

मिसिलस.- 8(26)/2016/डी.पी./एनपीपीए- डीवी-II

F. No. 8(26)/2016/DP/NPPA-Div. II

कार्यवाहीस. : 158/26/2016/F

Proceeding No : 158/26/2016/F

Minutes of the 158th and 26th meeting of Authority under DPCO, 2013 held on 24.02.2016 at 12.30 PM.

I. 1. The 158th overall meeting of the Authority, which is the 26th under the DPCO, 2013 was held on 24th February, 2016 at 12.30 PM 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) 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 R. Chandrashekar, 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)
- (iii) Shri A.K. Khurana, Director (Pricing & Admn.)
- (iv) Shri A.P.S. Sawhney, Director (Overcharging)
- (v) Shri Baljit Singh, Asstt. Director (Pricing/Legal)
- (vi) Shri Suneel Chopra, Pr. Legal Consultant

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 25th Meeting held on 29.10.2015.

Since no comments were received on the minutes of 157th and the 25th Meeting under DPCO, 2013, the Authority confirmed the minutes of the meeting.

2. Agenda Item no. 2: Action Taken Report

Noted.

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

3.1 The Authority in the light of the fact that the price fixation of several formulations in NLEM 2011 is pending since long because of non-availability of data and these drugs being essential drugs, discussed and deferred the proposal in the light of its earlier decision in the 150th overall meeting (i.e. 18th meeting under DPCO, 2013 held on 15. 9.2014) and the DoP's various communications on the issue of exercising restraint in resorting to powers under Paragraph 19 and also the fact that these formulations are not being retailed in any significant manner. Since these formulations are included in the NLEM, 2015 and fixing of prices two times in a short span of time will not be advisable, it was decided to revisit the issue under new NLEM after exploring the new market data.

4. Agenda Item no. 4: Revision of ceiling prices of Scheduled formulations based on Wholesale Price Index (WPI) of 2015 over 2014 as per provisions of DPCO, 2013.

4.1 The Authority members noted and approved the same.

5 Agenda Item no. 5: Review order of DOP on the application of M/s Ranbaxy Laboratories Limited (now M/s Sun Pharmaceutical Industries Ltd.) for fixation/revision of retail prices of Histac EVT tablet (2's) and Fucibet cream 15gm tube.

5.1 The Authority discussed in detail and taking into account the DOP orders in the review application, approved the following revised non-ceiling/retail prices as Rs. 3.68(excluding Excise Duty & Sales tax/Local tax/VAT, if any) for Histac EVT Tablet (2's) and Rs. 46.22(excluding Excise Duty & Sales tax/Local tax/VAT, if any) for Fucibet Cream 15 gm tube, under DPCO, 1995. Since the exercise was done under provisions of DPCO, 1995, WPI was not taken into consideration.

6. Agenda Item no. 6: Review order of DOP and Representation of M/s Bharat Serums and Vaccines Limited against S.O. 3371(E) and 3372 (E) dated 05.11.2013 for pricing of Antitetanus Human Immunoglobulin Injection 250 IU/pack and 500 IU/pack.

6.1 The Authority discussed in detail and taking into account the orders of DOP in the review application, approved the revised ceiling price as

(a) Rs. 1043.13/pack and Rs. 1014.86/pack (w.e.f. 01.4.2016 including WPI of 2015) for Antitetanus Human Immunoglobulin Injection 250 IU/pack, and

(b) Rs. 1738.93/pack and Rs. 1691.80/pack (w.e.f. 01.4.2016 including WPI of 2015) for Antitetanus Human Immunoglobulin Injection 500 IU/pack.

7. Agenda Item no. 7: Review order of DOP on the review application filed by M/s Torrent Pharmaceuticals Ltd in respect of New Drug "Nab Tortaxel" having Paclitaxel 100 mg and Human Albumin IP QS in each vial.

7.1 The Authority discussed the proposal in detail and taking into account the orders of DOP in the review application, approved the claimed retail price of the company i.e. Rs. 11590.00 per vial in the light of DOP's orders in the review petition.

