations covered under DPCO, 1995 as well as included in the DPCO, 2013. 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 upto and after 31st May, 2012; and thus, ceiling price fixation in DPCO, 2013 is to be carried out.

3.2 The Authority considered, discussed and approved the ceiling prices of the following 9 formulation packs for notification under DPCO, 2013. It was also observed that ceiling prices have not been fixed under Para 6(1) of DPCO, 2013 in compliance with DOP's review order.

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

S.No.	Formulation	Ceiling Price (Rs.)
1	Acetyl Salicylic Acid Tablet 300 mg	0.22/tablet
2	Chloroquine Phosphate Tablet 150 mg base	0.78/tablet
3	Rifampicin Tablet 50mg	0.62/tablet
4	Rifampicin Capsule 150mg	1.93/capsule
5	Rifampicin Capsule 300mg	3.49/capsule
6	Rifampicin Capsule 450mg	5.06/capsule
7	Rifampicin Syrup 100mg/5ml	0.35/ml

Amf

8	Ibuprofen Tablet 200mg	0.41/tablet
9	Ibuprofen Tablet 400mg	0.70/tablet

4. Agenda Item no. 4: Revision of ceiling prices of 6 common formulations pursuant to DOP order dated 05.02.2015 in respect of Sprinolactone 25mg Tablet of M/s RPG Life Sciences.

The Authority discussed the cases of 6 common formulations where prices were fixed by applying monopoly conditions and approved the revision after considering the MAT values involved in these 6 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	Revised ceiling price (Rs.)
1.	Acetyl Salicylic Acid Tablet 100 mg	0.17/Tablet
2.	Frusemide Injection 10 mg/ml	1.58/ml
3.	Methyldopa 250 mg tablet	2.48/Tablet
4.	Prednisolone Injection 20 mg (as sodium phosphate or succinate)	4.69/ml
5.	Verapamil Injection 2.5 mg/ml	1.12/ml
6.	Silver Sulphadiazine cream 1%	0.48/gm

5. Agenda Item no. 5: Fixation of retail price in respect of new drugs.

The Authority discussed the cases of retail price fixation of 13 new drugs in the light of decisions taken in 19th and 20th Authority Meetings in respect of permissions required from DCG(I)/SDCs. Accordingly, the retail prices for 13 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.)
5(i)	M/s Theon Pharmaceuticals Ltd. (Manufacturer) and M/s IVA Healthcare Pvt. Ltd. (Marketing company) – Cefpodoxime Proxetil eq. to Cefpodoxime 200mg + Ofloxacin 200mg (Cefpodoxime Proxetil & Ofloxacin tablet).	12.91/tablet
5 (ii)	M/s Swiss Garnier Lifesciences (Manufacturer) and M/s FDC Ltd. (Marketing company) –Voglibose 0.2mg + Metformin HCl 500mg SR (Zibose M 0.2 tablet).	52.38/strip of 10 tablets
5 (iii)	M/s Swiss Garnier Lifesciences (Manufacturer) and M/s FDC Ltd. (Marketing company) –Voglibose 0.3mg + Metformin HCl 500mg SR (Zibose M 0.3 tablet).	52.38/strip of 10 tablets

