

मिसिलस.- 8(37)/2016/डी.पी./एनपीपीए- डीवी-II

F. No. 8(37)/2016/DP/NPPA-Div. II

कार्यवाहीस. : 169/37/2016/F  
Proceeding No : 169/37/2016/F

**Minutes of the 169<sup>th</sup> and 37<sup>th</sup> meeting of Authority under DPCO, 2013 held on 06.10.2016 at 11.00 AM.**

- I. 1. The 169<sup>th</sup> overall meeting of the Authority, which is the 37<sup>th</sup> under the DPCO, 2013 was held on 06<sup>th</sup> October, 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) Dr. G.N. Singh, DCG(I).
- (iii) Shri Devendra Kumar, Adviser (Cost), Deptt. of Expenditure, Ministry of Finance.
- (iv) Shri R.Chandrashekhar, Deputy Drug Controller, Deptt. of Health & Family Welfare.

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)
- (v) Shri A.P.S. Sawhney, Director (Overcharging)
- (vi) Shri Baljit Singh, Asstt. Director (Pricing)
- (vii) Shri Prasenjit Das, Asstt. Director (Pricing)
- (viii) Shri Suneel Chopra, Pr. Legal Consultant

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

1.3 Dr. G.N. Singh, DCG(I) impressed upon the need for monitoring the availability of medicines and discontinuation of the non-scheduled formulations. He raised this point with particulars reference to the newspaper reports about shortage of the medicine 'Penicillamine' used for the treatment of Wilson's disease in the market. Further, he also discussed the requirement for preparation of database of manufacturers/pharmaceutical companies with complete details. Chairman discussed the details of the proposal that NPPA had placed before the DoP in this regard (vide Chairman's DO letter no. 16(10)/2014/Div.III/NPPA(pt.) [copy enclosed].

**II. Agenda Items**

**1. Agenda Item no. 1: Confirmation of Minutes of the 36<sup>th</sup> Meeting held on 14.9.2016.**

The Authority confirmed the minutes of the of overall 168<sup>th</sup> and the 36<sup>th</sup> Meeting under DPCO, 2013 to the following:- .

*Sharmila Mary Joseph*

- i. As regards guidelines for discontinuation of scheduled formulations, the Authority decided to make change in para 4.5 of the guidelines as follows:  
When a company has > 25% market share of a product and desires to discontinue production of formulation, NPPA may request Department of Pharmaceuticals to take action under para 3 of DPCO 2013.
- ii. Regarding the revised guidelines for overcharging, the Authority after detailed discussions, decided to make changes as discussed and approved.

**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-1 of DPCO, 2013 (NLEM, 2015).**

3.1 The Authority discussed in detail the data and calculation sheets of 34 formulations at the meeting. The Authority approved the ceiling prices in respect of all the following 34 formulations.

However, in case of Paracetamol 80mg suppository, Paracetamol 160mg suppository, Paracetamol 125mg/5ml Oral Liquid and Paracetamol 120mg/5ml Oral Liquid, keeping in view the current scenario of Dengue and Chikungunya fever/disease, the Authority decided to put on hold the notifications till the crisis situation eases so that availability of Paracetamol based formulations is not adversely affected.

