

**Minutes of the 199<sup>th</sup> (overall) and 67<sup>th</sup> meeting of the Authority under DPCO, 2013 held on 29.05.2019 at 11:00 AM**

The 199<sup>th</sup> meeting of the Authority (overall), which is the 67<sup>th</sup> meeting under the DPCO, 2013, was held on the 29<sup>th</sup> of May, 2019 at 11:00 AM under the Chairmanship of Ms. Shubhra Singh, Chairman, NPPA. The following members of the NPPA were present:

- (i) Ms. Ritu Dhillon, Member Secretary
- (ii) Shri Arun Kumar, Advisor, Dept of Economic Affairs, Ministry of Finance
- (iii) Shri B. Bandyopadhyay, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure

Shri A.K.Pradhan, Deputy Drug Controller, Deptt. of Health & Family Welfare was present as representative of DCGI.

1.1 The following officers of NPPA attended the meeting and assisted the Authority in its deliberations:

- (i) Shri Kalyan Nag, Advisor
- (ii) Shri Amarpal Singh Sawhney, Director (Pricing)
- (iii) Shri Prasenjit Das, Asstt. Director (Pricing)
- (iv) Shri Prakash Hemani, Asstt. Director (Pricing)

Chairman, NPPA welcomed all present in the meeting.

## **II. Agenda items**

### **1. Agenda item no. 1 - Confirmation of Minutes of the 66<sup>th</sup> Meeting held on 24.04.2019.**

1.1 Noted.

### **2. Agenda item no. 2 – Action Taken Report on decisions taken by NPPA in its 66th meeting dated 24.04.2019**

2.1 Noted.

### **3. Agenda item no. 3 – Ceiling Price fixation of Scheduled Drugs under NLEM, 2015**

3.1 The Authority deliberated upon the matter in detail and observed that the draft ceiling price of Ibuprofen 200 mg capsule is considerably higher in comparison to notified price of Ibuprofen 200 mg tablet and therefore, the Authority deferred the proposal with a direction to

check the PTR of subject formulation of all the months since its launch from Pharmatrac database and come with revised proposal.

#### 4. Agenda item no. 4 – Status of New Drug application

4.1 Noted.

#### 5. Agenda item no. 5 - New Drug application

5.1 The Authority discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 5 (i) to 5(xx) (total 20 Form I applications) falling under the purview of para 2(u) of DPCO, 2013 and approved the retail prices in 18 (eighteen) cases [except two cases at sl no vi and vii] under para 5 and/or para 15 of the DPCO 2013, as detailed below:

##### A. Retail price fixed under para 5 of DPCO, 2013

| Sl. No. | Name of the Formulation / Brand Name   | Strength  | Unit         | Manufacturer & Marketing Company                                       | Retail Price (Rs.)                 |
|---------|--|---|--------------|--|------------------------------------|
| (1)     | (2)  | (3)   | (4)          | (5)  | (6)                                |
| i.      | Alpha Lipoic + Methylcobalamin + Inositol USP + Folic Acid + Benfotiamine + Chromium Polynicotinate + Pyridoxine Hydrochloride Capsule | Each soft gelatine capsule contains:<br>Alpha Lipoic Acid USP 200 mg, Methylcobalamin 1500 mcg, Inositol USP NF 100 mg, Folic Acid IP 1.5mg, Benfotiamine 150 mg, Chromium Polynicotinate 200 mcg, Pyridoxine Hydrochloride IP 3 mg | 1 Capsule    | M/s Olive Healthcare / M/s Zydus Healthcare Limited                    | 15.66                              |
| ii.     | Voveran 1ml AQ Injection   | Each 1ml glass ampoule contains:<br>Diclofenac Sodium IP 75mg, Water for Injection  | Per 1ml Pack | M/s Nitin Life Sciences / M/s Novartis India Limited                   | 21.92                              |
| iii.    | Diclofenac + Thiocolchicoside Capsule  | Each Hard Gelatin capsule contains:<br>Diclofenac Sodium IP 50mg (As Enteric coated tablet) Thiocolchicoside 4mg  | 1 Capsule    | M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Novartis India Limited    | 12.61                              |
| iv.     | Diclofenac + Thiocolchicoside Capsule  | Each Hard Gelatin capsule contains:<br>Diclofenac Sodium IP 50mg (As Enteric coated tablet) Thiocolchicoside 8mg  | 1 Capsule    | M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Novartis India Limited    | 18.91                              |
| v.      | Amoxicillin + Clavulanic Acid Tablet (UNIMOX CV 1000)  | Each film coated tablet contains:<br>Amoxicillin Trihydrate IP eq. to Amoxicillin 875mg, Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 125mg  | 1 Tablet     | M/s Theon Pharmaceuticals Ltd. / M/s Macmillon Pharmaceuticals Limited | 30.75                              |
| vi.     | Clopidogrel + Aspirin Tablet   | Each film coated tablet contains:<br>Clopidogrel Bisulphate IP  | 1 Tablet     | M/s Sun Pharma Laboratories Limited                                    | Deferred in view of representation |

