गोपनीय: Confidential

मिसिल स.- 8(23)/2015/डी.पी./एनपीपीए- डीवी-II

F. No. 8(23)/2015/DP/NPPA-Div. II

कार्यवाहीस. : 155/23/2015/F
Proceeding No : 155/23/2015/F

Minutes of the 155th and 23rd meeting of Authority under DPCO, 2013 held on 13th July, 2015 at 12.00 Noon.

The 155th overall meeting of the Authority, which is the 23rd under the DPCO, 2013 was held on 13th July, 2015 at 12.00 Noon 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 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 Jagdish Kumar, Director (M&E)
(iii) Shri A.K. Khurana, Director (Pricing & Admn.)
(iv) Shri A.P.S. Sawhney, Director (Overcharging)
(v) Shri Suneel Chopra, Dy. Director (Legal)
(vi) Shri Naresh Arya, Dy. Director (Pricing)
(vii) Shri Rakesh Kakkar, Dy. Director (OC-I)
(viii) Shri Anand Prakash, Dy. Director (M&E)
(ix) Shri S.S. Agrawal, Asstt. Director (M&E)
(x) Smt. Babita Singh, Asstt. Director (M&E)
(xi) Shri T.R. Sathish Chandran, Asstt. Director (OC-II)

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(xii) Shri Baljeet Singh, Asstt. Director (M&E)

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

1. Agenda Item no. 1: Confirmation of Minutes of the 22nd Meeting held on 06.5.2015.

Members of the Authority who participated in the 154th overall and the 22nd Meeting under DPCO, 2013 confirmed the minutes of the meeting.

2. Agenda Item no. 2: Action Taken Report

Noted.

3. Agenda Item no. 3: Review order of DOP for Ceiling Price notification of Ciprofloxacin Hydrochloride Tablets 250mg issued vide S.O. 2352 (E) dated 15.9.2014 in case of M/s Zydus Healthcare Limited.

3.1 After receipt of DOP's review order, NPPA placed an O.M. dated 20.02.2015 requesting the concerned manufacturing/marketing companies to provide the data in respect of the subject formulation. The ceiling price has been re-worked out on the basis of PTRs duly supported with invoices received from M/s Zydus Healthcare Limited and M/s Zuventus Healthcare. The Authority discussed the proposal of price revision in detail and approved the revised ceiling price at Rs. 2.33/tablet.

4 Agenda Item no. 4: Review order of DOP for Ceiling Price notification of Cefotaxime 250mg and 500mg Injection issued vide S.O. 2350(E) dated 15.9.2014 in case of M/s Alkem Laboratories Limited.

4.1 After receipt of DOP's review order, NPPA placed an O.M. dated 20.02.2015 requesting the concerned manufacturing/marketing companies to provide the data in respect of the subject formulation. The ceiling price has been re-worked out on the basis of PTRs duly supported with invoices received from M/s Alkem, M/s Zuventus and M/s Emcure. The Authority discussed the proposal of price revision in detail and approved the revised ceiling price at Rs. 16.19/each pack for Cefotaxime 250mg and Rs. 21.12/each pack for Cefotaxime 500mg Injection.

5 Agenda Item no. 5: Review order of DOP for Retail Price notification of Bisoprolol Fumarate 5mg + Amlodipine 5mg tablet issued vide S.O. 2104(E) dated 20.8.2014 in case of M/s Mankind Pharma Ltd.

5.1 The price fixation was carried out by NPPA by considering the data of M/s USV Limited only under monopoly situation since M/s Merck had submitted incorrect information. After receipt of DOP's review order, NPPA placed an O.M. dated 16.02.2015 requesting the concerned manufacturing/marketing companies to provide data in respect of the subject formulation. M/s Merck was also requested to provide the correct information and the Company provided the information after two reminders. The

retail price has been re-worked out on the basis of PTRs duly supported with invoices received from M/s Merck. The Authority discussed the proposal of price revision in detail and approved the revised retail price at Rs. 7.28/tablet.

