

गोपनीय: Confidential

मिसिलस.- 8(43)/2017/डी.पी./एनपीपीए-डीवी-॥

F. No. 8(43)/2017/DP/NPPA-Div. II

कार्यवाहीस. : 175/43/2017/F

Proceeding No : 175/43/2017/F

Minutes of the 175th and 43rd meeting of Authority under DPCO, 2013 held on 29.3.2017 at 11.00A.M.

I. 1. The 175th overall meeting of the Authority, which is the 43rd under the DPCO, 2013 was held on 29th March, 2017 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 G.S. Negi, Adviser (Price, Money & Banking Unit), Deptt. of Economic Affairs, Ministry of Finance.
- (iii) Shri Devendra Kumar, Adviser (Cost), Deptt. of Expenditure, Ministry of Finance.
- (iv) Shri Umesh Dongre, Adviser (Cost), Deptt. of Expenditure, Ministry of Finance
- (v) Shri R. Chadrashekhar, Deputy Drug Controller, Deptt. of Health & Family Welfare (representing DCG(I)).

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 Baljit Singh, Asstt. Director (Pricing)
- (vi) Shri Prasenjit Das, Asstt. Director (Pricing)
- (vii) Shri Suneel Chopra, Pr. Legal Consultant

1.2 Chairman, NPPA welcomed all the members present in the meeting especially Shri Umesh Dongre, Adviser (Cost), Deptt. of Expenditure, Ministry of Finance, who has been recently nominated as ex-officio member in NPPA in place of Shri Devendra Kumar, Adviser (Cost).

1.3 The Authority directed to place the list of 'No Data' and 'Institutional Data' formulations in the next meeting. Further, it was decided to ask AIOCD AWACS to conduct a special market survey regarding these formulations and submit their estimates of professional charges in this regard separately.

II. Agenda Items

1. Agenda Item no. 1: Confirmation of Minutes of the 42nd Meeting held on 09.3.2017.

1.1 The Authority confirmed the minutes of the overall 174th and the 42nd Meeting held on 09.3.2017 under DPCO, 2013.

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2. Agenda Item no. 2: Action Taken Report

2.1 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 and calculation sheets of 36 formulations at the meeting. The Authority approved the ceiling prices in respect of all the following 36 formulations and directed to issue all notifications indicating the ceiling prices effective from 01.4.2017 after adding WPI @ 1.97186% for the year 2016 over 2015.

3.2 The cases relating to Lignocaine Injection 5% with 7.5% Glucose was discussed and it was decided to delete the 0% reduction in respect of Lignocaine 1% Injection from the monopoly table while working out reduction of 12.65%. Accordingly, the reduction was revised to 18.98% and the revised ceiling price works out to Rs. 3.41/ml (against earlier proposed revised ceiling price of Rs. 3.69/ml), as on 29.3.2017. Further, the cases relating to Anti-rabies immunoglobulin 150 IU/ML and 300 IU/ML were discussed in details. The Authority approved the revised ceiling prices of Rs. 2468.72/ml for 150IU/ml (human) and Rs. 87.03/ml for 300IU/ml (equine), as on 29.3.2017.