|       |   |   |              |   |  |
|-------|---|---|--------------|---|--|
|       |   | 75mg<br>Aspirin IP (As enteric coated)<br>75mg  |              |   | received from<br>the company   |
| vii.  | Clopidogrel +<br>Aspirin Tablet   | Each film coated tablet<br>contains:<br>Clopidogrel Bisulphate IP<br>75mg<br>Aspirin IP (As enteric coated)<br>150mg  | 1<br>Tablet  | M/s Sun Pharma<br>Laboratories<br>Limited   | Deferred in<br>view of<br>representation<br>received from<br>the company |
| viii. | Glimepiride +<br>Metformin +<br>Voglibose Tablet  | Each uncoated bilayered<br>tablet contains:<br>Glimepiride IP 2mg,<br>Metformin Hydrochloride IP<br>500mg (As Sustained Release<br>form),<br>Voglibose IP 0.2mg   | 1<br>Tablet  | M/s Theon<br>Pharmaceuticals<br>Limited / M/s<br>Indoco Remedies<br>Limited             | 11.80  |
| ix.   | Erythropoietin +<br>Human Albumin<br>+ Sodium<br>Chloride +<br>Sodium<br>Phosphate +<br>Sodium<br>Dihydrogen<br>Phosphate<br>Monohydrate<br>Injection<br>(Repoitin 40000) | Each 1.0ml contains:<br>Erythropoietin Concentrated<br>Solution IP 40000IU<br>Human Albumin IP 2.50mg,<br>Sodium Chloride IP 7.80mg,<br>Sodium Phosphate IP 2.20mg<br>Sodium Dihydrogen<br>Phosphate Monohydrate B. P.<br>0.96mg<br>Water for Injection IP q.s. | Per Vial     | M/s Serum<br>Institute of India<br>Pvt. Ltd.  | 6490.00  |
| x.    | Amlodipine +<br>Metoprolol<br>Tablet (Amlosafe<br>MT 25mg)  | Each film coated bilayered<br>Tablet contains:<br>Amlodipine Besilate eq. to<br>Amlodipine 5mg,<br>Metoprolol Succinate 23.75mg<br>eq. to Metoprolol Tartrate<br>25mg (As Prolonged Release)  | 1<br>Tablet  | M/s Pure & Cure<br>Healthcare Pvt. Ltd.<br>/ M/s Aristo<br>Pharmaceuticals<br>Pvt. Ltd. | 5.51   |
| xi.   | Rabeprazole +<br>Domperidone<br>Capsule (Instek D<br>Capsule)   | Each capsule contains:<br>Rabeprazole Sodium IP 20mg<br>(as enteric coated pellets),<br>Domperidone IP 30mg (as<br>sustained release pellets)   | 1<br>Capsule | M/s Inventia<br>Healthcare Limited  | 8.24   |
| xii.  | Pantoprazole +<br>Domperidone<br>Capsule<br>(Domelong P<br>Capsule)   | Each hard gelatin capsule<br>contains:<br>Pantoprazole Sodium IP (as<br>Pantoprazole Sodium<br>Sesquihydrate) eq. to<br>Pantoprazole 40mg (as<br>Gastro-resistant pellets)<br>Domperidone IP 30mg (as<br>Prolonged release pellets)                             | 1<br>Capsule | M/s Inventia<br>Healthcare Limited  | 8.007  |
| xiii. | Metformin +<br>Voglibose Tablet<br>(Proglutrol V 0.2)   | Each uncoated bilayered<br>tablet contains:<br>Metformin Hydrochloride IP<br>500mg (in Sustained release<br>form),<br>Voglibose IP 0.2mg  | 1<br>Tablet  | M/s Inventia<br>Healthcare Pvt. Ltd.  | 6.76   |
| xiv.  | Metformin +<br>Voglibose Tablet<br>(Proglutrol V 0.3)   | Each uncoated bilayered<br>tablet contains:<br>Metformin Hydrochloride IP   | 1<br>Tablet  | M/s Inventia<br>Healthcare Pvt. Ltd.  | 8.56   |