8. Agenda Item no. 8: Ceiling Price revision of Phenobarbitone Syrup 20mg/5ml & Tablet 30mg on the representation filed by M/s Abbott Healthcare Pvt. Ltd.

8.1 The Authority discussed the proposal in detail and approved the revised ceiling price as under:

(a) Rs. 0.56/ml and Rs. 0.54/ml (w.e.f. 01.4.2016 including WPI of 2015) for Fenobarbitone syrup 20mg/5ml, and

(b) Rs. 1.63/tablet and Rs. 1.59/tablet (w.e.f. 01.4.2016 including WPI of 2015) for Phenobarbitone tablet 30mg.

9. Agenda Item no. 9: Fixation of retail price in respect of the following new drugs under para 5 of DPCO, 2013.

9.1 The Authority discussed cases of retail price fixation of following 11 new drugs and approved the proposal as per para 5 of the DPCO 2013:

S. No. in agenda	Company name/Product name	Approved Retail Price (Rs.)
9(i)	M/s Innova Captab (Manufacturer) and M/s Gem Mankind (Marketing company)- Pantoprazole sodium eq. to Pantoprazole 40mg- (Mahapanta 40 tablet) .	Rs. 5.56 per tablet
9 (ii)	M/s Apex Lab. Pvt. Ltd. (Manufacturer as well as Marketing company) – Paracetamol Paediatric Oral suspension- Paracetamol 50mg.	Rs. 0.94per ml
9 (iii)	M/s Pharma Force Lab. (Manufacturer) and M/s Gem Mankind (Marketing company)-Amlodipine besilate eq. to amlodipine 5mg, Atenolol 50mg- (Atnoblok-AM tablet) .	Rs. 3.62per tablet
9 (iv)	M/s Scott Edil Pharmacia (Manufacturer) and M/s Gem Mankind (Marketing company) – Each 2ml vial contains- Amikacin sulphate eq. to Amikacin 500mg, Methyl Paraben 0.08% w/v (as preservative), Propyl Paraben 0.02% w/v (as preservative), Water for injection- (Mikagem-500 injection) .	Rs. 54.87 for each pack
9 (v)	M/s Scott Edil Pharmacia (Manufacturer) and M/s Gem Mankind (Marketing company) – Each 2ml vial contains- Amikacin sulphate eq. to Amikacin 100mg, Methyl Paraben 0.08% w/v (as preservative), Propyl Paraben 0.02% w/v (as preservative), Water for injection- (Mikagem-100 injection) .	Rs. 15.98 for each pack
9 (vi)	M/s Embiotic Lab. Pvt. Ltd. (Manufacturer as well as Marketing company) - Linseed Oil 3% w/w, Diclofenac Diethylamine 1.16% w/w eq. to Diclofenac Sodium 1% w/w, Methyl Salicylate 10% w/w and Menthol 5% w/w Gel.	Rs. 2.11 per gm
9 (vii)	M/s Apex Lab. Pvt. Ltd. (Manufacturer as well as marketing company) – Diclofenac Diethylamine 1.16% w/w eq. to Diclofenac Sodium 1% w/w, Linseed Oil 3% w/w, Methyl Salicylate 10% w/w and Menthol 5% w/w Gel.	Rs. 2.11per gm
9 (viii)	M/s Cadila Healthcare Ltd. (Manufacturer as well as Marketing company) – Methylprednisolone 8mg tablet - (Depotex 8 tablet) .	Rs. 4.78 per tablet
9 (ix)	M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) and M/s Abbott Healthcare Pvt. Ltd. (Marketing company) – Propranolol HCl 80mg SR- (Inderal LA 80mg tablet) .	Rs. 4.81per tablet
9 (x)	M/s Scott Edil Advance Research Lab. & Education Ltd. (Manufacturer) and M/s Gem Mankind (Marketing company) Amoxicillin Trihydrate eq. to Amoxicilline 250mg, Dicloxacillin Sodium eq. to Dicloxacillin 250mg- (Mahamox Plus Capsules) .	Rs. 5.21 per capsule
9 (xi)	M/s J.B. Chemicals & Pharmaceuticals Ltd. (Manufacturer as well as Marketing company)- Paracetamol Infusion - Paracetamol 10mg- (Ifimol IV 100ml Infusion I.V.) .	Rs. 2.06 per ml