| S. NO.  | Unique No. as per NLEM | Name of the formulation/ composition | Strength   | Dosage Form          | Unit for Ceiling Price | Approved ceiling price under NLEM, 2015 (Rs.) |
|---|------------------------|--------------------------------------|------------|----------------------|------------------------|---|
| <b>Section 1—Anesthetic agents</b>  |                        |                                      |            |                      |                        |   |
| <b>1.1—General Anesthetics and oxygen</b>   |                        |                                      |            |                      |                        |   |
| 1   | 1.1.3                  | Ketamine                             | 50 mg/ml   | Injection            | Per ml                 | 9.69  |
| 2   | 1.1.3                  | Ketamine                             | 10 mg/ml   | Injection            | Per ml                 | 9.83  |
| 3   | 1.1.6                  | Propofol                             | 10 mg/ml   | Injection            | Per ml                 | 6.70  |
| 4   | 1.1.8                  | Thiopentone                          | 1 gm       | Powder for Injection | Each Pack              | 45.86   |
| <b>1.2—Local anesthetics</b>  |                        |                                      |            |                      |                        |   |
| 5   | 1.2.1                  | Bupivacaine                          | 0.25%      | Injection            | Per ml                 | 2.27  |
| 6   | 1.2.1                  | Bupivacaine                          | 0.50%      | Injection            | Per ml                 | 3.64  |
| 7   | 1.2.2                  | Lignocaine                           | 1%         | Injection            | Each Pack              | 7.36  |
| 8   | 1.2.2                  | Lignocaine                           | 2%         | Injection            | Per ml                 | 0.91  |
| <b>Section 2—Analgesics, antipyretics, non steroidal anti-inflammatory medicines, medicines used to treat gout and disease modifying agents used in rheumatoid disorders.</b> |                        |                                      |            |                      |                        |   |
| <b>2.1— Non-opioid analgesics, antipyretics and nonsteroidal anti-inflammatory medicines</b>  |                        |                                      |            |                      |                        |   |
| 9   | 2.1.5                  | Paracetamol                          | 80 mg      | Suppository          | Each Suppository       | 6.04  |
| 10  | 2.1.5                  | Paracetamol                          | 170 mg     | Suppository          | Each Suppository       | 7.14  |
| 11  | 2.1.5                  | Paracetamol                          | 125 mg/5ml | Oral Liquid          | Per ml                 | 0.31  |

