

**Minutes of the 201<sup>st</sup> (overall) and 69<sup>th</sup> meeting of the Authority under DPCO, 2013 held on 08.08.2019 at 11:00 AM**

The 201<sup>st</sup> meeting of the Authority (overall), which is the 69<sup>th</sup> meeting under the DPCO, 2013, was held on the 8<sup>th</sup> of August, 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) Dr. E. Reddy, DCGI, Deptt. of Health & Family Welfare
- (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 also present.

Dr. D. Usha Rao, Asstt Controller of Patent and Design, DPIIT attended the meeting as a special invitee for Agenda item no. 4(xii), 4(xiii) & 4(xiv).

I.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) Ms. Sneha Divakaran, Asstt. Secretary

Chairman, NPPA welcomed all present in the meeting.

**II. Agenda items**

**I. Agenda item no. 1 - Confirmation of Minutes of the 68<sup>th</sup> Meeting held on 25.06.2019.**

I.1 Noted.

**2. Agenda item no. 2 – Action Taken Report on decisions taken by NPPA in its 68th meeting dated 25.06.2019**

2.1 Noted.

**3. Agenda item no. 3 – Status of New Drug application**

3.1 Noted.

#### 4. Agenda item no. 4 - New Drug application

4.1 The Authority discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 4 (i) to 4(xviii) (total 18 Form I applications) falling under the purview of para 2(u) of DPCO, 2013 and approved the retail prices in 12 (twelve) cases [except six cases at sl no. 4(iv, v, xii, xiii, xiv and xv)] under para 5 and 15 of the DPCO 2013, as detailed below:

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

Agenda Item No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(i)	Telmisartan + Amlodipine + Hydrochlorothiazide tablet	Each uncoated tablet contains: Telmisartan IP 40mg, Amlodipine Besylate IP eq. to Amlodipine 5mg Hydrochlorothiazide IP 12.5mg	I Tablet	M/s Sun Pharma Laboratories Limited / M/s Sun Pharmaceuticals Industries Limited	8.11
4(ii)	Telmisartan + Hydrochlorothiazide tablet	Each uncoated tablet contains: Telmisartan IP 40mg, Hydrochlorothiazide IP 12.5mg	I Tablet	M/s Sun Pharma Laboratories Limited / M/s Sun Pharmaceuticals Industries Limited	8.55
4(iii)	Telmisartan + Amlodipine tablet	Each uncoated tablet contains: Telmisartan IP 40mg, Amlodipine Besylate IP eq. to Amlodipine 5mg	I Tablet	M/s Sun Pharma Laboratories Limited / M/s Sun Pharmaceuticals Industries Limited	8.14
4(iv)	Metoprolol + Telmisartan + Cilnidipine Tablet	Each film coated bilayered tablet contains: Metoprolol Succinate USP 50mg, Telmisartan IP 40mg Cilnidipine 10mg	I Tablet	M/s Ajanta Pharma Limited	Form-I application withdrawn by Company
4(v)	Metoprolol + Telmisartan + Cilnidipine Tablet	Each film coated bilayered tablet contains: Metoprolol Succinate USP 25mg, Telmisartan IP 40mg Cilnidipine 10mg	I Tablet	M/s Ajanta Pharma Limited	Form-I application withdrawn by Company
4(vi)	Metoprolol + Ramipril Tablet	Each film coated bilayered tablet contains: Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate 25mg (as prolonged Release Form), Ramipril IP 2.5mg	I Tablet	M/s Micro Labs Limited	10.26
4(vii)	Rosuvastatin + Clopidogrel Capsule	Each hard gelatine capsule contains: Rosuvastatin Calcium IP eq.	I Capsule	M/s Safetab Life Science / M/s Intas Pharmaceuticals	13.85

		to Rosuvastatin 10mg (as a film coated tablet), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (as two film coated tablet),		Limited	
4(viii)	Rosuvastatin + Clopidogrel Capsule	Each hard gelatine capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (as two film coated tablet), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (as two film coated tablet),	I Capsule	M/s Safetab Life Science / M/s Intas Pharmaceuticals Limited	18.04
4(ix)	Amoxicillin + Potassium Clavulanate Suspension	(a) Each 5ml of reconstituted suspension contains: Amoxicillin Trihydrate IP eq. to Amoxicillin 400mg, Potassium Clavulanate Diluted IP eq. to Clavulanic acid 57mg, (b) Sterile water for Injection IP 30ml for reconstitution.	Per ml Suspension	M/s Medicef Pharma / M/s Cadila Pharmaceuticals Limited	3.55
4(x)	Metformin + Glimepiride Tablet (Glycophage – G 0.5mg)	Glycophage – G 0.5mg Each uncoated bilayered tablet contains: Metformin Hydrochloride IP 500mg, (in prolonged release form) Glimepiride 0.5mg	I Tablet	M/s Swiss Garnier Biotech Pvt. Ltd. /M/s Franco-India Pharmaceuticals Pvt. Ltd.	3.65
4(xi)	Diclofenac + Absolute Alcohol Spray	Spray contains: Diclofenac Diethylamine IP 4.64% w/v (eq. to Diclofenac Sodium IP 4.00%w/v), Absolute Alcohol IP 10.00% v/v in topical Solution Base (Non-Aqueous)	Per ml Spray	M/s Akums Drugs and Pharmaceuticals Limited / M/s Abbott Healthcare Pvt. Ltd.	6.60
4(xvi)	Formoteraol Fumarate + Beclomethasone Dipropionate Inhaler	Each actuation Delivers contains: Formoterol Fumarate Dihydrate IP 6mcg, Beclomethasone Dipropionate IP 100mcg Suspended in Propellants HFA134a qs.	Per Metered dose	M/s Cipla Limited	1.46

