

गोपनीय : Confidential

मिसिल स. 8(12)/2014 डी.पी./एन पी पी ए- डीवी-II

F. No. 8(12)/2014/DP/NPPA-Div. II

कार्यवाही स. : 144/12/2014/F

Proceeding No : 144/12/2014/F

Minutes of the 144th and 12th meeting of Authority under DPCO, 2013 held on 25th March, 2014 at 3.00 P.M.

The 144th meeting of the Authority which is 12th under the DPCO, 2013 was held on 25th March, 2014 at 3.00 PM under the Chairmanship of Sh. C. P. Singh Chairman, NPPA. The following members of the NPPA were present:-

- (i) Shri A.K. Gautam, Member Secretary Incharge, NPPA.
- (ii) Shri L.M. Kaushal, Director (Cost), Member (Ex-Officio), Deptt. of Expenditure, Ministry of Finance.
- (iii) Shri R. Chandrashekar, Deputy Drug Controller, representing the DCG(I), Department of Health.

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

- (i) Shri A.K. Saha, Director (Overcharging)
- (ii) Shri Jagdish Kumar, Director (Monitoring)
- (iii) Shri A.K. Khurana, Director (Pricing & OC)
- (iv) Shri S. K. Bhatt, Dy. Director (Technical)
- (v) Shri Singh Veer Pratap, Dy. Director (Cost)
- (vi) Shri G. Pradhan, Dy. Director (Cost)
- (vii) Smt. Manmohan Kaur, Dy. Director (Cost)
- (viii) Shri Manish Goswami, Dy. Director (Cost)
- (ix) Shri Suneel Chopra, Dy. Director (Legal)



- (x) Smt. Babita Singh, Asstt. Director (Cost)
- (xi) Shri T. R. Satish Chandran, 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 143rd and 11th Meeting under DPCO, 2013 confirmed the minutes of the meeting.

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

2.0 Noted. It was informed to the Authority that reply has been received recently from M/s Win Medicare in case of 5-Amino Salicylic Acid (5-ASA) 400 mg tablets and M/s Abbott in case of Phenobarbitone 30 mg and 60mg tablet. The Authority directed to examine the replies and put up the cases in next Authority meeting. Further, the Authority also directed that reminders to be issued to DCG(I) and others concerned to expedite the requisite details in the remaining cases.

3. Agenda Item no. 3:

3.1 The Authority discussed the price revision in respect of the two following cases based on the representations received from the companies. The details of these cases are as under:-

(i) Clotrimazole Pessaries 200mg

The Authority discussed the proposal and approved the ceiling price of Rs. 13.31/Pessary as against the earlier price of Rs. 12.71/Pessary notified vide S.O. 3358(E) on 05.11.2013.

(ii) Lignocaine HCL 2 % + Adrenaline Injection 1:200000



The Authority discussed the proposal in detail and approved the ceiling price of Rs. 0.92/ml as against the earlier price of Rs. 0.57/ml notified vide S.O. 2855(E) on 20.9.2013.

4. Agenda Item no. 4:

4.0 The Authority discussed the cases of retail price fixation of "new drugs" based on Form-I applications received from the following companies. The Authority discussed that NPPA has considered the definition of 'new drug' as per the provisions of DPCO, 2013 and in these cases there are various manufactures/marketers that already exist in the market. The Authority also decided that in the retail price notifications, in the footnote it should be mentioned that '*approved prices are subject to fulfillment of all the applicable statutory requirements as laid down by the Govt. under relevant statutes/ rules, by the concerned manufacturers/marketing companies*'. The Authority approved the proposed retail prices under Para 5 in respect of all the cases and decided that in cases where requisite data is not available with NPPA, reminders to be issued to all the Pharma Associations/Apex Bodies to provide the requisite details for fixation of retail prices. This reminder letter may also be uploaded on the NPPA's website. The details of approved prices are as under:

S.No	Company name/Product name	Approved Price (Rs.)
1.	M/s SunGlow Pharmaceuticals Pvt. Ltd. (Manufacturer) and M/s Alkem Lab. Ltd. (Marketing company) – Glucoryl MV 1/0.3 Tablet Each film coated tablet contains: Metformin HCL IP – 500mg (As Sustained Release) Voglibose – 0.3mg Glimepiride IP – 1mg	Rs. 8.47/ Tablet
2.	M/s SunGlow Pharmaceuticals Pvt. Ltd. (Manufacturer) and M/s Alkem Lab. Ltd. (Marketing company) – Glucoryl MV 2/0.3 Tablet Each film coated tablet contains: Metformin HCL IP – 500mg (As Sustained Release)	Rs. 10.46/ Tablet



