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F. No. 8(36)/2016/DP/NPPA-Div. II

कार्यवाहीस. : 168/36/2016/F

Proceeding No : 168/36/2016/F

Minutes of the 168th and 36th meeting of Authority under DPCO, 2013 held on 14.9.2016 at 11.00 AM.

I. 1. The 168th overall meeting of the Authority, which is the 36th under the DPCO, 2013 was held on 14th September, 2016 at 11.00 AM under the Chairmanship of Shri Bhupendra Singh, Chairman, NPPA. The following members of the NPPA were present:-

(i) Dr. Sharmila Mary Joseph K, Member Secretary, NPPA.
(ii) Shri Devendra Kumar, Adviser (Cost), Deptt. of Expenditure, Ministry of Finance.
(iii) Shri R.Chandrashekhar, Deputy Drug Controller, Deptt. of Health & Family Welfare (representing DCGI).

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

(i) Shri Kalyan Nag, Adviser (Cost)
(ii) Smt. Roshni Sohni, Director (M&E/Admn.)
(iii) Shri A.K. Khurana, Director (Pricing)
(iv) Shri A.P.S. Sawhney, Director (Overcharging)
(v) Shri Rakesh Kakkar, Dy. Director (M&E)
(vi) Shri Baljit Singh, Asstt. Director (Pricing)
(vii) Shri Prasenjit Das, Asstt. Director (Pricing)

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

II. Agenda Items

1. Agenda Item no. 1: Confirmation of Minutes of the 35th Meeting held on 17.8.2016.

As no comments were received on the minutes of 167th and the 34th Meeting under DPCO, 2013, the Authority confirmed the minutes of the meeting.

2. Agenda Item no. 2: Action Taken Report

Noted.

3. Agenda Item no. 3: Fixation of Ceiling Prices of Scheduled formulations in the revised Schedule-I of DPCO, 2013 (NLEM, 2015).

3.1 The Authority discussed in detail the data regarding 25 formulations. Data on Hydrochlorothiazide 25mg tablet was also discussed during the meeting. The Authority approved the ceiling prices in respect of the following 18 formulations.

S. NO.	UNIQUE NO. AS PER NLEM	NAME OF THE FORMULATION/ COMPOSITIONS	STRENGTH	DOSAGE FORM	UNIT FOR CEILING PRICE	APPROVED CEILING PRICE under NLEM, 2015 (Rs.)
Common Cases						
1	2.4.4	Methotrexate	5 mg tablet	Tablet	Per Tablet	7.45
2	5.1	Carbamazepine	100 mg tablet	Tablet	Per Tablet	0.64
3	5.9.2	Sodium Valproate	100 mg/ml Injection	Injection	Per ML	5.34
4	6.5.3.1.6	Primaquine	2.5 mg tablet	Tablet	Per Tablet	1.44
5	8.3.2	Cyclosporin	25 mg capsule	Capsule	Per Capsule	24.48
6	9.1.5	Levodopa + Carbidopa	250/25 mg tablet	Tablet	Per Tablet	3.46
7	10.2.1	Enoxaparin	40mg/0.4ml Injection	Injection	Per 0.1 ml	90.454
8	10.2.1	Enoxaparin	60mg/0.6ml Injection	Injection	Per 0.1 ml	90.454
9	12.3.4	Hydrochlorothiazide	12.5 mg tablet	Tablet	Per Tablet	0.91
10	12.3.4	Hydrochlorothiazide	25 mg tablet	Tablet	Per Tablet	1.57
New Cases						
1	2.1.5	Paracetamol	150 mg/5ml Oral Liquid	Oral Liquid	Per ml	0.54
2	2.1.5	Paracetamol	100 mg/5ml Oral Liquid	Oral Liquid	Per ml	0.47
3	2.1.5	Paracetamol	250mg/5ml Oral Liquid	Oral Liquid	Per ml	0.56
4	2.1.5	Paracetamol	650 mg/5ml Oral Liquid	Oral Liquid	Per ml	0.48
5	2.1.5	Paracetamol	500 mg/5ml Oral Liquid	Oral Liquid	Per ml	0.59
6	6.2.1.6	Cefadroxil	1 Gm tablet	Tablet	Per Tablet	5.83
7	6.2.1.7	Cefazolin	500 mg Powder for injection	Injection	Each Pack	14.44
8	6.2.4.6	Kanamycin	500 mg Powder for injection	Injection	Each Pack	19.80

