

गोपनीय : Confidential

मिसिल स. 8(16)/2014 डी.पी./एन पी पी ए- डीवी-II

F. No. 8(16)/2014/DP/NPPA-Div. II

कार्यवाही स. : 148/16/2014/F

Proceeding No : 148/16/2014/F

Minutes of the 148th and 16th meeting of Authority under DPCO, 2013 held on 10th July, 2014 at 12.00 noon.

The 148th meeting of the Authority which is 16th under the DPCO, 2013 was held on 10th July, 2014 at 12.00 noon 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, Drug Controller General of India DCG(I), 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 Jagdish Kumar, Director (M&E)
- (ii) Shri A.K. Khurana, Director (Pricing & Admin)
- (iii) Smt. Manmohan Kaur, Dy. Director (Cost)
- (iv) Shri Rakesh Kakkar, Dy. Director (Overcharging-I)
- (v) Shri Naresh Arya, Dy. Director (Cost)
- (vi) Smt. Babita Singh, Asstt. Director (Cost)
- (vii) 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 147th and 15th Meeting under DPCO, 2013 confirmed the minutes of the meeting.



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

2.0 Noted.

3. Agenda Item no. 3:

3.1 The Authority considered and approved the prices of 2 formulation packs for fixing/notifying the ceiling price under Para 4 of DPCO, 2013 based on the data furnished by IMS Health and companies.

3.2 The Authority considered and approved the prices of 2 formulation packs for fixing/notifying the ceiling price under Para 6 of DPCO, 2013 based on the Monopoly conditions/situations i.e. where data in respect of only one company is available.

3.3 The Authority considered and approved the price of the one formulation pack for revising the ceiling price under Para 4 of DPCO, 2013 based on the representation from the manufacturing company and clarifications/revised data received from IMS Health.

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

S.no	Particulars	Approved Ceiling Price including WPI (Rs.)
A	Cases based on data of the IMS Health/Companies	
1	Pyrimethamine Tablet 25mg	0.89/Tablet
2	Actinomycin D Injection 0.5 mg	562.98/Injection
B	Cases based on Monopoly situations	
1	Codeine Phosphate Tablet 10mg	0.98/Tablet
2	Sodium Nitrate Injection 30 mg/ml	19.83/ml
C	Cases based on Representation of the company	
1	Ciprofloxacin Hcl Injection 200mg/100ml.	0.27/ml

4. Agenda Item no. 4:

4.0 The Authority discussed the proposal of price revision in respect of Phenobarbitone 30 mg Tablet, based on the review order no. 31015/21/2013/PI.I dated 21.10.2013 received from the DOP and approved the revised ceiling price at Rs. 1.48 per tablet (including WPI factor of 6.32% as the base data is May, 2012) against the earlier ceiling price of Rs. 0.93 per tablet (Rs. 0.99 per tablet including WPI factor of 6.32%), notified vide S.O. 1877(E) dated 28.06.2013. However, the Authority also decided that in future, any formulation having a bearing on the price of another



Formulation(s), then the prices of all such formulations may be considered in the same Authority meeting.

5. Agenda Item no. 5:

5.0 The Authority discussed the proposal and approved the price revision in respect of the following 7 cases, based on the data received from the companies on account of revalidation of data as per the review orders issued by the DOP. The details of these cases are as under:-

S. No.	Name of the formulation	Review order no./ Date	Approved Ceiling Price including WPI (Rs.)
1	Atorvastatin tablet 10mg	31015/60/2013/Pl.I 20.12.2013	6.49/Tablet
2	Heparin Sodium Injection 5000IU/ml	31015/72/2013/Pl.I 18.02.2014	43.53 per ml
3	Tramadol capsule 50mg	31015/60/2013/Pl.I 20.12.2013	6.41/capsule
4	Pantoprazole Injection 40mg	31015/49/2013/Pl.I 20.12.2013	51.98 for each pack
5	Albendazole 400mg Tablet	31015/60/2013/Pl.I 20.12.2013	9.92/Tablet
6	Condoms	31015/92/2013/Pl.I 11.02.2014	8.04/each
7	Calamine Lotion	31015/73/2013/Pl.I 05.03.2014	1.01 per ml/gm