| <b>Section 3–Antiallergics and medicines used in anaphylaxis</b>   |          |                  |            |                      |             |          |
|--|----------|------------------|------------|----------------------|-------------|----------|
| 12   | 3.1      | Adrenaline       | 1 mg/ml    | Injection            | Per ml      | 12.33    |
| <b>Section 5–Anticonvulsants/ Antiepileptics</b>   |          |                  |            |                      |             |          |
| 13   | 5.3      | Diazepam         | 5mg/ml     | Injection            | Per ML      | 5.62     |
| 14   | 5.8      | Phenytoin        | 50 mg/ml   | Injection            | Per ml      | 4.98     |
| <b>Section 6–Anti infective medicines</b>  |          |                  |            |                      |             |          |
| <b>6.2.4–Antituberculosis medicines</b>  |          |                  |            |                      |             |          |
| 15   | 6.2.4.14 | Streptomycin     | 750 mg     | Powder for Injection | Each Pack   | 7.82     |
| <b>Section 8 –Antineoplastic/ immunosuppressives and medicines used in palliative care</b>   |          |                  |            |                      |             |          |
| <b>8.1–Antineoplastic medicines</b>  |          |                  |            |                      |             |          |
| 16   | 8.1.6    | Bleomycin        | 15 Units   | Powder for Injection | Each Pack   | 552.37   |
| 17   | 8.1.13   | Cyclophosphamide | 500 mg     | Powder for Injection | Each Pack   | 71.02    |
| 18   | 8.1.15   | Dacarbazine      | 500 mg     | Powder for Injection | Each Pack   | 919.54   |
| 19   | 8.1.36   | Vincristine      | 1 mg/ml    | Injection            | Per ml      | 46.37    |
| <b>8.4–Medicines used in palliative care</b>   |          |                  |            |                      |             |          |
| 20   | 8.4.7    | Haloperidol      | 5 mg/ml    | Injection            | Per ml      | 5.41     |
| 21   | 8.4.13   | Ondansetron      | 2 mg/5ml   | Oral Liquid          | Per ml      | 1.04     |
| <b>Section 10–Medicines affecting blood</b>  |          |                  |            |                      |             |          |
| <b>10.2–Medicines affecting coagulation</b>  |          |                  |            |                      |             |          |
| 22   | 10.2.4   | Protamine        | 10mg/ml    | Injection            | Per ml      | 8.23     |
| <b>Section 14–Dermatological medicines</b>   |          |                  |            |                      |             |          |
| <b>14.5–Scabicides and pediculicides</b>   |          |                  |            |                      |             |          |
| 23   | 14.5.1   | Permethrin       | 5%         | Cream                | Per gm      | 1.62     |
| <b>Section 27–Psychotherapeutic medicines</b>  |          |                  |            |                      |             |          |
| <b>27.2.2–Medicines used in Bipolar disorders</b>  |          |                  |            |                      |             |          |
| 24   | 27.2.2.1 | Lithium          | 300 mg     | Tablet               | Per Tablet  | 1.35     |
| <b>B. New formulations</b>   |          |                  |            |                      |             |          |
| <b>Section 2–Analgesics, antipyretics, non steroidal anti inflammatory medicines, medicines used to treat gout and disease modifying agents used in rheumatoid disorders</b> |          |                  |            |                      |             |          |
| <b>2.1– Non-opioid analgesics, antipyretics and nonsteroidal anti-inflammatory medicines</b>   |          |                  |            |                      |             |          |
| 1  | 2.1.5    | Paracetamol      | 120 mg/5ml | Oral Liquid          | Per ml      | 0.49     |
| <b>Section 6–Anti infective medicines</b>  |          |                  |            |                      |             |          |
| <b>6.4.2–Anti Cytomegalovirus (CMV) medicines</b>  |          |                  |            |                      |             |          |
| 2  | 6.4.2.1  | Ganciclovir      | 500 mg     | Powder for Injection | Each Pack   | 1,501.69 |
| <b>II. NLEM 2015 – Explanation (1) of Schedule-I</b>   |          |                  |            |                      |             |          |
| <b>C. Common Formulation</b>   |          |                  |            |                      |             |          |
| <b>Section 6–Anti infective medicines</b>  |          |                  |            |                      |             |          |
| <b>6.2.2–Other antibacterials</b>  |          |                  |            |                      |             |          |
| 1  | 6.2.2.5  | Doxycycline      | 100 mg     | Tablet               | Per Tablet  | 0.90     |
| <b>D. New Formulations</b>   |          |                  |            |                      |             |          |
| <b>Section 6–Anti infective medicines</b>  |          |                  |            |                      |             |          |
| <b>6.2.2–Other antibacterials</b>  |          |                  |            |                      |             |          |
| 1  | 6.2.2.1  | Azithromycin     | 250 mg     | Capsule              | Per Capsule | 9.75     |
| 2  | 6.2.2.1  | Azithromycin     | 500 mg     | Capsule              | Per Capsule | 15.38    |
| 3  | 6.2.2.8  | Nitrofurantoin   | 100 mg     | Capsule              | Per Capsule | 6.51     |

*Shamulay Joseph*

|   |        |             |       |         |             |       |
|---|--------|-------------|-------|---------|-------------|-------|
| <b>Section 7–Antimigraine medicines</b>                                 |        |             |       |         |             |       |
| <b>7.2–For prophylaxis</b>  |        |             |       |         |             |       |
| 4   | 7.2.2  | Propranolol | 40 mg | Capsule | Per Capsule | 3.53  |
| <b>Section 8 –Antineoplastic/ Immunosuppressives and medicines used</b> |        |             |       |         |             |       |
| <b>8.1–Antineoplastic medicines</b>                                     |        |             |       |         |             |       |
| 5   | 8.1.23 | Imatinib    | 100mg | Capsule | Per Capsule | 72.03 |
| <b>8.4–Medicines used in palliative care</b>                            |        |             |       |         |             |       |
| 6   | 8.4.6  | Fluoxetine  | 20 mg | Tablet  | Per Tablet  | 3.68  |
| <b>Section 20–Gastrointestinal medicines</b>                            |        |             |       |         |             |       |
| <b>20.1–Antiulcer medicines</b>   |        |             |       |         |             |       |
| 7   | 20.1.1 | Omeprazole  | 40 mg | Tablet  | Per Tablet  | 7.74  |