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10. Agenda Item no. 10: Fixation of retail price of following new drugs:

The Authority discussed cases of retail price fixation of following 5 new drugs where retail price claimed by the company was less than the worked out retail price. The claimed retail price, being lower was approved for the following 5 formulations:

S. No. in agenda	Company name/Product name	Approved Retail Price (Rs.)
10 (i)	M/s Innova Captab (Manufacturer) and M/s Gem Mankind (Marketing company)- Atorvastatin Calcium eq. to Atorvastatin 20mg- (Atorvakind 20 tablet) .	Rs. 11.00 per tablet
10 (ii)	M/s Mankind Pharma (Manufacturer) and M/s Gem Mankind (Marketing company)-Atorvastatin Calcium eq. to Atorvastatin 20mg- (Atorvakind 20 tablet) .	Rs. 11.00 per tablet
10 (iii)	M/s Cadila Pharmaceuticals Ltd. (Manufacturer as well as Marketing company) - Losartan Potassium 50mg, Chlorthalidone 6.25mg tablet.	Rs. 4.50 per tablet
10 (iv)	M/s Floreat Medica Pvt. Ltd. (Manufacturer) and M/s Indu Drugs Pvt. Ltd. (Marketing company)-Olmesartan Medoxomil 40mg, Hydrochlorothiazide 12.5mg- (Oliminorm-H tablet) .	Rs. 12.60 per tablet
10 (v)	M/s Jagsonpal Pharmaceuticals Ltd. (Manufacturer as well as Marketing company) -Tramadol HCl 100mg (in a controlled release system)- (Caybutl SR tablet) .	Rs. 12.00 per tablet

11. Agenda Item no. 11: Fixation of retail price in respect of following 7 new drugs:

The Authority discussed cases of retail price fixation of following 7 new drugs and approved the proposal under Para 5 of DPCO, 2013. In these cases, the lowest price – among the prices claimed by the company, 'worked out' retail price or retail price fixed for the same formulation in the last one year was approved.

S. No. in agenda	Company name/Product name	Approved Retail Price (Rs.)
11 (i)	M/s Innova Captab Pvt. Ltd. (Manufacturer) and M/s Galpha Lab. Ltd. (Marketing company) - Cefixime 200mg, Ofloxacin 200mg – (ODICEF OF tablet) .	Rs.9.86 per tablet
11 (ii)	M/s Apex Lab. Pvt. Ltd. (Manufacturer as well as Marketing company) –Clobetasol Propionate 0.05% w/w, Neomycin Sulphate 0.5% w/w, Miconazole Nitrate 2.00% w/w cream.	Rs. 2.27 per gm
11 (iii)	M/s Cadila Pharmaceuticals Ltd. (Manufacturer as well as Marketing company) – Azithromycin Oral Suspension 200mg/5ml- Azithromycin 200mg/5ml.	Rs. 2.68 per ml
11 (iv)	M/s Indoco Remedies Ltd. (Manufacturer as well as Marketing company)- Azithromycin (as dihydrate) eq. to Azithromycin anhydrous 40mg- (ATM Junior Suspension) .	Rs. 2.68 per ml
11 (v)	M/s Windlas Biotech Limited (Manufacturer) and M/s Glenmark Pharmaceuticals Ltd. (Manufacturer)- Glimpiride IP 1.0mg, Voglibose IP 0.2mg, Metformin Hydrochloride IP 500mg (as sustained release form)- (XMET- Trio 500/0.2/1 tablet) .	Rs. 71.43 for 10 tablets
11(vi)	M/s Windlas Biotech Limited (Manufacturer) and M/s Glenmark Pharmaceuticals Ltd. (Manufacturer)- Glimpiride IP 2.0mg, Voglibose IP 0.2mg, Metformin Hydrochloride IP 500mg (as sustained release form)- (XMET- Trio 500/0.2/2 tablet) .	Rs. 90.48 for 10 tablets