6. Agenda Item no. 6:

6.0 The Authority discussed the 34 cases for retail price fixation of new drug based on Form-I applications. In respect of 2 cases i.e. S. No. 8 and 9 of the agenda items pertaining to Thyroxin Sodium Tablets 25mcg and 75 mcg respectively, the Authority deferred the cases and directed NPPA to get the data confirmed/validated from the IMS Health. The details of remaining 32 approved retail prices of new drugs are as under:

S.No	Company name/Product name	Approved Retail Price (Rs.)
6(i)	M/s Hetero labs Limited (Manufacturer) and M/s Jubilant Life Sciences Limited (Marketing company) – Metformin Hydrochloride (Prolonged Release) 500 mg, &	38.46/10's Tabs

	<p>Glimepiride 1 mg Tablets (JubiglimTM M 1)</p> <p>Each uncoated bilayered tablet contains:</p> <p>Metformin Hydrochloride IP 500 mg (In Prolonged Release form)</p> <p>Glimepiride IP 1 mg</p> <p>Excipients q.s</p> <p>Colour : Lake Ponceau 4R</p>	
6(ii)	<p>M/s Hetero labs Limited (Manufacturer) and M/s Jubilant Life Sciences Limited (Marketing company) – Metformin Hydrochloride (Prolonged Release) 500 mg & Glimepiride 2 mg Tablets (JubiglimTM M 2)</p> <p>Each uncoated bilayered tablet contains:</p> <p>Metformin Hydrochloride IP 500 mg (In Prolonged Release form)</p> <p>Glimepiride IP 2 mg</p> <p>Excipients q.s</p> <p>Colour : Ferric Oxide USP-NF Red</p>	4.50/tablet
6(iii)	<p>M/s Astam Healthcare Pvt. Ltd., (Manufacturer) and M/s Alkem Laboratories Ltd (Marketing company) – ES-Omepraz-DSR</p> <p>Each hard gelatin capsule contains:</p> <p>Esomeprazole Magnesium Trihydrate eq. Esomeprazole 40mg (as enteric coated pellets)</p> <p>Domperidone 30mg (as sustained release pellets)</p>	7.03/capsule
6(iv)	<p>M/s Maxim Pharmaceuticals Pvt. Ltd., (Manufacturer) and M/s Mankind Pharma Ltd., (Marketing company) – Cefixime Oral Suspension 100mg (Sachet)</p> <p>Each 1gm Sachet Contains:</p> <p>Cefixime IP as Trihydrate eq.to Anhydrous Cefixime 100mg</p>	9.53 per 1gm sachet pack
6(v)	<p>M/s ANG Lifesciences (I) Pvt. Ltd (Manufacturer) and M/s Emcure Pharmaceuticals Limited, (Marketing company) – Artezem Injection</p> <p>Each vial contains:</p> <p>Artesunate (Sterile) IP 60 mg</p> <p>The pack contains: 1 ml ampoule of Sterile Sodium Bicarbonate Injection 5% w/v and 5 ml ampoule of Sterile Sodium Chloride Injection 0.9% w/v.</p>	180.04 per vial of 60 mg
6(vi)	<p>M/s Synkem Pharmaceuticals Ltd. (Manufacturer) and M/s Emcure Pharmaceuticals Ltd., (Marketing company) – Desogestrel and Ethinylestradiol Tablets USP (DESO-ECP</p>	4.72/tablet