6. **Agenda Item no. 6: Review order of DOP for Retail Price notification of Metformin 500mg+Gliclazide 60mg+Pioglitazone HCL eq. to Pioglitazone 7.5mg tablet issued vide S.O. 2101(E) dated 20.8.2014 in case of M/s Micro Labs Ltd.**

6.1 The price fixation exercise was carried out by NPPA by considering the data of M/s Panacea Biotec only under monopoly situation. After receipt of DOP's review order, NPPA placed an O.M. dated 23.12.2014 requesting the concerned manufacturing/ marketing companies to provide data in respect of the subject formulation. It was found that the subject formulation was manufactured by M/s Inventia Healthcare and marketed by M/s Panacea Biotec as well as M/s IPCA Labs. The 19th Authority Meeting had taken an in-principle decision that where a manufacturer supplies to different marketing companies, the lower PTR of the manufacturer (for supply of formulation to any marketing company), is to be applied in price fixation for another applicant marketing company, instead of average formula. However, in this case, PTR of both the companies (i.e. M/s IPCA and M/s Panacea Biotec supplied by M/s Inventia) is same. Thus, both methodologies result in the same retail price. The Authority discussed the proposal of price revision in detail and approved the revised retail price at Rs. 6.25/tablet.

6.2 In this context, the Authority was also informed that a reference was received from the Prime Minister's Office (PMO) to devise a mechanism to check the exorbitant trade margins allowed by the Pharma Companies.

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

7.1 The Authority discussed the cases of retail price fixation of 33 new drugs in the light of decisions taken in respect of approval/permission required from DCG(I)/SDCs.

7.2 The Authority reiterated that the provisions of para 6 of DPCO, 2013 relate to ceiling price of a scheduled formulation, in case of no reduction in price due to absence of competition. This issue was discussed in the 17th Authority meeting and approval was obtained to apply provisions of para 6 in case of New Drugs also. This would help in timely fixation of retail price of new drugs in cases where data/reply from only one company is available. Now, the Authority after detailed deliberations decided that the retail prices of New Drugs may not be fixed by applying Para 6(1) in case of existence of only one manufacturer. Henceforth, the methodology in such monopoly cases is to be adopted as under:-

(i) The PTR of a single manufacturer may be extended to the applicant of new drug in order to encourage competition and curtail monopoly. The retailer margin of 16% will be added to arrive at the retail price.

(ii) If the applicant company's claimed retail price is lower than the thus worked out retail price, then the claimed retail price will be approved.

(iii) The onus of furnishing the details of competitors lies with the applicant company.

(iv) This methodology is to be applied prospectively across the board.

On the basis of the above laid down principles, cases mentioned at S.No. 7. (xxxv) to (xliv) of the agenda, where prices have been proposed under monopoly situation, have been deferred and the Authority directed that these cases may be revisited in view of above said principles and be put up in the next meeting.

7.3 Application of M/s Akums Drugs & Pharmaceuticals (Manufacturer) and M/s Abbott Healthcare Pvt. Ltd. (Marketing company) for price fixation of the kit containing 1 Azithromycin 1gm + 1 Fluconazole 150mg and 2 Secnidazole 1gm Tablets – (Secnil Kit) mentioned at S.No. (xxii) was discussed in detail. The Authority was of the view that the kit contained three separate medicines and there was no added therapeutic advantage of such a kit. Moreover, there was no change in chemical composition. Further, the Kit did not conform to the definition of 'New Drug' as per Para 2(u) of DPCO, 2013 and Rule 122(E) of Drugs and Cosmetics Rules, 1945. The Authority, therefore, rejected this new drug application.

7.4 Accordingly, the retail prices for the following 33 formulations are fixed and approved as per para 5 of the DPCO, 2013, as under:

S. No.	Company name/Product name	Approved Retail Price (Rs.)
7(i)	M/s Pure & Cure Healthcare Pvt. Ltd. (Manufacturer) and M/s Dey's Medical Store (Mfg) Ltd. (Marketing company) – Glimepiride 2mg + Metformin HCl 500mg (Grid 2 M tablet).	4.50/Tab
7 (ii)	M/s Cadila Pharmaceuticals Ltd. (Manufacturer as well as Marketing company) – Chlorthalidone 12.50mg + Metoprolol tartrate 50mg (as extended release form) (Chlorthalidone 12.50mg + Metoprolol 50mg tablet).	7.22/Tab
7 (iii)	M/s Nu Therapeutics Pvt. Ltd. (Manufacturer) and M/s Cipla Ltd. (Marketing company) – Ondansetron HCl eq. to Ondansetron 4mg – (Ondansetron HCl 4mg Orally Disintegrating Strip-Emeset Fast 4mg).	5.56/Strip
7 (iv)	M/s Nu Therapeutics Pvt. Ltd. (Manufacturer) and M/s Cipla Ltd. (Marketing company) – Ondansetron HCl eq. to Ondansetron 8mg – (Ondansetron HCl 8mg Orally Disintegrating Strip-Emeset Fast 8mg).	12.61/Strip
7 (v)	M/s Mankind Pharma Ltd. (Manufacturer as well as Marketing company) – Azithromycin dehydrate eq. to Azithromycin anhydrous 200mg – (Azithromycin Oral Suspension)	2.68/ml
7 (vi)	M/s Ravian Lifescience Pvt. Ltd. (Manufacturer) and M/s Zuventus Helathcre Ltd. (Marketing company) – Paracetamol 250mg (Koolpara DS suspension).	26.50/60ml bottle
7 (vii)	M/s Akums Drugs & Phrmaceuticals Ltd. Manufacturer) and M/s Abbott Healthcare Pvt. Ltd. (Marketing company) – Cefixime Trihydrate eq. to Cefixime Anhydrous 400mg + Ofloxacin 400mg (Zimnic O 400 SR tablet).	16.75/Tab
7 (viii)	M/s Surein Pharmaceuticals Pvt. Ltd. (Manufacturer) and Torrent Pharmaceuticals Ltd. (Marketing company) – Clopidogrel 75mg + Atorvastatin calcium 20mg + Aspirin 150mg (Deplatt CV 20 Forte capsule).	7.00/Capsule
7 (ix)	M/s Windlas Biotech Ltd. (Manufacturer) and Life Star Pharma Pvt. Ltd. (Marketing company) – Diclofenac Potassium 50mg + Metaxalone 400mg (Diclofenac Potassium & Metaxalone	9.12/Tab

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	tablet).	
7 (x)	M/s Ranvenbhel Healthcare Pvt. Ltd. (Manufacturer) and M/s FDC Ltd. (Marketing company) – Metoprolol succinate 25mg + Telmisartan 40mg (ZITELMI M 25 tablet).	7.96/Tab
7 (xi)	M/s Ranvenbhel Healthcare Pvt. Ltd. (Manufacturer) and M/s FDC Ltd. (Marketing company) – Metoprolol succinate 50mg + Telmisartan 40mg (ZITELMI M 50 tablet).	9.59/Tab
7 (xii)	M/s Apex Labs. Pvt. Ltd. (Manufacturer as well as Marketing company) – Clobetasol Propionate 0.05% w/w + Salicylic Acid 6% w/w (Zincoderm- S 6% ointment).	3.27/gm
7 (xiii)	M/s Apex Labs. Pvt. Ltd. (Manufactuer as well as Marketing company) – Clobetasol Propionate 0.05% and Neomycin sulphate 0.5% w/w – (Zincoderm – N ointment).	3.00/gm
7 (xiv)	M/s Mepromax Lifescience Pvt. Ltd. (Manufacturer) and M/s Adcock Ingram Healthcare Pvt. Ltd. (Marketing copany) – Clobetasol Propionate 0.05% w/w + Neomycin Sulphate 0.5% w/w + Micronazole Nitrate 2.00% w/w and Chlorocresol (preservative) 0.1% w/w - (Rovate GM Neo Cream).	2.27/gm
7 (xv)	M/s Apex Labs. Pvt. Ltd. (Manufacturer as well as Marketing company) – Clobetasol Propionate 0.05% + Neomycin Sulphate 0.5% w/w and Miconazole Nitrate 2.00% w/w - (Zincoderm – NM cream).	2.27/gm
7 (xvi)	M/s All Kind Healthcare (Manufacturer) and M/s Leeford Healthcare Ltd. (Marketing copany) – Paracetamol 650mg - (Leemol – 650 tablet).	1.62/Tab
7 (xvii)	M/s Innova Cap Tab Pvt. Ltd. (Manufacturer) and M/s Zuventus Healthcare Ltd. (Marketing copany) – Ceftriazone 1000mg + Sulbactum socium 500mg & water for injection 10 ml - (Trusten S Injection).	98.69/Each Pack
7 (xviii)	M/s Galpha Labs. Ltd., (Manufacturer as well as Marketing company) – Ofloxacin 200mg + Ornidazole 500mg – (GALOXIN OZ tablet).	6.60/Tab
7 (xix)	M/s Indu Drugs Pvt. Ltd. (Manufacturer as well as Marketing company) – Ferrous Ascorbate 100mg + Folic Acid 1500mcg and Zinc Sulphate 22.5mg – (Fcount-XT).	6.47/Tab
7 (xx)	M/s Indu Drugs Pvt. Ltd. (Manufacturer) and M/s Regardia Pharmaceuticals (Marketing company) – Ferrous Ascorbate 100mg + Folic Acid 1500mcg and Zinc Sulphate 22.5mg - (SHIFER).	6.47/Tab
7 (xxi)	M/s Rusoma Labs. Pvt. Ltd. (Manufacturer as well as Marketing company) – Paracetamol 1gm – (Paracetamol Infusion 1% w/v).	2.10/ml
7 (xxiii)	M/s Sirmour Remedies Pvt. Ltd. (Manufacturer) and M/s Mankind Pharma Ltd. (Marketing company) – Domperidone 10mg – (Domperidone Oral Drops).	4.51/ml
7 (xxiv)	M/s Theon Pharmaceuticals Ltd. (Manufacturer) and M/s Blue Cross Labs. Pvt. Ltd. (Marketing company) – Pantoprazole sodium (as enteric coated tablet) – 40mg + Levosulpiride (as sustained release tablet) – 75mg (PPPI-L Capsule).	8.00/Tab
7 (xxv)	M/s All Kind Healthcare (Manufacturer) and M/s Leeford Healthcare Ltd. (Marketing company) – Ofloxacin 100mg- (OLTEF 100 suspension).	1.03/ml
7 (xxvi)	M/s Synokem Pharmaceuticlas Ltd. (Manufacturer) and M/s Zuventus Healthcare Ltd. (Marketing company) – Trypsin 48mg, Broelain 90mg, Rutoside trihydrate 100mg and Diclofenac sodium 50mg) - (Tribrolin D tablet).	13.82/Tab