Data on 7 formulations viz. Dexamethasone 4mg/ml Injection (30ml, 20ml & 10ml pack), Gentamicin 40mg/ml Injection (20ml & 10ml pack), Water For Injection-1000ml pack as well as Water For Injection-3000ml pack, was deferred for further discussions/deliberations.

The Authority also noted that in case of some common formulations, some companies were selling their products at prices higher than the ceiling prices fixed by NPPA earlier. It was decided that action will be taken against these companies for non-compliance of ceiling prices fixed by NPPA earlier.

Authority took a note of the pendency of cases under NLEM, 2015 and observed that because of sizable pendency, NPPA needs to give top priority to fixing the ceiling prices of remaining NLEM drugs. The number of cases of 'ceiling price' should be at least twice the number of new drug cases in future for consideration of the Authority.

4. Agenda Item no. 4: Fixation of retail price in respect of new drugs.

4.1 The Authority discussed the following 21 cases of retail price fixation of new drugs falling under the purview of para 2(u) of DPCO, 2013 and approved the retail prices of the following under para 5 of the DPCO 2013, as under:

S. No.	Company name/Product name	Approved Retail Price (Rs.)
4(i)	M/s Chiros Pharma (Manufacturer) and M/s Biochem Pharmaceuticals Industries Ltd. (Marketing company) - Amoxycillin trihydrate eq. to Amoxycillin 875mg and Potassium Clavulanate diluted eq. to clavulanic Acid 125mg – (Pencalv 1000 tablet).	Rs. 28.93/tablet
4(ii)	M/s Windlas Biotech Ltd. (Manufacturer) and M/s Alkem Lab. Ltd. (Marketing company) - Glimepiride 3mg and Metformin HCl 1000mg (as sustained release form) – (Glucoryl M3 Forte tablet).	Rs. 9.35/tablet
4(iii)	M/s Windlas Biotech Ltd. (Manufacturer) and M/s Alkem Lab. Ltd. (Marketing company) - Glimepiride 3mg and Metformin HCl 500mg as sustained release form – (Glucoryl M3 tablet).	Rs. 6.61/tablet
4(iv)	M/s Merril Pharma Pvt. Ltd. (Manufacturer) and M/s Alkem Lab. Ltd (Marketing company) - Tolperisone Hydrochloride 150mg and Diclofenac sodium 50mg – (Tolkem-D tablet).	Rs. 11.52/tablet
4(v)	M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) and M/s Lupin Ltd. (Marketing company) 2ml respule containing - Formoterol Fumarate Dihydrate eq. to Formoterol Fumarate 20mcg and Budesonide 1mg (In Isotonic solution) – (Budamate Neb 1mg).	Rs. 40.88/2ml respule
4(vi)	M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) and M/s Lupin Ltd. (Marketing company) - Formoterol Fumarate Dihydrate eq. to Formoterol Fumarate 20mcg and Budesonide 0.5mg (In Isotonic solution) – (Budamate Neb 0.5mg).	Rs. 35.09/2ml respule
4(vii)	M/s Windlas Biotech Ltd (Manufacturer) and M/s Cadila Healthcare Ltd (Marketing company) - Rosuvastatin calcium eq. to Rosuvastatin 10mg (film coated) and Aspirin 150mg (enteric coated pellets) – (Zyrova ASP 150 capsule) .	Rs. 50.05 for 10 capsules
4(viii)	M/s Alkem Lab. Ltd. (Manufacturer as well as Marketing company) - Metoprolol succinate eq. to Metoprolol tartrate 25mg (extended release form) and Olmesartan Medoxomil 20mg – (Olkem Beta 25 tablet).	Rs. 9.28/tablet
4(ix)	M/s Alkem Lab. Ltd. (Manufacturer as well as Marketing company) - Metoprolol succinate eq. to Metoprolol tartrate 50mg (extended release form) and Olmesartan Medoxomil 20mg – (Olkem Beta 50 tablet).	Rs. 11.12/tablet
4(x)	M/s Innova Captab Pvt. Ltd. (Manufacturer) and M/s Pfizer Ltd. (Marketing company) - Cefixime (as trihydrate) eq. to anhydrous Cefixime 200mg and Ofloxacin 200mg – (Jetex Of Tablet).	Rs. 9.86/tablet