	<p>Tablet)</p> <p>Each film coated tablet contains: Desogestrel BP 0.15 mg Ethinylestradiol IP 0.03 mg Excipients q.s Colour : Erythrosine Lake</p>	
6(vii)	<p>M/s Windlas Biotech Limited (Manufacturer) and M/s Micro Labs Ltd., (Marketing company) – Glimepiride + Voglibose + Metformin Hydrochloride Tablets</p> <p>Each uncoated bilayered tablet contains: Glimepiride IP 2 mg Voglibose IP – 0.3 mg Metformin Hydrochloride IP 1000 mg (as sustained release form) Colour : Quinoline Yellow Lake</p>	10.61/tablet
6(x)	<p>M/s Akums Drugs & Pharmaceuticals Pvt. (Manufacturer) and M/s RPG Life Sciences Ltd., (Marketing company) – Glimepiride, Voglibose, & Metformin (SR) Tablets (GVMET)</p> <p>Each uncoated bilayered tablet contains: Glimepiride IP 1mg Voglibose – 0.2 mg Metformin Hydrochloride IP 500 mg (as sustained release) Colour : Red Oxide of iron</p>	8.46/Tablet
6(xi)	<p>M/s Synokem Pharmaceuticals Limited (Manufacturer) and M/s Intas Pharmaceuticals Ltd., (Marketing company) – CLAVILIP 20</p> <p>Each hard gelatin capsule contains: Atrovastatin Calcium IP Eq. to Atrovastatin 20 mg (As pellets) Clopidogrel Bisulphate IP Eq. to Clopidogrel 75mg (As pellets) Colour: Approved colours used</p>	15.07/Capsule
6(xii)	<p>M/s Ajanta Phamra Ltd (Manufacturer and Marketing company) – Nadifloxacin, Mometasone Furoate and Miconazole Nitrate Cream</p> <p>Each gm contains: Nadifloxacin 10 mg (1.0% w/w) Mometasone Furoate IP 1.0 mg (0.1% w/w) Miconazole Nitrate IP 20 mg (2.0% w/w) Cream Base q.s Preservatives: Methylparaben IP 0.18% w/w Propylparaben IP 0.02% w/w</p>	6.37 per gm

6(xiii)	M/s Windlas Biotech Limited. (Manufacturer) and M/s Lifestar Pharma Pvt. Ltd. (Marketing company) – Paracetamol 250 mg & Mefenamic Acid 100 mg Suspension Each 5 ml contains: Paracetamol IP 250 mg Mefenamic Acid IP 100 mg Flavoured Syrup Base q.s Colour : Sunset Yellow Supra	0.59 per ml
6(xiv)	M/s Finecure Pharmaceuticals Ltd (Manufacturer) and M/s Yash Pharma Laboratories Pvt. Ltd. (Marketing company) – Cefixime with ofloxacin Tablets Each film coated tablet contains: Cefixime Tryhydrate IP Equivalent to Anhydrous Cefixime 200 mg Ofloxacin IP 200 mg Excipients Q.S. Colour Tartarazine	9.94/tablet
6(xv)	M/s Hetero Labs Limited (Manufacturer) and M/s Jubilant Life Sciences Limited (Marketing company) – Metformin Hydrochloride (Prolonged Release) 500 mg, Pioglitazone 15 mg & Glimepiride 2 mg Tablets (Jubiglim™ Trio 2) Each uncoated bilayered tablet contains: Metformin Hydrochloride IP 500 mg (In Prolonged Release form) Pioglitazone Hydrochloride eq. to Pioglitazone - IP 15mg Glimepiride – 2 mg Excipients q.s Colour : Lake Quinoline Yellow	6.94/tablet
6(xvi)	M/s Theon Pharmaceuticals Ltd. (Manufacturer) and M/s Jubilant Life Sciences Limited (Marketing company) – Telmisartan & Amlodipine Tablets (80 mg + 5 mg) Telmijub™ AM 80 Each uncoated tablet contains: Telmisartan IP 80 mg Amlodipine Besilate IP eq. to Amlodipine 5 mg Excipients q.s	110.58/10's tabs
6(xvii)	M/s Hetero Labs Limited (Manufacturer) and M/s Jubilant Life Sciences Limited (Marketing company) – Metformin Hydrochloride (Prolonged Release) 500 mg & Voglibose 0.2 mg Tablets (Agivog™ M 0.2) Each uncoated bilayered tablet contains: Metformin Hydrochloride (In prolonged release form) IP 500 mg	52.38/10's tabs