	Voglibose – 0.3mg Glimepiride IP – 2mg	
3	M/s Zuventus Healthcare Ltd (Marketing Company) and M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) – Tusformin Plus Tablet Each uncoated tablet contains: Glimepiride IP – 2mg Metformin HCL IP – 500 mg	Rs. 4.50/ Tablet
4	M/s Zuventus Healthcare Ltd (Marketing Company) and M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) – Tusformin G Tablet Each uncoated tablet contains: Gliclazide IP – 80 mg Metformin HCL IP – 500 mg	Rs. 4.63/ Tablet
5	M/s Micro Labs Ltd. (Marketing Company) and M/s Innova Captab Pvt. Ltd. (Manufacturer) – Cefpodoxime and Ofloxacin Tablet. Each film coated tablet contains: Cefpodoxime Proxetil IP eq. to Cefpodoxime – 200mg Ofloxacin IP – 200mg	Rs. 12.91/ Tablet
6	M/s. Alkem Lab Ltd (Marketing Company) and M/s Savi Pharma (Manufacturer) – Glucoryl MV 1 Forte Each film coated tablet contains: Metformin HCL IP - 850 mg (As a Extended Release) Voglibose - 0.2 mg Glimepiride IP - 1 mg	Rs. 8.48/ Tablet
7	M/s. Alkem Lab Ltd (Marketing Company) and M/s Savi Pharma (Manufacturer) – Glucoryl MV 2 Forte Each film coated tablet contains: Metformin HCL IP- 850 mg (As a Extended Release) Voglibose - 0.2 mg Glimepiride IP- 2 mg	Rs. 10.46/ Tablet
8	M/s. Dr. Reddy's Lab Ltd (Manufacturer as well as Marketing company) - Metformin HCL Tablet Each sustained release tablet contains: Metformin HCL -1000 mg	Rs. 3.34/ Tablet
9	M/s Galpha Laboratories Ltd. (Marketing Company) and M/s Crescent Therapeutics Limited (Manufacturer) - Thramacet Tablet Each film coated tablet contains: Paracetamol IP 325 mg	Rs. 5.32/ Tablet

10	<p>Tramadol Hydrochloride IP 37.5 mg</p> <p>M/s Mankind Pharma Ltd. (Manufacturer as well as Marketing company)- Bisoprolol Fumarate 2.5 mg & Amlodipine 5 mg Tablet</p> <p>Each film coated tablet contains: Bisoprolol Fumarate- 2.5 mg Amlodipine Besilate eq. to Amlodipine – 5 mg</p>	Rs. 5.08/ Tablet
11	<p>M/s Ipca Laboratories Ltd. (Marketing Company) and M/s Hetero Labs Limited (Manufacturer) - Azibact –L 250 Tablet</p> <p>Each film coated tablet contains: Azithromycin (as dihydrate) Eq. to Azithromycin IP 250 mg Levofloxacin Hemihydrate Eq. to Levofloxacin IP 250 mg q.s excipients</p>	Rs. 12.26/ Tablet
12	<p>M/s Ipca Laboratories Ltd (Marketing Company) and M/s Hetero Labs Limited (Manufacturer) - Azibact –L 500 Tablet</p> <p>Each film coated tablet contains: Azithromycin (as dihydrate) Eq. to Azithromycin IP 500 mg Levofloxacin Hemihydrate Eq. to Levofloxacin IP 500 mg q.s excipients</p>	Rs. 21.77/ Tablet
13	<p>M/s Ipca Laboratories Ltd (Marketing Company) and M/s Hetero Labs Limited (Manufacturer) - Glyree MV1 Tablet</p> <p>Each uncoated bilayered tablet contains: Metformin Hydrochloride IP 500 mg (In sustained release form) Glimepiride IP 1mg Voglibose IP 0.2 mg Excipients q.s.</p>	Rs. 8.46/ Tablet
14	<p>M/s Centaur Pharmaceuticals Pvt. Ltd. (Marketing Company) and M/s Akums Drugs & Pharmaceuticals Pvt. Ltd. (Manufacturer) - Glimitab MV1 Tablet</p> <p>Each uncoated bilayered tablet contains: Glimepiride IP 1mg Metformin Hydrochloride IP -500 mg (as Sustained release) Voglibose – 0.2 mg</p>	Rs. 8.46/ Tablet
15	<p>M/s Ipca Laboratories Ltd (Marketing Company) and M/s Hetero Labs Limited (Manufacturer) - Glyree MV2 Tablet</p> <p>Each uncoated bilayered tablet contains: Metformin Hydrochloride IP 500 mg (In sustained release form) Glimepiride IP 2mg Voglibose IP 0.2 mg, Excipients q.s.</p>	Rs. 10.47/ Tablet

