गोपनीय: Confidential

मिसिल स.- 8(25)/2015/डी.पी./एनपीपीए- डीवी-II

F. No. 8(25)/2015/DP/NPPA-Div. II

कार्यवाहीस. : 157/25/2015/F

Proceeding No : 157/25/2015/F

Minutes of the 157th and 25th meeting of Authority under DPCO, 2013 held on 29.10.2015 at 12.30 PM.

1. i. The 157th overall meeting of the Authority, which is the 25th under the DPCO, 2013 was held on 29th October, 2015 at 12.30 PM 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 Sanjeev Kumar, Assistant 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) Shri Jagdish Kumar, Director (M&E)
(iii) Shri A.K. Khurana, Director (Pricing & Admn.)
(iv) Shri A.P.S. Sawhney, Director (Overcharging)
(v) Shri Anand Prakash, Dy. Director (M&E)
(vi) Shri Manoj K. Singh, Dy. Director (M&E)
(vii) Shri T.R. Sathish Chandran, Asstt. Director (OC-II)
(viii) Shri Baljit Singh, Asstt. Director (Legal)
(ix) Shri Suneel Chopra, Pr. Legal Consultant

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

2. At the outset, the Authority took note of the progress of IPDMS/Pharma Data Bank (PDB). The Chairman expressed his displeasure that IPDMS/PDB has not become fully operational. NPPA launched IPDMS/PDB for collection of data in various forms from the pharmaceutical companies in line with provisions of Para 9(2) of DPCO, 2013. Although 508 companies have registered and 39076 products have been registered, only details of 2916 products have been entered in Form V through IPDMS.

2.1 The Authority observed that the software for IPDMS/PDB tool was designed, developed and fine-tuned after detailed and extensive consultation with the industry.

The IPDMS when fully operationalized will be a useful tool for collection of information, monitoring and analysis of data for the industry, the consumer and the regulator. The IPDMS/PDB once developed fully will be an authentic database, from which data on production, import and pricing of scheduled and non-scheduled formulations can be accessed, analyzed and reports generated.

2.2 Companies are legally bound to report information through IPDMS/PDB. Non-submission of return/information through IPDMS/PDB tantamounts to violation of the provisions of DPCO, 2013.

2.3 After detailed deliberations, the Authority decided to give four weeks times to the companies to furnish mandatory information/data as specified in various forms of Schedule-II of DPCO, 2013, online, through IPDMS link on NPPA's website, failing which prosecution proceedings may have to be initiated against defaulters under the Essential Commodities Act, 1955.

II. Agenda Item

1. Agenda Item no. 1: Confirmation of Minutes of the 24th Meeting held on 24.8.2015.

Members of the Authority who participated in the 156th and the 24th Meeting under DPCO, 2013 confirmed the minutes of the meeting.

2. Agenda Item no. 2: Action Taken Report

Noted.

3. Agenda Item no. 3: Revision of ceiling prices of 6 common formulations pursuant to DOP orders dated 08.9.2015 in respect of Metronidazole injection 500 mg/100ml, Metronidazole 200 mg tablet and Metronidazole 400 mg tablet of M/s J.B. Chemicals & Pharmaceuticals Ltd. and order dated 09.9.2015 in respect of Chloroquine Phosphate injection (40mg/ml- 64.5mg eq. to 40 mg Chloroquine), Metronidazole 200mg tablet, Metronidazole 400mg tablet, Ibuprofen 200mg tablet and Ibuprofen 400mg tablet of M/s Abbott India Ltd.

3.1 The Authority discussed and considered the revision of ceiling prices of 6 formulation packs which are common in DPCO, 2013 as well as in DPCO, 1995 in compliance with DOP's review orders; and approved the following revised ceiling prices subject to receipt of proof of compliance of existing ceiling prices (i.e. price list in Form-V and/or copy of samples) from the concerned petitioners/companies.