|        |   |  |              |   |       |
|--------|---|--|--------------|---|-------|
|        |   | 500mg (in Sustained release form),<br>Voglibose IP 0.3mg   |              |   |       |
| xv.    | Metformin +<br>Glimepiride<br>Tablet<br>(Proglutrol G1)                         | Each uncoated bilayered tablet contains:<br>Metformin Hydrochloride IP 500mg (in prolonged release form),<br>Glimepiride IP 1mg  | 1<br>Tablet  | M/s Inventia<br>Healthcare Pvt. Ltd.  | 5.13  |
| xvi.   | Metformin +<br>Glimepiride<br>Tablet<br>(Proglutrol G2)                         | Each uncoated bilayered tablet contains:<br>Metformin Hydrochloride IP 500mg (in prolonged release form),<br>Glimepiride IP 2mg  | 1<br>Tablet  | M/s Inventia<br>Healthcare Pvt. Ltd.  | 6.76  |
| xvii.  | Metformin +<br>Glimepiride<br>Tablet<br>(Proglutrol G1 Forte)                   | Each uncoated bilayered tablet contains:<br>Metformin Hydrochloride IP 1000mg (in prolonged release form),<br>Glimepiride IP 1mg   | 1<br>Tablet  | M/s Inventia<br>Healthcare Pvt. Ltd.  | 6.47  |
| xviii. | Metformin +<br>Glimepiride<br>Tablet<br>(Proglutrol G2 Forte)                   | Each uncoated bilayered tablet contains:<br>Metformin Hydrochloride IP 1000mg (in prolonged release form),<br>Glimepiride IP 2mg   | 1<br>Tablet  | M/s Inventia<br>Healthcare Pvt. Ltd.  | 8.75  |
| xix.   | Pantoprazole<br>Sodium +<br>Itopride<br>Hydrochloride<br>Capsules<br>(PANZO-IT) | Each hard gelatine capsules contains:<br>Pantoprazole Sodium IP eq. to Pantoprazole 40mg (as enteric coated pellets),<br>Itopride Hydrochloride 150mg (as sustained release pellets) | 1<br>Capsule | M/s Vidhyasha<br>Pharmaceuticals /<br>M/s Macmillon<br>Pharmaceuticals<br>Limited | 16.72 |
| xx.    | Atorvastatin<br>Tablet<br>(TORVASON -80)  | Each film coated tablet contains:<br>Atorvastatin Calcium IP eq. to Atorvastatin 80mg  | 1<br>Tablet  | M/s Unison<br>Pharmaceuticals<br>Pvt. Ltd.  | 27.54 |

## 6. Agenda item no. 6 – Status of implementation of Review Cases

6.1 Noted.

6.2 With respect to the 5 (five ) pending review orders relating to Ringer Lactate injection, the Authority observed that despite clear directive in last meeting, the companies are yet to submit additional data/ information. It was decided that a last opportunity be given and a reminder be issued to the concerned companies to provide the requisite data within 15 days failing which the cases will be rejected for lack of reliable data.

**7. Agenda item no. 7 - Review order no. 31015/15/2014-PI.I dated 04.09.2018 for M/s Ranbaxy Laboratories Ltd (M/s Sun Pharmaceutical Industries Ltd) for Ciprofloxacin 0.3% Eye drops.**

7.1 The Authority deliberated upon the matter in detail and noted that the review order no. 31015/15/2014-PI.I dated 04.09.2018 issued for M/s Ranbaxy Laboratories Ltd (M/s Sun Pharmaceutical Industries Ltd) relates to ceiling price of Ciprofloxacin Hydrochloride Drop 0.3% fixed vide SO. 1017(E) dated 02.04.2014 (fixed under NLEM 2011). The Authority also noted that NPPA has once again refixed the ceiling price of Ciprofloxacin Hydrochloride Drop 0.3% under NLEM 2015 vide SO. 443(E) dated 14.02.2017 by superseding the then applicable S.O. under NLEM 2011, which was again challenged by M/s Sun Pharmaceutical Industries Ltd. However, Department of Pharmaceutical vide review order no. 31015/41/2017-Pricing dated 04.02.2019 rejected the review application filed by M/s Sun Pharmaceutical Industries Ltd under NLEM 2015. It was noted that the review order no. 31015/15/2014-PI.I dated 04.09.2018 issued under NLEM 2011 could not be implemented since the present applicable ceiling price of Ciprofloxacin Hydrochloride drop 0.3% is under NLEM 2015, had already superseded the price fixed under NLEM 2011. Therefore, the Authority decided to close the review order no. 31015/15/2014-PI.I dated 04.09.2018 without any change in the price of Ciprofloxacin Hydrochloride Drop 0.3%.

**8. Agenda item no. 8 – Intimation of Minutes of 10th meeting of Multidisciplinary Committee of Experts held on 21.05.2019**

8.1 Agenda No. 1 of Minutes - The Authority noted that the retail price application of M/s Bharat biotech International Ltd for JENVAC has been recommended for rejection by the Multidisciplinary Committee of Experts based on the letter received from Ministry of Health and Family Welfare. The Authority also observed that as per the minutes of the 20<sup>th</sup> Standing Technical Sub Committee (STSC) meeting of the National Technical Advisory Group on Immunization (NTAGI) “ ...a head-to-head comparison of the three available JE vaccines should be undertaken by ICMR, using the same laboratories for assays, to investigate immunogenicity following one or two doses...”. Accordingly, the Authority decided to reject the retail price application of M/s Bharat Biotech International Ltd for JENVAC injection.

8.2 Agenda No. 2 of Minutes – The Authority deliberated upon the matter and directed that this can be examined to see whether it qualifies as a fit case for an ‘incremental innovation’ and hence, separate price.

8.3 Agenda No. 3 of Minutes – The Authority deliberated upon the matter and directed that this can be examined to see whether it qualifies as a fit case for an ‘incremental innovation’ and hence, separate price.

8.4 Agenda No. 4, 5, 6 and 7 of the Minutes – Noted.

**9. Agenda item no. 9 - Recommendation of the Committee constituted for examination of cases under para 19 of DPCO 2013**

9.1 Record of discussion for members being circulated separately.

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

Sd/-  
(Ritu Dhillon)  
Member Secretary