4(xi)	M/s Hetero Labs Ltd. (Manufacturer) and M/s Indoco Remedies Ltd. (Marketing company) - Diclofenac Colestyramine (Diclofenac resinate) 145.60mg Eq. to Diclofenac Sodium IP 75mg – (IER- 75 Capsule).	Rs. 5.28/capsule
4(xii)	M/s Glenmark Pharmaceuticals Ltd. (Manufacturer) and M/s Aristo Pharmaceuticals Pvt. Ltd. (Marketing company) - Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg and Metformin HCl 1000mg (as extended release) – (Megagliptin MF Forte Tablets).	Rs. 11.65/tablet
4(xiii)	M/s Windlas Biotech Ltd. (Manufacturer) and M/s Mankind Pharma Ltd. (Marketing company) - Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg and Metformin HCl 1000mg (as sustained release form) – (Dynaglipt- M Forte tablets).	Rs. 11.65/tablet
4(xiv)	M/s Innova Captab (Manufacturer) and M/s Lupin Ltd. (Marketing company) - Povidone Iodine IP 5.00% w/w (available Iodine 0.5% w/w) and Ornidazole IP 1.00% w/w – (Lupidine OZ ointment).	Rs. 3.30/gm
4(xv)	M/s Savi Pharma (Manufacturer) and M/s Alkem Lab. Ltd. (Marketing company) - Glimepiride 3mg film coated tablet (Glucoryl 3mg tablet).	Rs. 80.00 for 15 tablets
4(xvi)	M/s Jenburkt Pharmaceuticals Ltd. (Manufacturer as well as Marketing company) - Clotrimazole 1% w/v and (Triben Lotion)	Rs. 96.93 for pack of 30ml lotion
4(xvii)	M/s Glenmark Pharmaceuticals Ltd. (Manufacturer) and M/s Koye Pharmaceuticals Pvt. Ltd. (Marketing company) - Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg and Metformin HCl 500mg (as extended release) – (Teneligliptin 20mg + Metformin HCl 500mg ER tablet).	Rs. 11.14/tablet
4(xviii)	M/s Windlas Biotech Ltd. (Manufacturer) and M/s Mankind Pharma Ltd. (Marketing company) - Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg and Metformin HCl 500mg (as sustained release form) – (Dynaglipt-M tablets).	Rs. 11.14/tablet
4(xix)	M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) and M/s Blue Cross Lab. Pvt. Ltd. (Marketing company) - Paracetamol 500mg, Caffeine (anhydrous) 30mg, Phenylephrine HCl 5mg, Diphenhydramine HCl 25mg – (Kolq-C tablet).	Rs. 2.68/tablet
4(xx)	M/s Intas Pharmaceuticals Ltd. (Manufacturer as well as Marketing company) - Atorvastatin calcium eq. to Atorvastatin 10mg and Choline Fenofibrate eq. to Fenofibric acid 135mg delayed release – (Atorvastatin 10mg+ Choline Fenofibrate DR 135mg capsules).	Rs. 14.73/capsule
4(xxi)	M/s Intas Pharmaceuticals Ltd. (Manufacturer as well as Marketing company) - Atorvastatin calcium eq. to Atorvastatin 20mg and Choline Fenofibrate eq. to Fenofibric acid 135mg delayed release – (Atorvastatin 20mg+ Choline Fenofibrate DR 135mg capsules).	Rs. 19.70/capsule

The Authority discussed that in cases, where NPPA had notified the retail price for formulations with same composition earlier under DPCO, 2013 at any period more than a year ago, 10% per annum increase on the retail price fixed earlier will be considered.