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11 (vii)	M/s Theon Pharmaceuticals Ltd. (Manufacturer) and M/s Abbott Healthcare Pvt. Ltd. (Marketing company)- Pantoprazole sodium sesquihydrate eq. to Pantoprazole (as enteric coated pellets) – 40mg, Levosulpiride (as sustained release pellets) – 75mg- (NICOPENTA LSR capsule)	Rs. 8.00 per capsule
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12. Agenda Item no. 12: Fixation of retail price in respect of the following 11 monopoly cases:

The Authority discussed cases of retail price fixation of following 9 new drugs under Para 5 of DPCO, 2013. The Authority observed that these cases were monopoly cases. The Authority applied the principle decided in respect of such cases at the 23rd Authority meeting (held on 13.7.2015), where the PTR of the single manufacturer could be fixed for the new drug and 16% retailer margin added to arrive at the retail price. Accordingly, the retail price of the following new drugs was approved as follows:

S. No. in agenda	Company name/Product name	Approved Retail Price (Rs.)
12 (i)	M/s Apex Lab. Pvt. Ltd. (Manufacturer as well as Marketing company)-Halobetasol Propionate 0.05% w/w, Salicylic Acid 6% w/w ointment.	Rs. 9.99 per gm
12 (ii)	M/s Kemwell Biopharma Pvt. Ltd. (Manufacturer) and M/s Boehringer Ingelheim India Pvt. Ltd. (Marketing company)-Hyoscine Butyl Bromide 10mg, Paracetamol 325mg – (Buscogast Plus Tablet).	Rs. 3.76 per tablet
12 (iii)	M/s Nu Therapeutics Pvt. Ltd. (Manufacturer) and M/s Leads Pharma (Marketing company)- Ondansetron Orally Disintegrating Strips 4 mg.	Rs. 9.11 per strip
12 (iv)	M/s Nu Therapeutic Pvt. Ltd. (Manufacturer) and M/s Delvin Formulation Pvt. Ltd. (Marketing company) – Ondansetron Orally Disintegrating Strips 4 mg.	Rs. 9.11 per strip
12 (v)	M/s Nu Therapeutics Pvt. Ltd. (Manufacturer) and M/s Mankind Pharma Ltd. (Marketing company) – Ondansetron Orally Disintegrating Strips 4 mg.	Rs. 9.11 per strip
12 (vi)	M/s Nu Therapeutics Pvt. Ltd. (Manufacturer as well as Marketing company) – Ondansetron Orally Disintegrating Strips 4 mg.	Rs. 9.11 per strip
12 (vii)	M/s Zim Lab. Ltd. (Manufacturer as well as marketing company) – Ondansetron Orally Disintegrating Strips 4 mg.	Rs. 9.11 per strip
12 (viii)	M/s Nu Therapeutics Pvt. Ltd. (Manufacturer) and M/s Mankind Pharma Ltd. (Marketing company) – Ondansetron Orally Disintegrating Strips 8 mg.	Rs. 14.14 per strip
12 (ix)	M/s Nu Therapeutics Pvt. Ltd. (Manufacturer as well as Marketing company) – Ondansetron Orally Disintegrating Strips 8 mg.	Rs. 14.14 per strip

13. Agenda Item no. 13: Retail Price fixation of new drug on the basis of recommendation of Standing Committee of Experts under Para 15 of the DPCO 2013.

The Authority discussed such cases of retail price fixation of following 6 new drugs, where the retail prices were proposed by the Standing Committee of Experts under applying the principles of pharmacoeconomics. The retail prices of the following 6 drugs have been approved as follows:

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S. No.	Company name/Product name	Approved Price (Rs.)
1	Meganeuron Forte Injection (Each 2ml contains Mecobalamin 1000mcg, Pyridoxine HCL 100mg, Nicotinamide 100mg, D-Panthenol 50mg, Benzyl Alcohol (as preservative) 0.9% and Water for injection of M/s Aristo Pharmaceuticals Pvt. Ltd.(Manufacturer as well as Marketing company).	Rs. 26.50 for Each Pack
2	Lipid based Amphotericin B Gel 0.1% tube (Each gm contains Amphotericin B 1mg) of M/s Intas Pharmaceuticals Limited (Manufacturer as well as Marketing company).	Rs. 200 for 15g Tube
3	Tablets containing Diclofenac Pottasium 50mg and Chlorzoxazone 500mg of M/s Windlas Biotech Limited (Manufacturer) and M/s Magnet Labs Pvt. Ltd. (Marketing company).	Rs. 6.50 per tablet
4	3ml Vial of Azithromycin and Dexamethosone Phosphate Eye Drops, each ml containing Azithromycin Dihydrate 10mg/ml, Dexamethasone Sodium Phosphate 1mg/ml, Benzalkonium chloride (0.01%W/v) of M/s Ajanta Pharma Ltd. (Manufacturer as well as Marketing company).	Rs. 76.02 Each Pack
5	Tablets SUDIN cold Tablets each uncoated tablet containing Paracetamol 500mg, Phenylephrine HCL 5mg, Caffeine (anhydrous) 30mg and Diphenhydramine HCL 25mg of M/s Embiotic Laboratories Ltd. (Manufacturer) and M/s Group Pharmaceuticals (P) Ltd. (Marketing company).	Rs. 3.30 per tablet
6	Extended Release Tablet containing Teneligliptin Hydrobromide Hydrate equivalent to Teneligliptin 20mg and Metformin Hydrochloride 500mg of M/s Glenmark Pharmaceuticals Ltd. (Manufacturer as well as Marketing company).	Rs. 17.61 per tablet

14. Agenda Item no. 14:

(i) Withdrawal of notification of S.O. 2947(E) dated 29.10.2015, relating to retail price fixation of Moxifloxacin+Prednisolone Acetate Ophthalmic Solution for 1ml, manufactured by M/s Akums Drugs & Pharmaceuticals Ltd. and marketed by M/s Entod Pharmaceuticals Ltd.

(ii) Withdrawal notification of S.O. 1892(E) dated 13.7.2015, relating to retail price fixation of Clopidogrel + Atorvastatin + Aspirin Capsule (Deplatt CV 20 Forte) for 1 Capsule, manufactured by M/s Surein Pharmaceuticals Pvt. Ltd. and Marketed by M/s Torrent Pharmaceuticals Ltd.

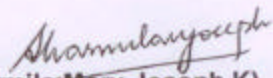
14.1 The Authority members noted and approved the same.

15. Agenda Item no. 15: Checklist of the documents to be attached along with Form-I application for retail price fixation of 'new drug' under Para 5 of DPCO, 2013.

15.1 The Authority, taking into consideration the DOP's communication dated 29.01.2016 conveying the advice of the Ministry of Law that NPPA cannot insist on asking the companies some information beyond the existing provisions of Drugs and Cosmetics Act, 1940 and also the

views of DCG(I) representative on the fact that NPPA's concerns about issues like 'contract manufacturing', 'accountability about quality of drugs' and 'asymmetry of information in labeling' and 'variable pricing' of drugs are being taken care of either by the existing provisions of law or is to be taken care of by the proposed amendment in Drugs and Cosmetics Act, discussed the issue in detail and approved an amended checklist of the documents. Authority also discussed and realized the fact that even if the companies produce the copy of the license jointly endorsed as manufacturer and marketer, such licenses are against the provisions of Drugs and Cosmetics Act, 1940 and the accountability of the marketing company by such joint endorsement is not established. In revising the checklist, the Authority also took a note of the fact that by rejecting applications for price approval of new drugs because of non-production of jointly endorsed licenses, the NPPA, in spite of all its best intentions in the interest of consumers, is left with a situation where large number of such cases have been approved in the past and the new applicants are holding NPPA accountable for discrimination and discouraging competition. Industry associations have already raised this issue at various fora.

15.2 The Authority, however, in the interest of checking the growth of irrational FDCs, decided to seek clarification from the DCG(I) whether 'new drug' applications which were rejected by the NPPA earlier and also the future applications which are allowed to be manufactured and marketed in India are not treated as irrational FDCs.


(Dr. Sharmila Mary Joseph K)
Member Secretary