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7 (xxvii)	M/s Akums Drugs & Pharmaceutials Ltd. (Manufacturer) and M/s Blue Cross Labs. Pvt. Ltd. (Marketing company) – Metformin HCl 500mg and Voglibose 0.2mg - (K-MET Duo 0.2 tablet).	4.40/Tab
7 (xxviii)	M/s Akums Drugs & Pharmaceutials Ltd. (Manufacturer) and M/s Blue Cross Labs. Pvt. Ltd. (Marketing company) – Metformin HCl 500mg and Voglibose 0.3mg- (K-MET Duo 0.3 tablet).	52.38/10's
7 (xxix)	M/s Theon Pharmaceuticals Ltd. (Manufacturer) and M/s Leeford Healthcare Ltd. (Marketing company) – Amoxycillin 875mg + Potassium Clavulanic Acid 125mg – (EVOXIL-CV DUOS tablet).	26.71/Tab
7 (xxx)	M/s Theon Pharmaceuticals Ltd. (Manufacturer) and M/s Abbott Healthcare Pvt. Ltd. (Marketing company) – Pantoprazole sodium sesquihydrate eq. to Pantoprazole 40mg (as entric coated pellets) and Domperidone 30mg (as sustained release pellets) – (NICOPENTA DSR capsule).	7.63/Cap
7 (xxxi)	M/s Oxalis Labs. (Manufacturer) and M/s Macleods Pharmaceuticals Ltd. (Marketing company) – Metformin HCl (as sustained release) - 500mg and Gliclazide 80mg tablet – (GCZ M 80 tablet).	4.63/Tab
7 (xxxii)	M/s Galpha Labs. Ltd. (Manufacturer as well as Marketing company) - Ofloxacin 50mg and Ornidazole 125mg – (Galoxin OZ suspension).	0.99/ml
7 (xxxiii)	M/s All Kind Healthcare (Manufacturer) and M/s Leeford Healthcare Ltd. (Marketing company) – Aciclovir 800mg – (ZOSTER 800 tablet).	22.00/Tab
7 (xxxiv)	M/s Embiotic Labs. Pvt. Ltd. (Manufacturer) and M/s Group Pharmaceuticals Ltd. (Marketing company) – Ferrous Ascorbate eq. to elemental Iron 100mg and Folic Acid 1.5mg – (HEMOGOLD-XT Tablet).	7.31/Tab

8. Agenda Item no. 8: Retail Price fixation of new drug on the basis of recommendations of the Standing Committee of Experts under Para 15 of the DPCO 2013- (a) Mannitol Injection 15% w/v, 100ml pack of M/s Rusoma Lab. Pvt. Ltd. (b) Mannitol Injection 15% w/v, 350ml pack of M/s Rusoma Lab. Pvt. Ltd. and for deliberations only:- Electral Z combi Kit of M/s FDC Ltd.