The least amongst the notified retail price so worked out after applying increase, company's claim and the draft retail price worked out (based on Pharma Trac/Company's data) will be considered and approved as retail price. The Authority decided to follow this practice in future also, since it protects the interest of the consumers, helps in encouraging the competition and price predictability without harming the interest of the manufacturer.

Accordingly, at S.No. 4(vii) i.e. case of M/s Windlas Biotech Ltd (Manufacturer) and M/s Cadila Healthcare Ltd (Marketing company) - Rosuvastatin calcium eq. to Rosuvastatin 10mg and Aspirin 150mg – (Zyrova ASP 150 capsule), the retail price of Rs. 50.05 for 10 capsules (i.e. Rs. 45.50+10% increase), being lowest among (a) retail price worked out with 10% added to retail price fixed for same formulation by NPPA earlier (b) retail price worked out at present (based on Pharma Trac data) i.e. Rs. 6.08/capsule and (c) company's claim of Rs. 8.85/capsule, has been approved.

Similarly, at S.No. 4(xiv) i.e. case of M/s Innova Captab (Manufacturer) and M/s Lupin Ltd. (Marketing company) - Povidone Iodine IP 5.00% w/w (available Iodine 0.5% w/w) and Ornidazole IP 1.00% w/w – (Lupidine OZ ointment), the retail price of Rs. 3.30/gm (i.e. Rs. 3.00+10% increase), being lowest among (a) retail price worked out earlier by NPPA for same formulation, (b) the retail price worked out at present (based on Pharma Trac data) i.e. Rs. 3.80/gm and (c) company's claim of Rs. 3.33/gm (i.e. Rs. 50.00 per 15 gm ointment), has been approved.

Applying the same principle, in Sl. No. 4 (viii) where retail price worked out by NPPA earlier for same formulation in November, 2013 was modified applying 10% per annum twice. In this case, however, the retail price worked out based on current pharmatrac data was the lowest and hence, this price i.e. (Rs. 9.28/tablet) was approved by the Authority. Similarly, in Sl. No. 4 (i) where retail price worked out by NPPA earlier for same formulation in July, 2015 was modified applying 10% per annum. In this case, however, the retail price worked out based on current pharmatrac data was the lowest and hence, this price i.e. (Rs. 28.93/tablet) was approved by the Authority.

5. Agenda Item no. 5: Representation for Price revision of Levetiracetam 100mg/ml Oral Liquid notified vide S.O. No. 1561(E) dated 27.4.2016.

5.1 This case was discussed in detail and the Authority approved the revised ceiling price of Levetiracetam oral liquid 100mg/ml at Rs. 3.38/ml.

6. Agenda Item no. 6: (A) Representation for Price revision of Cholecalciferol (Vitamin D3) 60000 IU tablet notified vide S.O. 1253(E) dated 29.03.2016.

(B) Representation for Price revision of Cholecalciferol (Vitamin D3) 60000 IU capsule notified vide SO 1687(E) dated 09.05.2016.

6.1 These cases were discussed in detail and the Authority approved the revised ceiling price of Cholecalciferol (Vitamin D3) 60000 IU tablet at Rs. 22.50/tablet and Cholecalciferol (Vitamin D3) 60000 IU capsule at Rs. 27.40/capsule.

7. Agenda Item no. 7: Guidelines regarding discontinuation of scheduled formulations under para 21(2) of DPCO, 2013.

7.1 Paragraph 21 of the Drugs (Prices Control) Order, 2013 provides for monitoring the availability of scheduled formulations. In this regard, manufacturers of scheduled formulations and the active pharmaceutical ingredients contained in the scheduled formulations are required to furnish

the information in respect of production and sales data of such drugs in Form-III as stipulated in paragraph 21(1) of this order on quarterly basis.