3.2 A Table showing the ceiling prices approved is given below:

S.No.	Formulation	Ceiling Price (Rs.)
1	Chloroquine phosphate Injection 40 mg/ml (64.5mg = 40mg chloroquine)	1.32/ml
2	Metronidazole Injection 500mg/100ml	0.15/ml

3	Metronidazole Tablet 200mg	0.46/tablet
4	Metronidazole Tablet 400mg	0.83/tablet
5	Ibuprofen Tablet 200mg	0.45/tablet
6	Ibuprofen Tablet 400mg	0.74/tablet

4. Agenda Item no. 4: 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.

4.1 This issue was discussed in detail and the Authority observed that NPPA took a conscious decision at the Authority Meeting held on 10.12.2014 and extended the price of Paclitaxel +Human Albumin IP QS (100 mg/vial pack) of M/s Panecea, to the product marketed by M/s Torrent also (but manufactured by M/s Panecea under the same manufacturing license for itself and for M/s Torrent). The products NAB Tortaxel (M/s Torrent) and PacliALL (M/s Panacea) are one and the same; and manufactured by M/s Panacea. While M/s Panacea sells its product PacliALL at a much lesser rate, M/s Torrent claims a much higher rate for its product NAB Tortaxel. This is obviously one of the fallacies in market-based pricing mechanism.

4.2 Further, the Authority noted that premium linked to the brand of M/s Torrent may not be allowed as it has a far reaching impact on accessibility and affordability of medicines to the public. The Authority decided to refer this case back to DOP for reconsideration.

5 Agenda Item no. 5: Representation of companies against S.O. 3128(E) dated 10.12.2014 for pricing of Hormone Releasing IUD.

5.1 The Authority discussed the case in detail and observed that ceiling price of Hormone Releasing IUD was fixed at Rs. 455.01/IUD vide S.O 3128(E) dated 10.12.2014 and again notified at Rs. 472.52/IUD (after allowing WPI for 2014) vide S.O. 619(E) dated 26.02.2015. However, the calculation sheet was based on the price data provided by IMS-Health, of devices which were actually copper containing IUDs and not hormone releasing IUDs. The companies manufacturing/marketing Hormone Releasing IUDs represented to NPPA in this regard, pointing out the anomaly. This was also independently verified by NPPA. The Authority also discussed the observations of NIPER regarding technical and scientific aspects of non-hormonal and hormonal intra-uterine devices.

5.2 The Authority analyzed the current data available with NPPA. The MRP and PTR of hormone releasing IUDs is as follows (current data):-

Name of Company & Brand	MRP/Unit(Rs.)	PTR/unit(Rs.)
M/s Bayer–Mirena	8205	6892
M/S HLL- Emily	2424	1940
M/s Pregna- Eloira	4500	3200

5.3 The Authority noted that all the 3 companies had not by themselves availed of WPI increase as provided for in para 16(2) of DPCO, 2013.

5.4 After detailed discussions the Authority approved the revised ceiling price of 4652.45 for one hormone releasing IUD, worked out based on the current data, as per the provisions of DPCO, 2013.

6. Agenda Item no. 6: Representation by M/s Cipla Ltd. in respect of Ondansetron 4mg & 8mg Orally Disintegrating Strips.

6.1 The Authority discussed the revised retail price of Ondansetron 4mg and 8mg orally disintegrating strips of M/s Cipla. After detailed deliberations and based on the comments received from NIPER, the Authority approved the revised retail price of Rs. 9.11/strip and Rs. 14.14/strip for Ondansetron 4mg and 8mg orally disintegrating strips respectively as per the provisions of DPCO, 2013.

7. Agenda Item no. 7: Representation regarding Bleaching Powder.

7.1 The Authority noted that the DPCO 2013, Schedule-I has specified Bleaching Powder (containing not less than 30% w/w of available chlorine as per I.P) in section 15.2 (Disinfectants). The Authority discussed the representation received from some State Governments/State Government Undertakings regarding the anomaly in price fixed for Bleaching Powder. The Authority noted that NPPA's earlier calculations were based on the PTRs of May, 2012 as submitted by the three companies viz. M/s. Priyanka Chemicals Pvt. Ltd., M/s. Rajashree Chloro Chem & M/s. Sutar Pharma Chemicals Pvt. Ltd. All the three companies replied that their products are of 'Commercial Grade'. In view of this, it was decided to withdraw the notification S.O. 3126 (E) dated 10.12.2014.