3.3 The Authority approved the ceiling prices in respect of all the following 36 formulations:-

| S. NO | UNIQU E NO. AS PER NLEM | NAME OF THE FORMULATION/ COMPOSITIONS | STRENGTH | Dosage Form | Unit for ceiling price | Revised ceiling price under NLEM, 2015 (as on 29.3.2017 (Rs.)) | Revised ceiling price under NLEM, 2015 (wef 01.4.2017 incl. WPI @ 1.97186%) (Rs.) |
|--|-------------------------|---------------------------------------|--------------------------------|----------------------|-------------------------|--|--|
| A. Common Formulations | | | | | | | |
| 1.2-Local anesthetics | | | | | | | |
| 1 | 1.2.2 | Lignocaine | Injection 5% with 7.5% Glucose | Per ml | Per ml | 3.41 | 3.48 |
| Section 2-Analgesics, antipyretics, non steroidal anti inflammatory medicines, medicines used to treat gout and disease modifying agents used in rheumatoid disorders | | | | | | | |
| 2.2-Opioid analgesics | | | | | | | |
| 2 | 2.2.3 | Tramadol * | 100 mg capsule | Per Capsule | Per Capsule | 8.90 | 9.08 |
| 3 | 2.2.3 | Tramadol | Injection 50 mg/ml | Per ML | Per ML (20 ML Pack) | 1.16 | 1.18 |
| 4 | 2.2.3 | Tramadol | Injection 50 mg/ml | Per ML | Per ML (upto 2 ML Pack) | 9.72 | 9.91 |
| Section 5-Anticonvulsants/ Antiepileptics | | | | | | | |
| 5 | 5.6 | Magnesium sulphate | Injection 500 mg/ml | PER ML | PER ML | 4.43 | 4.52 |
| Section 6-Anti infective medicines | | | | | | | |
| 6.2.2-Other antibacterials | | | | | | | |
| 6 | 6.2.2.6 | Gentamicin | Injection 10 mg/ml | PER ML | PER ML | 2.94 | 3.00 |
| 6.2.3-Antileprosy medicines | | | | | | | |
| 7 | 6.2.3.2 | Dapsone | Tablet 100 mg | Per Tablet | Per Tablet | 0.21 | 0.21414 |
| Section 8 -Antineoplastic/ immunosuppressives and medicines used in palliative care | | | | | | | |
| 8.1-Antineoplastic medicines | | | | | | | |
| 8 | 8.1.24 | L-Asparaginase | Powder for injection 5000 KU | Powder for Injection | Each Pack | 961.45 | 980.41 |
| 8.2-Hormones and antihormones used in cancer therapy | | | | | | | |
| 9 | 8.2.3 | Prednisolone | 20mg/2ml Injection | PER ML | PER ML | 3.32 | 3.39 |
| 8.4-Medicines used in palliative care | | | | | | | |
| 10 | 8.4.10 | Metoclopramide | Injection 5mg/ml | Per ML | Per ML (10ml pack) | 1.32 | 1.35 |
| 11 | 8.4.10 | Metoclopramide | Injection 5mg/ml | Per ML | Per ML (2ml pack) | 2.18 | 2.22 |
| Section 15 -Diagnostic agents | | | | | | | |
| 15.2-Radiocontrast media | | | | | | | |
| 12 | 15.2.4 | Megluminediatrizoate | Injection 76% w/v | PER ML | PER ML | 8.86 | 9.03 |
| 13 | 15.2.4 | Megluminediatrizoate | Injection 60% w/v | PER ML | PER ML | 7.67 | 7.82 |
| Section 20-Gastrointestinal medicines | | | | | | | |
| 20.3-Anti inflammatory medicines | | | | | | | |
| 14 | 20.3.1 | 5-aminosalicylic acid | Tablet 400 mg | Per Tablet | Per Tablet | 6.93 | 7.07 |