7.2 Paragraph 21(2) of the DPCO, 2013 provides that any manufacturer of scheduled formulation, intending to discontinue any scheduled formulation from the market shall issue a public notice and also intimate the Government in Form-IV of this order in this regard at least six months prior to the intended date of discontinuation and the Government may, in public interest, direct the manufacturer of the scheduled formulation to continue with required level of production or import for a period not exceeding one year, from the intended date of such discontinuation within a period of sixty days of receipt of such intimation. A copy of the draft public notice is attached.

7.3 Form IV applications received earlier were processed and finalized for granting permission under para 21 (2) of DPCO, 2013 considering the details as available with NPPA such as number of market players, usage of the drug, market share/sales data of the company etc. In a few cases, permission for discontinuation of the product was granted where number of market players was found to be ten or more and the market share of the applicant company was one percent or below. In few cases, where market share was more than one percent, the respective companies were advised to lower the production / import and sales over a period of next twelve months, in order to ensure gradual substitution by other brands and also to avoid any shortage in the market.

7.4 Taking the above into consideration, the Authority approved the internal guidelines to dispose of Form-IV applications of discontinuation of production/import of scheduled formulations under paragraph 21 (2) of the DPCO, 2013 for issuance of "no objection certificate" by the NPPA as per the following:

7.4.1 No objection will be granted by the NPPA without referring the cases to the Authority for gradual discontinuation and the applicant company will be advised within a period of 60 days from the receipt of Form-IV to continue to manufacture / import and sell the drug for a period of minimum six months from the intended date of discontinuation, wherever MAT (in units) of the applicant company is upto ten percent. The company should not reduce level of production by more than 40% (of last year's production in each quarter) after getting permission from NPPA. During this period the company shall follow the ceiling price fixed by the NPPA and notified from time to time. The company intending to discontinue the scheduled formulation from the market shall also issue a public notice in the attached format in atleast two national newspapers (one in English and one in Hindi newspaper).

7.4.2 In cases where Form-IV application is received for a formulation which is legally banned, "no objection" will be issued by the NPPA after being satisfied in this regard without referring the cases to the Authority.

7.4.3 No objection will be granted by the NPPA for gradual discontinuation and the applicant company will be advised within a period of 60 days from the receipt of Form-IV to continue to manufacture / import and to sell the drug for a period of minimum nine months from the intended date of discontinuation, wherever MAT (in units) of the applicant company is more than ten percent but less than twenty five percent subject to approval of the Authority. The company should not reduce level of production by more than 40% (of last year production in each quarter) after getting permission from NPPA. During this period the company shall follow the ceiling price fixed by the NPPA and notified from time to time. The company intending to discontinue the scheduled formulation from the market shall also issue a public notice in the attached format in atleast two national newspapers (one in English and one in Hindi newspaper).

7.4.4 No objection will be granted by the NPPA for gradual discontinuation and the applicant company may be advised within a period of 60 days from the receipt of Form-IV to continue to manufacture/import and to sell the drug for a period of twelve months from the intended date of

discontinuation, wherever MAT (in units) of the applicant company is more than twenty five percent subject to approval of the Authority, if no other issues are involved.

7.4.5 In exceptional circumstances like where the manufacturer under consideration has more than 50% of share and other, the cases will be examined on case-to-case basis and decided on merits, subject to approval of the Authority. NPPA will also explore the possibility of alternative arrangements to supplement the production gap likely to be caused by such withdrawl by referring the matter to DoP to request the Government PSU's to produce such drug. NPPA may also consider an upwards price revision under Para 19 if the drug is being discontinued because of non-remunerative pricing. The company in any case, should not reduce level of production by more than 40% (of last year's production in each quarter) after getting permission from NPPA. During this period the company shall follow the ceiling price fixed by the NPPA and notified from time to time. The company intending to discontinue the scheduled formulation from the market shall also issue a public notice in the attached format in atleast two national newspapers (one in English and one in Hindi newspaper).

7.4.6 Authority observed that in some of the discontinuation cases, the manufacturers had not followed the ceiling price. It was decided that NPPA shall follow up all such cases on priority and recover the overcharged amount, if any, within a period of three months.