8. Agenda Item no. 8: Fixation of retail price in respect of new drugs.

The Authority discussed the cases of retail price fixation of 17 new drugs and approved the proposal as per para 5 and 6 of the DPCO 2013, as under:

S. No. in agenda	Company name/Product name	Approved Price (Rs.)
8(i)	M/s Inventia Healthcare Pvt. Ltd. (Manufacturer) and M/s Merck Ltd. (Marketing company) – Metformin HCL 500mg (SR) + Voglibose 0.2mg and Glimepiride 1mg - (Metformin HCl SR + Voglibose and Glimepiride tablet).	Rs. 71.43 per 10 tablets
8 (ii)	M/s Inventia Healthcare Pvt. Ltd. (Manufacturer) and M/s Franco Indian Pharmaceuticals Pvt. Ltd. (Marketing company) – Metformin HCL 500mg (SR) + Voglibose 0.2mg and Glimepiride 1mg - (Metformin HCl SR + Voglibose and Glimepiride tablet).	Rs. 71.43 per 10 tablets
8 (iii)	M/s Inventia Healthcare Pvt. Ltd. (Manufacturer) and M/s Merck Ltd. (Marketing company) – Metformin HCL 500mg (SR) + Voglibose 0.2mg and Glimepiride 2mg - (Metformin HCl SR + Voglibose and Glimepiride tablet).	Rs. 90.48 per 10 tablets

8 (iv)	M/s Inventia Healthcare Pvt. Ltd. (Manufacturer) and M/s Franco Indian Pharmaceuticals Pvt. Ltd. (Marketing company) – Metformin HCL 500mg (SR) + Voglibose 0.2mg and Glimepiride 2mg - (Metformin HCl SR + Voglibose and Glimepiride tablet).	Rs. 90.48 per 10 tablets
8 (v)	M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) and M/s Entod Pharmaceuticals Ltd. (Marketing company) - Moxifloxacin HCl eq. to Moxifloxacin 0.5% w/v, Prednisolone Acetate 1% w/v and Benzalkonium Chloride Solution 0.02% v/v (As preservative) – (Moxifloxacin and Prednisolone Acetate Opthalmic Solution).	Rs. 3.69 per ml
8 (vi)	M/s Acme Formulation Ltd. (Manufacturer) and M/s Alembic Pharmaceuticals Ltd. (Marketing company) - Ferrous Ascorbate eq. to Elemental Iron 100mg and Folic Acid 1.5mg – (FERISIS XT tablet).	Rs. 7.33 per tablet
8 (vii)	M/s Ordain Healthcare Global Pvt. Ltd. (manufacturer) and M/s Unichem Lab. Ltd. (marketing company) - Bisoprolol Fumarate 2.5mg and Amlodipine Besylate eq. to Amlodipine 5mg – (CORBIS AM 2.5/5 tablet).	Rs. 61.78 per 10 tablets
8 (viii)	M/s Ordain Healthcare Global Pvt. Ltd. (manufacturer) and M/s Unichem Lab. Ltd. (marketing company) - Bisoprolol Fumarate 5mg and Amlodipine Besylate eq. to Amlodipine 5mg – (CORBIS AM 5/5 tablet).	Rs. 73.36 per 10 tablets
8 (ix)	M/s Apex Lab. Pvt. Ltd. (manufacturer as well as marketing company) - Sodium Fusidate eq. to Fusidic Acid 2% w/w and Beclomethasone Dipropionate 0.025% w/w – (Sodium Fusidate and Beclomethasone Dipropionate cream).	Rs. 9.42 per gm
8 (x)	M/s Swiss Garnier Genexiaa Sciences (manufacturer) and M/s Zuventus Healthcare Ltd. (marketing company) – Aceclofenac 100mg and Paracetamol 325mg) – (Mahadol Tablet).	Rs. 2.77 per tablet
8 (xi)	M/s Anglo-French Drugs & Industries Ltd. (manufacturer as well as marketing company) – Metformin HCl 1000mg- (Metformin HCl Prolonged Release Tablet).	Rs. 3.40 per tablet
8 (xii)	M/s Scott Edil Advance Research Labs. & Education Ltd. (manufacturer) and M/s Gem Mankind (marketing company) – Ceftriaxone Sodium (Sterile) eq. to anhydrous Ceftriaxone – 500mg with one FFS Ampoule containing, Sterile water for injections (as diluent) – 5ml – (Cefaclass Injection).	Rs. 41.96 each pack
8 (xiii)	M/s Scott Edil Advance Research Labs. & Education Ltd. (manufacturer) and M/s Gem Mankind (marketing company) – Cefixime (as trihydrate) eq. to anhydrous Cefixime – 50mg - (Cefaclass Dry Syrup).	Rs. 1.39 per ml
8 (xiv)	M/s Scott Edil Advance Research Labs. & Education Ltd. (manufacturer) and M/s Gem Mankind (marketing	Rs. 6.60 per tablet