5 (iv)	M/s G.M.H. Organics (Manufacturer) and M/s Cadila Pharmaceuticals Ltd. (Marketing company) –Sterile Ceftriaxone sodium eq. to Ceftriaxone 1000mg and Sterile Tazobactam sodium eq. to Tazobactam 125mg (Ceftriaxone + Tazobactam injection).	113.16/vial
5 (v)	M/s G.M.H. Organics (Manufacturer) and M/s Cadila Pharmaceuticals Ltd. (Marketing company) –Sterile Ceftriaxone sodium eq. to Ceftriaxone 250mg and Sterile Tazobactam sodium eq. to Tazobactam 31.25mg (Ceftriaxone + Tazobactam injection).	44.81/vial
5 (vi)	M/s Windlas Biotech Ltd. (Manufacturer) and M/s Hegde & Hegde Pharmaceuticals (Marketing company) – Glimepiride 1mg + Metformin HCl 500mg ER (HHGLIM-M1 tablet).	38.46/strip of 10 tablets
5 (vii)	M/s Pure & Cure Healthcare Pvt. Ltd. (Manufacturer) and M/s Dey's Medical Stores (Manufacturing) Ltd. (Marketing company) – Glimepiride 1mg + Metformin HCl 500mg SR (GRID 1M tablet).	38.46/strip of 10 tablets
5 (viii)	M/s Windlas Biotech Ltd. (Manufacturer) and M/s Hegde & Hegde Pharmaceuticals (Marketing company) – Glimepiride 2mg + Metformin HCl 500mg ER (HHGLIM-M2 tablet).	4.50/tablet
5 (ix)	M/s Windlas Biotec Ltd. (Manufacturer) and M/s Emcure Pharmaceuticals Ltd. (Marketing company) – Diluted Glyceryl Trinitrate eq. to Glyceryl Trinitrate 2.6mg (G3N 2.6 tablet).	3.69/tablet
5 (x)	M/s Windlas Biotec Ltd. (Manufacturer) and M/s Emcure Pharmaceuticals Ltd. (Marketing company) – Diluted Glyceryl Trinitrate eq. to Glyceryl Trinitrate 6.4mg (G3N 6.4 tablet).	4.77/tablet
5 (xi)	M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) and M/s Blue Cross Lab. Ltd. (Marketing company) – Diclofenac sodium 75mg (Diclotal – AQ injection).	14.00/ml
5 (xii)	M/s Radicura Pharmaceuticals Pvt. Ltd. (Manufacturer as well as Marketing company) – Cefixime Oral Suspension- Each 5ml after reconstitution contains Cefixime eq. to anhydrous cefixime 100mg (Novafex 100 Dry Syrup).	2.10/ml
5 (xiii)	M/s Lupin Ltd. (Manufacturer as well as Marketing company) – Ramipril 5mg + Amlodipine 5mg (Ramistar – A5 tablet).	4.29/tablet

6. Agenda Item no. 6: Retail Price fixation of new drug on the basis of recommendation of Standing Committee of Experts under Para 15 of the DPCO 2013- (a) Hyoscine Butylbromide 20mg tablet of M/s Cadila Healthcare Ltd. and (b) Salbutamol Sulphate Inhaler 100mcg/dose, 200metered dose of M/s Cipla Ltd. with dose counter.

The Authority discussed the retail price fixation of these 2 new drugs on the basis of the recommendations made by Standing Committee of Experts under Para 15 of the DPCO 2013 and approved the retail price of Rs. 5.63/tablet of Hyoscine Butylbromide 20mg of M/s Cadila Healthcare Ltd. and Rs. 121.08 for Salbutamol Sulphate Inhaler 100mcg/dose with dose counter (200 metered dose) of M/s Cipla Ltd.

7. Agenda Item no. 7: Corrigendum relating to (a) ceiling price of Amoxicillin+Clavulinic acid Powder for suspension 228.5mg/5ml issued vide S.O. 619(E) dated 26.02.2015, and (b) ceiling price of Specific Antisnake Venom- Injection Polyvalent Solution and Lyophilized Polyvalent Serum vide S.O. 838(E) dated 25.03.2015.

(a) Noted and Approved.

(b) The Authority considered that the ceiling prices in respect of Specific Antisnake Venom- Injection Polyvalent Solution and Lyophilized Polyvalent Serum may be fixed in per ml unit. Thus, corrigendum may be issued by changing the ceiling price to per ml as given below:-

Specific Antisnake Venom	Instead of		May be read as	
	From 25.3.2015 to 31.3.2015	w.e.f. 01.4.2015	From 25.3.2015 to 31.3.2015	w.e.f. 01.4.2015
Injection Polyvalent Solution	Rs. 466.79/ml	Rs. 484.76/ml	Rs. 46.679/ml	Rs. 48.476/ml
Lyophilized Polyvalent Serum	Rs. 566.85/ml	Rs. 588.67/ml	Rs. 56.685/ml	Rs. 58.867/ml

8. Agenda Item no. 8: Consumer awareness about the drugs included in the list of essential medicines as specified in the Scheduled category of DPCO, 2013 for which ceiling prices notified in the Gazette of India Extraordinary (M&E Division).

Noted and Approved.

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

Sharmila Mary Joseph
 (Dr. Sharmila Mary Joseph K) 6/5/15
 Member Secretary