	Voglibose IP 0.2 mg - Excipients q.s Colour- Lake Quinoline Yellow	
6(xviii)	M/s Theon Pharmaceuticals Ltd. (Manufacturer) and M/s Jubilant Life Sciences Limited (Marketing company) – Telmisartan & Amlodipine Tablets (40 mg + 5 mg) Telmijub™ AM 40 Each uncoated tablet contains: Telmisartan IP 80 mg Amlodipine Besilate IP eq. to Amlodipine 5 mg Excipients q.s	7.02 per tablet
6(xix)	M/s Ipca Laboratories Limited (Manufacturer) and (Marketing company) – Acetaminophen & Tramadol Hydrochloride Tablets USP (325 mg + 37.5 mg) (Tolydol Tablet) Each film coated tablet contains: Acetaminophen IP 325 mg Tramadol Hydrochloride IP 37.5 mg Colour : Ferric Oxide Yellow USP NF Titanium Dioxide IP	4.00/tablet
6(xx)	M/s Nuclotec Remedies Pvt. Ltd (Manufacturer) and M/s Seagull Pharmaceuticals Pvt. Ltd. (Marketing company) – Diclofenac Sodium Injection(Superspas –AQ Injection) Each ml contains: Diclofenac Sodium IP 75 mg Benzyl Alcohol IP 4% w/w (as preservative) Water for Injection Ip q.s	14.30 per ml
6(xxi)	M/s Akums Drugs & Pharmaceuticals Ltd., (Manufacturer) and M/s FDC Ltd (Marketing company) – Amlodipine, Telmisartan & Hydrochlorothiazide tablet Each film coated tablet contains: Amlodipine – 5 mg Telmisartan - 40mg Hydrochlorothiazide – 12.5mg	6.00/tablet
6(xxii)	M/s Crescent Therapeutics Limited (Manufacturer) and M/s Galpha Laboratories Limited (Marketing company) – Kofrest Q Each film coated tablet contains: Bromhexine Hydrochloride IP 8 mg Phenylephrine Hydrochloride IP 5 mg Guaiphenisin IP 100 mg Chlorpheniramine Maleate Ip 2 mg Paracetamol IP 325 mg	2.73/tablet
6(xxiii)	M/s Acme formulation Pvt. Ltd. (Manufacturer) and M/s Micro Labs. Ltd. (Marketing company) – Trypsin Chymotrypsin & Diclofenac Potassium Tablet	5.80/tablet

	Each enteric coated tablet contains: 50,000 Armour units of enzymatic activity (supplied by a purified concentrate which has specific Trypsin and Chymotrypsin activity in a ratio of approximately six to one) (As enteric coated) IP 50,000 Armour Units + Diclofenac Potassium BP – 50mg	
6(xxiv)	M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) and M/s Jenburkt Pharmaceuticals Ltd. (Marketing company) – Ojen OZ suspension Each 5ml contains: Ofloxacin – 50mg Ornidazole - 125mg	31.00 per 30ml pack
6(xxv)	M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) and M/s Jenburkt Pharmaceuticals Ltd. (Marketing company) – Zydol-P suspension Each 5ml contains: Paracetamol – 125mg Mefenamic Acid – 50mg	0.45 per ml
6(xxvi)	M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) and M/s Torrent Pharma. (Marketing company) – Modlip D 10 tablet Each film coated tablet contains: Atorvastatin calcium eq. to Atorvastatin 10mg Vitamin D3 (Cholecalciferol) 1000 I.U.	8.27/tablet
6(xxvii)	M/s Hetero Labs Limited (Manufacturer) and M/s Jubilant Life Sciences Limited (Marketing company)– Metformin Hydrochloride (Prolonged Release) 500 mg, Pioglitazone 15 mg & Glimpiride 1 mg Tablets (Jubiglim™ Trio 1) Each uncoated bilayered tablet contains: Metformin Hydrochloride IP 500 mg (In Prolonged Release form) Pioglitazone Hydrochloride eq. to Pioglitazone - IP 15mg Glimpiride – 1 mg Excipients q.s Colour : Lake Indigo Caramine	53.56/10's tabs
6(xxviii)	M/s Hetero Labs Ltd. (Manufacturer) and M/s Hetero Healthcare Ltd. (Marketing company) – Hifen LZ tablets Each film coated tablet contains: Cefixime (as trihydrate) eq. to Anhydrous Cefixime - 200mg, Linezolid – 600mg	29.50/tablet
6(xxix)	M/s Hetero Labs. Ltd. (Manufacturer) and M/s Unichem Lab. Ltd. (Marketing company) – Linox Total Tablet Each film coated tablet contains: Cefixime (as trihydrate) eq. to Anhydrous Cefixime - 200mg, Linezolid – 600mg	29.50/tablet