8. Agenda Item no. 8: Agenda note in respect of discontinuation of Prednisolone Acetate 1% ophthalmic suspension under para 21(2) of DPCO, 2013 by M/s. Alcon Lab. Ltd.

8.1 The company applied for discontinuation of product from September 2016 vide its application dated 18.3.2016.

8.2 As per the pharmatrac data, company was having 63.1% and 61.5% market share during Feb. 2016 and March, 2016 calculated at MAT volume basis.

8.3 Allowing the company to discontinue the product, will/may create shortage of medicine in the country. Hence, the Authority decided to direct company to continue production for one year from the intended date of discontinuation (September, 2016). However, before allowing discontinuation of this product, the company has to inform details regarding substitutes of the formulation available in the market and how the vacuum created by allowing discontinuation of this formulation will be fulfilled.

8.4 As there are only 2-3 more manufacturers of this formulation having more than 1% market share (MAT volume) in the market as of today, the Authority decided to request Department of Pharmaceuticals to direct Pharma PSUs to manufacture this formulation, to cover any unanticipated shortage of this medicine.

9. Agenda Item no. 9: A note in respect of discontinuation of (i) Taxol 30mg/5ml vial (Paclitaxel) (ii) Taxol 100mg/16.7ml vial, (iii) Baraclude 0.5mg tablet (Entecavir) and (iv) Baraclude 1mg tablet under para 21(2) of DPCO, 2013 by M/s. Birstol Mayer Squibb India Pvt. Ltd.

9.1 The company applied for discontinuation of product from December 2016 vide its application dated 13.6.2016.

9.2 As per Pharmatrac data, the market share of these formulations is observed as below, calculated on MAT volume basis.

No	Name of formulation	% MAT Volume-June-2016	% MAT Volume-May-2016
1	TAXOL 30mg/5ml	6.23	5.86
2	TAXOL 100mg/16.7ml	7.61	5.99
3	Baraclude 0.5mg tablet	8.63	9.41
4	Baraclude 1.0 mg tablet	8.01	8.14

9.3 As the company has market share of less than 10% in all 4 cases, and as there are many other formulations of same composition manufactured by different manufacturers available in market. The Authority decided to ask the company to continue to manufacture/ import and sell the drug for a period of six months from the intended date of discontinuation. The company will be asked not to reduce the level of production by more than 40% of last year's production in each quarter. The company will also be asked to issue a public notice in this regard in prescribed format, in at least two national newspapers. During this period, the company shall follow the ceiling price fixed by NPPA and notified from time to time.

10. Agenda Item no. 10: A note in respect of discontinuation of Alphadopa 500mg tablet under para 21(2) of DPCO, 2013 by M/s. Wockhardt Ltd.

10.1 It is observed that the formulation is a monopoly product having 100% market share. Allowing the company to discontinue the product, will definitely create shortage of medicine in the country. Hence, the Authority decided to direct the company to continue production for one year from the intended date of discontinuation (September, 2016). However, before allowing discontinuation of this product, the Authority decided to call for details from the company regarding substitutes of the formulation available in the market and how the vacuum created by allowing discontinuation of this formulation will be fulfilled. The Authority also decided to seek clarification from the company as to why it launched a product with a similar brand name (Alphadopa-L), but which has entirely different composition (Labetalol).

10.2 As there are no other manufacturers/marketers of Methyldopa 500mg tablet, in the market as of today, the Authority decided to request the Department of Pharmaceuticals to direct Pharma PSUs to manufacture this formulation. The Authority also noted that IDPL was manufacturing this formulation till a few years back.

10.3 The Authority further observed that M/s Wockhardt has also filed a review application with respect to the price fixation done for this formulation. The application is pending with DOP.

11. Agenda Item no. 11: Status of Review orders issued by DOP which are pending with NPPA for implementation.

11.1 Noted.

12. **Approval of revised 'Overpricing guidelines'.**

12.1 Draft was circulated and the members were requested to send their comments if any, within 10 working days. Guidelines will stand deemed to be adopted if no comments received.

13. The meeting ended with a vote of thanks to the Chair.

(Dr. Sharmila Mary Joseph K)
Member Secretary