8.1 The Authority discussed the retail price fixation of 2 new drugs on the basis of the recommendations made by the Standing Committee of Experts under Para 15 of the DPCO, 2013 and approved the retail price of Rs. 26.25 for 100ml pack and Rs. 91.88 for 350ml pack of Mannitol Injection 15% of M/s Rusoma Labs. Pvt. Ltd.

8.2 The proposal of M/s FDC for retail price fixation of Electral Z combi Kit was also discussed in detail. The Authority was of the view that the kit contained two types of medicines placed separately. There was no added therapeutic advantage of such a kit. Moreover, there was no change in chemical composition. Further, the Kit did not conform to the definition of 'New Drug' as per Para 2(u) of DPCO, 2013 and Rule 122(E) of Drugs and Cosmetics Rules, 1945. The Authority, therefore, rejected this new drug application.

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9. Agenda Item no. 9: Discontinuation of eight scheduled formulations by M/s Astrazeneca Pharma as per para 21(2) of DPCO, 2013.

9.1 The Authority discussed the agenda note circulated in respect of discontinuation of eight scheduled formulations of M/s Astrazeneca Pharma under para 21(2) of DPCO, 2013. The Authority noted that the company is a dominant player in the market with substantial market share for the formulations listed at S.No. 1 to 7 in the agenda. Also, there were not many market players for these formulations used as local anesthetics. The Authority further noted that the major reason for discontinuation as indicated by the company relate to quality of API and compliance deficiencies observed by their Global Audit team. The Authority after due deliberations decided that the company may be asked to continue to produce the average of last two years' production levels of all such formulations for next one year. In this regard, the company may be accordingly directed under para 21(2) of DPCO, 2013 to carry out the production so that the availability of these formulations to the consumers is not adversely affected.

The Authority approved the proposal for discontinuation of Partocin 5IU Inj. mentioned at S.No. 8 as per para 4.1 of the guidelines followed in this regard.

Additional Agenda items discussed:-

10. Agenda Item no. 10:

10.1 The Authority in its 14th Meeting, decided that in case of Form I applications, price fixed by NPPA shall be valid for one year for the formulation having same composition & strength and no increase in price will be allowed. However, in case the current retail price worked out/claimed by the company is lower than the existing notified retail price, the benefit of lower price has to be passed on to the consumers.

10.2 NPPA fixed 2 retails prices of M/s FDC Ltd. in 22nd Authority meeting, by applying the above mentioned principle. M/s FDC filed a review application under Para 31 challenging the price notification based on this principle. NPPA informed DOP about the decision taken in 14th Authority Meeting. It was informed to the Authority that DOP vide its letter dated 02.7.2015 sought clarification as to whether the Authority's decision in the matter is in accordance with DPCO, 2013.

10.3 The Authority deliberated on this issue and considered that the above said decision of one year was taken in right spirit keeping in view the larger interest of the consumers as WPI is eligible only after completion of one year from the date of notification.

11. Agenda Item no. 11:

NPPA launched IPDMS/Pharma Data Bank for collection of various forms from the Pharmaceuticals companies in line with provisions of Para 9(2) of DPCO, 2013. Thus, the Authority decided that a notification may be issued in this regard directing all the concerned manufacturers/marketing companies to furnish mandatory information/

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data as specified in Form I to V of Schedule-II of DPCO, 2013 online through IPDMS link on NPPA's website.

12. Agenda Item no. 12:

The Authority while discussing the pending cases of 'new drug' price fixation also took note of letters received from various applicant companies related to status of their Form-I applications. In this regard, the Authority deliberated on issues related to price fixation with a view that Drugs and Cosmetics Act, 1940 provides for issuance of license for manufacture of formulations to (i) manufacturing unit and/or (ii) manufacturing on loan license. As such there is no provision in the Act to give recognition to contract manufacturing/third party manufacturing as far as licensing is concerned. The O.M. No. X.11011/1/2011-DFQC dated 01.10.2012, issued by Deptt. of Health & Family Welfare, inter-alia, states that the grant of drug manufacturing licenses under a trade or brand name is not in accordance with the spirit of the legislation. Manufacturing license for drug formulation should be granted in proper/generic name only for single ingredient formulation. As such there is no anomaly regarding information sought by NPPA for processing/disposal of application of price fixation of new drugs. The Authority, however, directed to bring out a 'checklist' clearly specifying documents/information required alongwith Form-I application filed for price fixation; and also to fix a timeline for price fixation as 60 days from the date of receipt of complete information in this regard.

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

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(Dr. Sharmila Mary Joseph K)
Member Secretary