16	<p>M/s Centaur Pharmaceuticals Pvt. Ltd. (Marketing Company) and M/s Akums Drugs & Pharmaceuticals Pvt. Ltd. (Manufacturer) - Glimitab MV2 Tablet</p> <p>Each uncoated bilayered tablet contains: Glimepiride IP 2mg Metformin Hydrochloride IP -500 mg (as Sustained release) Voglibose – 0.2 mg</p>	Rs. 10.47/ Tablet
17	<p>M/s Inventia Healthcare Pvt. Ltd. (Manufacturer) and M/s Alkem Laboratories Ltd. (Marketing Company) - Euclide M 30 OD Tablet</p> <p>Each Uncoated bilayered tablet contains: Gliclazide IP (30 mg) (In modified release form) & Metformin Hydrochloride IP (500 mg) (In extended release form) Excipients : q.s., Colour : Red Oxide of Iron</p>	Rs. 4.43/ Tablet
18	<p>M/s Galpha Laboratories Ltd. (Marketing Company) and M/s Innova Captab Pvt. Ltd. (Manufacturer) - Flucon-AS3 Kit</p> <p>Each Combikit contains:- (A) 1 Fluconazole Tablet IP 150 mg Each uncoated tablet contains: Fluconazole IP 150 mg Colour : poncear 4R (B) 1 Azithromycin Tablet IP 1 g Each film coated tablet contains: Azithromycin IP (as dihydrate) Eq. to Azithromycin 1 gm Colour : poncear 4R (C) 2 Secnidazole Tablet IP 1 gm Each film coated tablet contains: Secnidazole IP 1 gm Colour : Titanium Dioxide IP</p>	Rs. 86.70 per Kit of 4 Tablets
19	<p>M/s Magnet Labs Pvt. Ltd. (Marketing Company) and M/s Innova Captab Pvt. Ltd. (Manufacturer)- Cefixime Oral Suspension IP 100 mg</p> <p>Each 5 ml of constituted suspension contains:- Cefixime IP as Trihydrate Equivalent to Anhydrous Cefixime -100 mg Excipients – q.s</p>	Rs. 2.11 per ml
20	<p>M/s Obsurge Biotech Ltd. (Marketing Company) and M/s Unicare India Ltd. (Manufacturer) - Hydroxychloroquine Sulphate- 400 mg Tabs</p> <p>Each film coated tablet contains: Hydroxychloroquine Sulphate USP 400 mg</p>	Rs. 10.12/ Tablet

	Colour : Titanium Dioxide IP	
21	M/s Inventia Healthcare Pvt. Ltd. (Manufacturer) and M/s Alkem Laboratories Ltd. (Marketing Company) - Euclide M 60 OD Tablet Each Uncoated bilayered tablet contains: Gliclazide IP (60 mg) (In modified release form) & Metformin Hydrochloride IP (500 mg) (In extended release form) tablets Excipients : q.s., Colour : Red Oxide of Iron, Yellow Oxide of Iron	Rs. 6.88/ Tablet

5. Agenda Item no 5: Noted

6. Supplementary Agenda Item no. 1:

6.0 The Authority discussed the provisions of Para 10 (1) and 10 (2) of DPCO, 2013 in detail. The Authority noted that this agenda also includes the cases of price fixation of drugs under DPCO, 1995 where the prices were notified after 31st May, 2012. The Authority also discussed various cases where the prices were notified even after 31st May, 2013 i.e. after announcement of new DPCO, 2013 due to and in compliance with the review orders issued by the Department of Pharmaceuticals (DOP). The Authority after due deliberation decided that as per Para 10(1) of DPCO, 2013, the cases where prices were notified upto 31st May, 2012, alone are to be decided and new prices will be notified in April, 2014 and in all other cases where prices were notified after 31st May, 2012, prices in such cases will have to be notified only in April, 2015 or in the month of April of succeeding financial year as the case may be, as per the provisions of Para 10(2) of DPCO, 2013 because prices fixed under DPCO, 1995 are required to remain frozen for a period of one year and thereafter as provided the manufacturers themselves may revise the prices as per the annual wholesale price index for the previous calendar year. Further, the Authority observed that in case of Gentamycin Drop 0.3%, the prices in respect of packs of M/s Indoco and M/s Sunways are higher as compared to the notified ceiling prices under DPCO, 1995, it directed that in these two packs, PTR should be considered upto the level of derived ceiling price (including



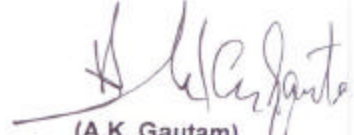
excise duty) under DPCO, 1995 while calculating the ceiling price under DPCO, 2013. The Authority also decided to examine these cases from Overcharging point of view, if any and take appropriate action. Accordingly, the Authority approved the ceiling prices in 9 cases under Para 10(1) where the prices were notified upto 31st May, 2012 under DPCO, 1995. The details of these cases are enclosed as Annexure A, which will be effective from 01st April, 2014.