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

4.1 The Authority discussed the following 7 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 Windias Biotech Ltd. (Manufacturer) and M/s Alkem Lab. Ltd. (Marketing company) - Glimepiride 4mg and Metformin HCl 1000mg (SR) – (Glucoryl M4 Forte tablet).   | Rs. 9.45/tablet             |
| 4(ii)  | M/s Raptakos, Bertt & Co. Ltd. (Manufacturer as well as Marketing company) – Cholecalciferol (vitamin D3) 800 IU (Arbivit – 3 Forte Drops).   | Rs. 4.33 per ml             |
| 4(iii) | M/s Cadila Healthcare Ltd. (Manufacturer as well as Marketing company) - Cefazidime Pentahydrate eq. to Cefazidime – 1gm (added sterile sodium carbonate as buffering agent) and Tazobactam Sodium eq. to Tazobactam – 125mg supplied with 10ml sterile water for injection) – (Zytaz – T injection). | Rs. 268.45 per vial         |
| 4(iv)  | M/s Synkem Pharmaceuticals Ltd. (Manufacturer) and M/s Intas Pharmaceuticals Ltd. (Marketing company) – Rosuvastatin calcium 5mg and clopidogrel bisulphate 75mg capsule – (Rosuvastatin calcium 5mg and clopidogrel bisulphate 75mg capsule).  | Rs. 10.35 per capsule       |
| 4(v)   | M/s Synkem Pharmaceuticals Ltd. (Manufacturer) and M/s Intas Pharmaceuticals Ltd. (Marketing company) – Rosuvastatin calcium 10mg and Clopidogrel bisulphate 75mg capsule – (Rosuvastatin calcium 10mg and Clopidogrel bisulphate 75mg capsule).  | Rs. 13.94 per capsule       |
| 4(vi)  | M/s Innova Captab (Manufacturer) and M/s Leeford Healthcare Ltd. (Marketing company) - Propranolol HCL 40mg (as sustained release pellets) and Flunarizine Dihydrochloride eq. to Flunarizine 10mg (as pellets) – (Migraf-P Capsule).   | Rs. 8.53 per capsule        |
| 4(vii) | M/s Panacea Biotec Ltd. (Manufacturer) and M/s Cadila Healthcare Ltd. (Marketing company) – Tacrolimus 0.25mg – (Tacromus 0.25mg capsule).  | Rs. 11.28 per capsule       |

#### 5. Agenda Item no. 5: Representation for Price revision of Metronidazole oral liquid 200mg/5ml notified vide S.O. 1561(E) dated 27.4.2016.

5.1 This case was discussed in detail and the Authority approved the revised ceiling price of Metronidazole oral liquid 200mg/5ml at Rs. 0.27 per ml.

**Additional agenda items circulated during the meeting:-**

**6. Agenda Item no. 6: Status of Review orders issued by DOP which are pending with NPPA for implementation.**

6.1 Noted.

**7. Agenda Item no. 7: Review order dated 19.9.2016 and the clarificatory order dated 04.10.2016 in respect of M/s B. Braun Medical (India) Pvt. Ltd. against S.O. 2210 (E) dated 24.6.2010 for Ceiling prices of the IV Fluids Glucose 5%, Sodium Chloride 0.9%, Glucose 5% + Sodium Chloride 0.9%.**

7.1 This review order and the clarificatory order were discussed in detail. The Authority directed to comply with the directions of DOP and issue notification in this regard.

**8. Agenda Item no. 8: Review orders of Dr. Reddy's Laboratories Ltd., M/s J.B. Chemicals & Pharmaceuticals Pvt. Ltd and M/s Abbott India Ltd.**

8.1 The review orders were discussed in detail. As the issue is sub-judice, the Authority decided to keep these cases in abeyance till discussions with Secretary, DoP.

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

  
(Dr. Sharmila Mary Joseph K)  
Member Secretary