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| Section 22-Immunologicals | | | | | | | |
|--|-----------|---|---|-------------|-------------|-----------|-----------|
| 22.2-Sera and immunoglobulins (Liquid/ Lyophilized) | | | | | | | |
| 15 | 22.2.1 | Anti-rabies immunoglobulin | 150 IU/ML | Per ML | Per ML | 2,468.72 | 2,517.40 |
| Section 23-Muscle relaxants and cholinesterase inhibitors | | | | | | | |
| 16 | 23.4 | Succinyl choline | Injection 50 mg/ml | PER ML | PER ML | 4.49 | 4.58 |
| Section 26-Oxytocics and Antioxytocics | | | | | | | |
| 26.1-Oxytocics and abortifacient | | | | | | | |
| 17 | 26.1.5 | OXYTOCIN | Injection 10 IU/ml | PER ML | PER ML | 36.55 | 37.27 |
| Section 29-Solutions correcting water, electrolyte disturbances and acid-base disturbances | | | | | | | |
| B. New Formulations | | | | | | | |
| Section 6-Anti infective medicines | | | | | | | |
| 6.2.2-Other antibacterials | | | | | | | |
| 18 | 6.2.2.2 | Ciprofloxacin | Oral liquid 250 mg/5ml | PER ML | PER ML | 0.58 | 0.59 |
| 6.2.4-Antituberculosis medicines | | | | | | | |
| 19 | 6.2.4.11 | Pyrazinamide | Oral liquid 250 mg/5 ml | PER ML | PER ML | 0.55 | 0.56 |
| 6.4.2-Anti Cytomegalovirus (CMV) medicines | | | | | | | |
| 20 | 6.4.2.1 | Ganciclovir | Capsule 250 mg | Per Capsule | Per Capsule | 106.98 | 109.09 |
| 6.4.2-Anti Cytomegalovirus (CMV) medicines | | | | | | | |
| 6.4.3.1-Nucleoside reverse transcriptase inhibitors | | | | | | | |
| 21 | 6.4.3.1.2 | ABACAVIR (A)+ LAMIVUDINE (B) | Tablet 60 mg (A) +30 mg (B) | Per Tablet | Per Tablet | 18.63 | 19.00 |
| 22 | 6.4.3.1.3 | Lamivudine (A) + Nevirapine (B) + Stavudine (C) | Dispersible Tablet 30 mg (A) + 50 mg (B) + 6 mg (C) | Per Tablet | Per Tablet | 4.59 | 4.68 |
| 6.4.3.4-Protease inhibitors | | | | | | | |
| 23 | 6.4.3.4.3 | Lopinavir (A) + Ritonavir (B) | Tablet 100 mg (A) + 25 mg (B) | Per Tablet | Per Tablet | 21.82 | 22.25 |
| 6.4.4-Medicines for hepatitis B and hepatitis C | | | | | | | |
| 24 | 6.4.4.2 | Pegylated interferon alfa 2b | Injection 120 mcg | Each Pack | Each Pack | 13,518.36 | 13,784.92 |
| 25 | 6.4.4.2 | Pegylated interferon alfa 2a | Injection 180 mcg | Each Pack | Each Pack | 7,341.91 | 7,486.68 |
| 6.5.3-Antimalarial medicines | | | | | | | |
| 6.5.3.1-For curative treatment | | | | | | | |
| 26 | 6.5.3.1.1 | Artemether (A) + Lumefantrine (B) | Oral liquid 80 mg (A) + 480 mg (B)/5 ml | PER ML | PER ML | 3.75 | 3.82 |
| Section 8 -Antineoplastic/ immunosuppressives and medicines used in palliative care | | | | | | | |
| 8.2-Hormones and antihormones used in cancer therapy | | | | | | | |
| 27 | 8.2.3 | Prednisolone | Tablet 40 mg | Per Tablet | Per Tablet | 2.61 | 2.66 |
| 8.3-Immunosuppressive medicines | | | | | | | |
| 28 | 8.3.2 | Cyclosporine | Injection 50 mg/ml | PER ML | PER ML | 240.02 | 244.75 |
| 8.4-Medicines used in palliative care | | | | | | | |
| 29 | 8.4.15 | Zoledronic acid | Powder for Injection 4 mg | Each Pack | Each Pack | 3,738.38 | 3,812.10 |
| Section 9-Antiparkinsonism medicines | | | | | | | |
| 30 | 9.1 | Levodopa (A) + Carbidopa (B) | CR Tablet 200 mg (A) + 50 (B) mg | Per Tablet | Per Tablet | 3.81 | 3.89 |
| Section 10-Medicines affecting blood | | | | | | | |
| 10.2-Medicines affecting coagulation | | | | | | | |
| 31 | 10.2.6 | Warfarin | Tablet 3 mg | Per Tablet | Per Tablet | 2.89 | 2.95 |
| 32 | 10.2.6 | Warfarin | Tablet 2 mg | Per Tablet | Per Tablet | 2.47 | 2.52 |
| Section 21-Hormones, other endocrine medicines and contraceptives | | | | | | | |
| 33 | 21.1.3 | Hydrocortisone | Tablet 10 mg | Per Tablet | Per Tablet | 5.24 | 5.34 |
| 34 | 21.1.3 | Hydrocortisone | Tablet 5 mg | Per Tablet | Per Tablet | 2.70 | 2.75 |
| 21.3-Estrogens | | | | | | | |
| 35 | 21.3.2 | Levonorgestrel | Tablet 0.75 mg | Per Tablet | Per Tablet | 21.36 | 21.78 |
| 22.2-Sera and immunoglobulins (Liquid/ Lyophilized) | | | | | | | |
| 36 | 22.2.1 | Anti-rabies immunoglobulin | 300 IU/ML | Per ML | Per ML | 87.03 | 88.75 |
| C. Common (Explanation to Scheduled-I) NIL | | | | | | | |
| D. New (Explanation to Scheduled-I) - NIL | | | | | | | |

* The Authority also noted that although Tramadol 100mg capsule is a common formulation, yet its ceiling price was not fixed under NLEM, 2011 (original Schedule I) of DPCO 2013 as data was not available).

4. Agenda Item no. 4: Review order by DoP in respect of M/s Astellas Pharma India Pvt. Ltd. against price fixation of Tacrolimus 0.5 mg and 1 mg capsule vide S.O. 1405(E) dated 12.4.2016 issued under DPCO, 2013.

4.1 This case was discussed in detail and the Authority approved the revised ceiling price of Tacrolimus 0.5mg capsule at Rs. 20.52 per capsule (against earlier notified ceiling price of Rs. 16.76 per capsule) as on 29.3.2017 and Rs. 20.92 per capsule as on 01.4.2017 (after adding WPI @ 1.97186%) and Tacrolimus 1mg capsule as Rs. 36.25 per capsule (against earlier notified ceiling price of Rs. 32.18 per capsule) as on 29.3.2017 and Rs. 36.96 per capsule as on 01.4.2017 (after adding WPI @ 1.97186%).

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5. Agenda Item no. 5: Review order of DoP in respect of M/s Abbott Healthcare Pvt. Ltd against price fixation of Phenytoin 100mg tablet vide S.O. no. 1816(E) [corrected SO No. 1819(E)] dated 18.5.2016 issued under DPCO, 2013.