	company) – Ofloxacin 200mg and Ornidazole 500mg - (Brutaflox-OZ tablet).	
8 (xv)	M/s Embiotic Lab. Pvt. Ltd. (manufacturer as well as marketing company) – Ferrous Ascorbate eq. to elemental Iron 30mg and Folic Acid 550mcg – (HAEMIRON XT suspension).	Rs. 135.00 for 200 ml
8 (xvi)	M/s Nu Therapeutics Pvt. Ltd. (Manufacturer) and M/s Cipla Ltd., (Marketing company) – Ondansetron Hcl eq. to Ondansetron 2mg (Ondansetron HCl 2mg Disintegrating Strip – Emeset Fast 2mg).	Rs. 8.04 per strip
8 (xvii)	M/s Theon Pharmaceuticals Ltd. (Manufacturer) and M/s Wilshire Healthcare (Marketing company) – Ferrous Ascorbate 100mg, Methylcobalamin/Mecobalamin 1.5mg, Folic Acid 1.1mg and Zinc Sulphate Monohydrate eq. to Elemental Zinc 22.5mg – (FMF Plus tablet).	Rs. 9.99 per tablet

9. Agenda Item no. 9: Compendium of the important policy/in principle decision taken at the Authority Meetings held under DPCO, 2013.

9.1 Noted.

10. Agenda Item no. 10: Amendment of Price fixation order no. S.O. 2302(E) dated 24.8.2015 regarding Albendazole 400mg + Ivermectin 6mg tablet (Albekem plus Tablet) manufactured and marketed by M/s Astam Healthcare Pvt. Ltd. and M/s Alkem lab Ltd. respectively.

10.1 Noted.

11. Agenda Item no. 11: Non-application of provisions of DPCO, 2013 in respect of new strength, 200 IU/ml recombinant Human Insulin formulation under para 32 (iii) of DPCO, 2013; (i) Insulin Human Injection 200 IU/ml (ii) Isophane Insulin Human Suspension 200 IU/ml and (iii) 70% Isophane Insulin Human Suspension and 30% Insulin Human Injection 200 IU/ml (M & E Division).

11.1 The Authority was informed that the Expert Committee constituted for the said purpose recommended the above said new strength, 200IU/ml recombinant Human Insulin formulation approved by the DCG(I) as 'new drug' under Rule 122E of Drugs and Cosmetic Rules, for exemption from price control for five years under para 32(iii) of DPCO, 2013.

11.2 The Authority discussed the agenda note circulated for its consideration of non-application of provisions of DPCO, 2013 in respect of the said recombinant Human Insulin formulations developed indigenously by the company in their R&D unit approved by DSIR, Ministry of Science and Technology. The Authority also noted that this

presentation, 200IU/ml of recombinant insulin formulation is intended to be used for improving compliance to the dosage requirement specially in diabetic patients having high body mass index.

11.3 The Authority after due deliberations and taking into account the recommendations of the Expert Committee approved (i) Insulin Human Injection 200IU/ml (ii) Isophane Insulin Human Suspension 200IU/ml and (iii) 70% Isophane Insulin Human Suspension and 30% Insulin Human Injection 200IU/ml of M/s Wockhardt Limited under para 32(iii) of DPCO, 2013 for a period of five years from the date of its market approval granted by DCG(I) i.e. 08.01.2015, subject to the receipt of declaration of price charged i.e. MRPs of these formulations by M/s Wockhardt.

12. Agenda Item no. 12: Status of Overcharging cases – (Overcharging Division).

12.1 The Authority noted the status and directed the office to strengthen the efforts to monitor the cases vigorously, and to work out an action plan to enhance recovery of overcharged amount.

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

Sharmilajoseph 29/10/15

(Dr. Sharmila Mary Joseph K)
Member Secretary