6(xxx)	M/s Innova Captab Pvt. Ltd., (Manufacturer) and M/s Cadila Pharmaceuticals Ltd (Marketing company) – Cefixime 200mg + Linezolid 600mg tablet Each film coated tablet contains: Cefixime (as trihydrate) eq. to Anhydrous Cefixime - 200mg Linezolid – 600mg	29.50/tablet
6(xxxi)	M/s Hetero Labs. Ltd., (Manufacturer) and M/s Micro Lab. Ltd. (Marketing company) – Cefixime 200mg + Linezolid 600mg tablet Each film coated tablet contains: Cefixime (as trihydrate) eq. to Anhydrous Cefixime - 200mg Linezolid – 600mg	29.50/tablet
6(xxxii)	M/s Hetero Labs Limited (Manufacturer) and M/s Glenmark Pharmaceuticals Ltd. (Marketing company) – Lizolid Plus tablets Each film coated tablet contains: Cefixime (as trihydrate) eq. to Anhydrous Cefixime - 200mg Linezolid – 600mg	29.50/tablet
6(xxxiii)	M/s Hetero Labs Limited (Manufacturer) and M/s Aristo Pharmaceuticals Pvt. Ltd. (Marketing company) – Megazolid Plus tablet Each film coated tablet contains: Cefixime (as trihydrate) eq. to Anhydrous Cefixime - 200mg Linezolid – 600mg	29.50/tablet
6(xxxiv)	M/s Onco Therapies Ltd (Manufacturer) and M/s Eli Lilly (Marketing company) – Lixapla (Oxaliplatin) injection 100mg/vial Each vial contains: Oxaliplatin – 100mg Lactos Monohydrate – 900mg	4178.11 for 100 mg vial

Agenda Item No. 7:

7.0 The Authority discussed the guideline formulated for granting permission of discontinuation of production based on Form-IV application received from the manufacturers of scheduled formulations under para 21 of DPCO, 2013. After due deliberations, the Authority decided that the said guidelines should be placed on NPPA's website as 'Draft Guidelines' for comments of different stakeholders/Industry



Associations for their comments within a period of 21 days from the date of placing the same on website.

Agenda Item No. 8

8.1 The Authority discussed the agenda put up for price fixation of Anti-diabetic non-scheduled formulations under para 19 of DPCO, 2013. In this regard, the Authority recalled that vide its 147th Meeting held on 16.05.2014 the guidelines were approved for price fixation of non-scheduled formulations showing extreme inter-brand price difference, under para 19 of DPCO, 2013. It was decided that, to start with inter-brand price variation will be examined in respect of single ingredient formulations in eight therapeutic groups, namely, anti-cancer, HIV/AIDS, anti-TB, anti-malaria, cardiovascular, anti-diabetics, anti-asthmatic, and immunological (sera/ vaccines); and wherever the maximum retail price (MRP) of the brand(s) of medicine of a particular formulation exceeds 25 percent of the simple average price the same will be capped at the 25 per cent level.