7. Supplementary Agenda Item no. 2:

7.0 The Authority discussed the case of retail price fixation of a new drug based on Form-I application received. The Authority noted that in the absence of any specific provision regarding fixing of retail price under para 5 for a new drug in case of monopoly situation, the price may be worked out based on the PTR of both the two drugs of which one is non-scheduled drug, included in the formulation under reference as it is a combination of Dicyclomine Hydrochloride 10 mg and Diclofenac Sodium 25 mg. By adding the MRP (including 16% retailer's margin) of Rs. 1.49/ml for Diclofenac Injection 25 mg and the same for Dicyclomine Hydrochloride 10 mg i.e. Rs. 2.54/ml, the retail price for the new drug under reference works out to Rs. 4.03/ml i.e. Rs. 8.06/2 ml as against Rs. 11.00 for 2 ml ampoule claimed by the company. Since, the claim of the company is more than the price worked out (based on the IMS data), the retail price so worked out considering MRP of both the drugs i.e. Rs. 8.06 per 2 ml ampoule was approved by the Authority. The Authority decided that this principle be followed uniformly. The details are as under:-

S.No	Company name/Product name	Approved Price (Rs.)
1.	M/s Nitin Life Sciences Ltd. (Manufacturer) & M/s Seagull Pharmaceuticals Pvt. Ltd. (Marketing company) - Superspas-RF 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 Injections IP QS	Rs. 8.06 for 2 ml ampoule

80 This issues with the approval of Chairman, NPPA.



(A.K. Gautam)

Member Secretary Incharge 28/3/14

Summary of Prices worked out based on Data furnished by M/S-Health/Companies

Sl. No.	Medicines	Category	Route of Administration	Strengths	Proposed prices under GPOC 2015 according to local taxes (Rs./pack)	Highest PTR (Rs./unit)	Lowest PTR (Rs./unit)	% Reduction as compared to Highest PTR	Ceiling price under GPOC 1995 (Rs./ E.O.J./box/ unit)	Demanded Ceiling Price under GPOC 1995 (Rs./ E.O.J./box/ Pack)	% change as compared to Demanded	SO No. & Date	Ceiling price under GPOC (Rs./ E.O.J./box)	
Section: 2 - Analgesic, Antipyretic, Non-steroid Anti-inflammatory Medicines, Medicines used to treat														
2.1. Non-Opioid Analgesics; Antipyretics and Non-steroidal Anti-inflammatory Medicines														
1	Paracetamol	P.S.T	Tablet	100mg/5ml	0.21	0.18	0.17	0.00%	0.20	0.21	0.00	1978 (E.O.J. dt. 06.08.2008)	12.02/85 ml/box	
Section: 3 - Antileptics and Medicines used in Anaphylaxis & Section: 18 - Hormones, other endocrine medicines and gonadotropins														
2	Prodrivone	P.S.T	Inject	20 mg	1.72	1.45	1.48	0.00%	1.57	1.77	-2.82	76(N.E) dt. 10.04.2012	16.72/100 AL/50	
Section: 8 - Antihistaminic Medicines														
3	Benzathine Benzylpenicillin	P.S.T	Injection	12 linc units	11.07	10.45	8.72	8.71%	10.06	10.68	-3.65	444 (E.O.J. dt. 29.03.2008)	10.06	
4	Streptomycin Sulphate	P.S.T	Injection	1 g	9.87	8.77	7.90	4.80%	9.46	10.04	-3.89	629(E) dt. 27.05.2008	9.46	
Section: 9 - Antiparasitic/antemelmintic medicines														
5	Levodopa- Carbidopa	P.S.T	Tablets	100 mg+10 mg	1.44	1.24	1.24	0.00%	1.49	1.99	-8.86	1511 (E.O.J. dt. 07.07.2011)	14.82/100 AL/50	
6	Levodopa- Carbidopa	P.S.T	Tablets	250 mg+25 mg	3.46	2.98	2.87	0.00%	3.98	3.80	-8.98	1511 (E.O.J. dt. 07.07.2011)	35.84/100 AL/50	
Section: 12 - Cardiovascular medicines														
12.1 & 12.2: Antihypertensive & Antithrombotic medicines														
7	Acetyl Salicylic Acid	P.S.T	Tablets	75mg	0.26	0.24	0.21	8.33%	0.25	0.26	0.00	395(E) dt. 02.04.2003	3.48/14.5 TR/5	
Section: 21 - Ophthalmological Preparations														
21.1: Anticholinergic agents														
8	Cyclopentolate Hydrochloride	P.S.T	Chlmyert	0.33%	1.08	0.94	0.89	8.30%	1.04	1.11	-3.64	869(E) dt. 16.04.2010	5.20/5ml/box	
9	Gerfenilan	P.S.T	Drops	0.30%	0.80	0.84	0.64	18.75%	1.03	1.29	-19.35	546 (E.O.J. dt. 10.03.2011)	10.34/10 ml/box	