5.1 This case was discussed in detail and the Authority approved the revised ceiling price of Phenytoin 100mg tablet at Rs. 1.44 per tablet (against earlier notified ceiling price of Rs. 1.27 per tablet) as on 29.3.2017 and Rs. 1.47 per tablet as on 01.4.2017 (after adding WPI @ 1.97186%).

6. Agenda Item no. 6: Request for correction/corrigendum regarding fixation of price of Atracium Injection 10mg/ml vide notification SO 4128(E) dated 22.12.2016 from 'each pack' to 'per ML'.

6.1 This case was discussed in detail. The Authority rejected the proposal & directed the office to take action against the companies for overcharging, if any.

7. Agenda Item no. 7: Review order of DOP in respect of price fixation of Azithromycin 250mg and 500 mg tablets for M/s Alembic Pharmaceuticals Ltd against S.O. 1686(E) dated 09.5.2016 issued under Drugs Prices Control Order, 2013 (DPCO 2013).

7.1 This case was discussed in detail and the Authority approved the revised ceiling price of Azithromycin 250mg at Rs. 9.10 per tablet (against earlier notified ceiling price of Rs. 9.06 per tablet) as on 29.3.2017 and Rs. 9.28 per tablet as on 01.4.2017 (after adding WPI @ 1.97186%) and Azithromycin 500mg tablet at Rs. 18.46 per tablet (against earlier notified ceiling price of Rs. 17.83 per tablet) as on 29.3.2017 and Rs. 18.82 per tablet as on 01.4.2017 (after adding WPI @ 1.97186%).

8. Agenda Item no. 8: Review order of DOP in respect of price fixation of Rifampicin Capsule and Rifampicin Syrup for M/s Lupin Ltd. against S.O. 1202(E) dated 06.5.2015 issued under Drugs Prices Control Order, 2013 (DPCO 2013).

8.1 This case was discussed in detail and the Authority approved the following revised ceiling prices, in accordance with the directions outlined in the review order:-

| Product /Dosage form & strength | Existing Ceiling Price (Rs.) | Revised Ceiling Price as on 29.3.2017 (Rs.) | Revised Ceiling Price (wef 01.4.2017 incl. WPI @ 1.97186%) (Rs.) |
|---------------------------------|------------------------------|---|--|
| Rifampicin 150mg Capsule | 1.82/capsule | 1.86/capsule | 1.90/capsule |
| Rifampicin 300mg Capsule | 3.37/capsule | 3.53/capsule | 3.60/capsule |
| Rifampicin 450mg Capsule | 4.43/capsule | 4.58/capsule | 4.67/capsule |
| Rifampicin syrup 100mg/5ml | 0.34/ml | 0.36/ml | 0.37/ml |

9. Agenda Item no. 9: Review order of DoP in respect of M/s Sun Pharma Lab. Ltd. against price fixation of Imatinib Mesylate 100mg tablet vide S.O. no. 2730(E) dated 17.8.2016 issued under DPCO, 2013.

9.1 This case was discussed in detail and the Authority approved the revised ceiling price of Imatinib Mesylate 100mg tablet at Rs. 73.70 per tablet (against earlier notified ceiling price of Rs. 71.66 per tablet) as on 29.3.2017 and Rs. 75.15 per tablet as on 01.4.2017 (after adding WPI @ 1.97186%).

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10. **Agenda Item no. 10: Clarifications regarding Coronary Stents**

10.1 This case was discussed in detail and the Authority directed to issue an addendum clarifying that the permissible trade margin in the supply channel of Coronary stents not exceeding 8% in any form and same should be strictly monitored and enforced.

11. **Agenda Item no. 11: Implementation of Review Orders passed by Department of Pharmaceuticals (DoP).**

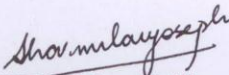
11.1 The Authority directed the NPPA office to take action in these cases without further delay. Authority expressed concern on the fact that office was giving unnecessary opportunities to companies to submit documents which delayed the process. Authority accordingly directed office to issue a revised O.M. clarifying the documents to be submitted by the petitioners and in no case the decision should be delayed because of non-submission of documents by companies after the prescribed time. Authority also requested the Chairman/MS to take up policy related issues with the Govt; explain difficulties in compliance and seek guidance.

12. **Agenda Item no. 12: Standard Operating Procedure (SOP) for initiating action against the companies for overcharging cases received by Overcharging Division from M&E Division.**

12.1 Noted.

13. The Authority put on record its deep appreciation of the distinguished services rendered by Shri Devendra Kumar, Adviser (Cost), Deptt. of Expenditure, Ministry of Finance since May, 2015. The Authority took special note of the detailed and systematic analysis of price calculations of various formulations under NLEM 2011 as well as NLEM, 2015, that Shri Devendra Kumar used to present at the Authority meetings, which enabled the Authority to take reasoned discussions.

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


(Dr. Sharmila Mary Joseph K)
Member Secretary