8.2 The Authority noted that there is a very high incidence of diabetes in the country, which affects around 61 million persons and the figure is expected to cross 100 million by 2030 as per the projection of the International Diabetes Federation; further it is estimated that every year nearly 1 million people in the country die due to diabetes. While considering the proposal submitted for price fixation of non-scheduled formulations, the Authority noted that there exist huge inter-brand price differences in branded-generics, which is indicative of a severe market failure, as different brands of the same drug formulation, which are identical to each other in terms of active ingredient(s), strength, dosage, route of administration, quality, product characteristics, and intended use, vary disproportionately in terms of price. It is observed that, the different brands of the drug formulation may sometimes differ in terms of binders, fillers, dyes, preservatives, coating agents, and dissolution agents, but these differences are not significant in terms of therapeutic value. The market failure in respect of pharmaceuticals in the context of India can be attributed to several factors, but the main reason is that the demand for medicines is largely prescription driven and the patient has very little choice in this regard. While market failure alone may not constitute



sufficient grounds for government intervention, but when such failure is considered in the context of the essential role of pharmaceuticals play in the area of public health, which is a social right, such intervention becomes necessary, especially when exploitative pricing makes medicines unaffordable and beyond the reach of most and also puts huge financial burden in terms of out-of-pocket expenditure on healthcare.

8.3 Taking the above into consideration, the Authority approved the maximum retail price in respect of 120 anti-diabetic non-scheduled formulations based on 9 molecules, where reduction in price was worked out as per the data provided by the IMS-Health for the month of April, 2014. The drug-wise details of molecules / drug for which reduced prices were approved is given below:

S.No.	Molecule	No. of packs considered	No. of packs Approved
1	GLICLAZIDE	66	12
2	GLIMEPIRIDE	171	42
3	MIGLITOL	18	1
4	REPAGLINIDE	9	2
5	PIOGLITAZONE	85	21
6	SITAGLIPTIN	8	2
7	VOGLIBOSE	113	28
8	ACARBOSE	20	2
9	METFORMIN H	78	10
Total		568	120

8.4 The Authority also decided that concerned company shall maintain the maximum retail price so approved for a period of one year from the date of notification after which annual price increase not exceeding 10% of MRP will be permissible as per para 20 (1) of DPCO, 2013.

Agenda Item No. 9:

9.1 The Authority noted that there is a very high incidence of cardiovascular disease (CVD) in the country, which is estimated to affect around 10 per cent of the population and is responsible for 25% of the deaths in the age group of 25-69. The Authority approved the maximum retail price under para 19 of DPCO, 2013 in respect of




Cardiovascular non-scheduled formulations based on the agenda note submitted for consideration on similar lines as mentioned in agenda item no.8 above. The drug-wise details of molecules/drug for which reduced prices were approved is given below:

S.No.	Molecule	No. of packs considered	No. of packs Approved
1	Ambrisentan	8	1
2	Amlodipine	28	6
3	Atenolol	31	13
4	Atorvastatin	133	38
5	Bisoprolol	15	5
6	Bosentan	6	1
7	Carvedilol	43	7
8	Clopidogrel	12	5
9	Coumarin	2	1
10	Diltiazem	25	2
11	Dobutamine	2	1
12	Enalapril	9	4
13	Enoxaparin	15	1
14	Eplerenone	8	1
15	Esatenolol	5	1
16	Fenofibrate	28	1
17	Heparin	6	2
18	Indapamide	13	3
19	Irbesartan	8	3
20	Isosorbide	47	8
21	Ivabradine	15	2
22	Labetalol	15	2
23	Levocarnitine	18	3
24	Lisinopril	33	6
25	Metolazone	8	2
26	Metoprolol	47	5
27	Nebivolol	45	1
28	Nicorandil	29	6
29	Nitroglycerin	25	2
30	Olmесartan	87	9
31	Prasugrel	24	2
32	Prazosin	15	1
33	Propranolol	28	5

34	Ramipril	108	26
35	Rosuvastatin	159	34
36	Simvastatin	30	10
37	Telmisartan	159	13
38	Terazosin	8	3
39	Torasemide	77	6
40	Trimetazidine	19	3
41	Valsartan	17	2
Total		1410	247

9.2 The Authority also decided that concerned company shall maintain the maximum retail price so approved for a period of one year from the date of notification after which annual price increase not exceeding 10% of MRP will be permissible as per para 20 (1) of DPCO, 2013.

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


(A.K. Gautam)
Member Secretary Incharge 10/7/14