B. Retail price fixed under para 15 of DPCO, 2013

Agenda Item No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(xvii)	Emtricitabine + Tenofovir Tablet	Each film coated tablet contains: Emtricitabine IP 200mg. Tenofovir Alafenamide Hemifumarate eq. to Tenofovir Alafenamide 25mg	I Tablet	M/s Hetero Labs Ltd. / M/s Emcure Pharmaceuticals Ltd.	51.34
4(xviii)	Dolutegravir + Emtricitabine + Tenofovir Alafenamide Tablet	Each film coated tablet contains: Dolutegravir Sodium eq. to Dolutegravir 50mg, Emtricitabine IP 200mg, Tenofovir Alafenamide Fumarate eq. to Tenofovir Alafenamide 25mg.	I Tablet	M/s Emcure Pharmaceuticals Limited	130.61

**Explanatory Notes:**

**4.2. Agenda item no. 4(xi, xvii, xviii):** The retail prices are to be notified after 10 days of uploading the draft working sheet.

**4.3 Agenda item no. 4(xii, xiii & xiv):** The Form-I applications filed by M/s Zydus Healthcare Ltd relating to retail price fixation of Vildagliptin + Metformin fixed dose combination tablets was discussed at length and the representative of DPIIT was requested to expedite their comments of the Department of Promotion of Industry and Internal Trade (DPIIT).

**4.4 Agenda item no. 4(xv):** The Authority deliberated upon the matter relating to retail price fixation of Paclitaxel protein bound particles for injection suspension 100 mg for M/s Intas pharmaceuticals Ltd and noted that

- i. The draft retail price worked out at Rs. 8926.76 per vial excluding GST as per the provisions of DPCO based on December 2018.
- ii. The subject formulation is also covered under Trade Margin Rationalization (TMR) of anti cancer drugs vide SO. No. 1041(E) of NPPA dated 27.02.2019.
- iii. After implementation of the above order, the companies refixed MRP based on TMR in the month of March, 2019 and MRP of the formulation, company wise, ranges between Rs. 4622/vial to Rs. 7918.20/vial.

The Authority also took note of insertion made in DPCO on 3<sup>rd</sup> January, 2019 vide paragraph 9(7) of DPCO, 2013 that for fixing or revising the ceiling price for formulations, the Government may, if it is necessary to do so, consider market based data available for *any month*, as deemed fit. After taking all the above into consideration, the Authority directed NPPA to rework the retail price based on the price to retailer (PTR) and Moving Annual Turnover (MAT) of the period post implementation of the TMR Order. Further, the Authority also

directed that a notice may be issued to the companies which have not applied for TMR for revision of MRP.

**4.5 Agenda item no. 4(xvi):** The representation received against draft upload of the working sheet was deliberated in the 12<sup>th</sup> meeting of the Multidisciplinary Committee of Experts held on 31.07.2019. M/s Cipla Ltd provided another representation on 07.08.2019 requesting for special price which was considered in the meeting. The Authority noted no separate license of new drugs has been obtained from DCGI regarding the incremental innovation as claimed. Accordingly, the Authority decided to reject the representation of M/s Cipla Ltd and approved the retail price at Rs. 1.46 per metered dose excluding GST as per the draft working sheet.

**4.6 Agenda item no. 4(xvii):** The Authority observed that as M/s Hetero Healthcare Ltd had not obtained prior price approval, before launch of the subject formulation, a notice was issued to M/s Hetero Healthcare Ltd for non-compliance to the orders of DPCO 2013. The retail price proposed for M/s Emcure Pharmaceuticals (marketer)/ M/s Hetero Labs Ltd (manufacturer) was approved.

## **5. Agenda item no. 5 – Status of implementation of Review Cases**

5.1 Noted.

**6. Agenda item no. 6 - Review application against ceiling price fixation of 'Tiotropium Inhalation (MDI) 9 mcg/dose vide S.O. 1028(E) dated 26.02.2019 filed by M/s Zydus Healthcare Ltd.**

6.1 The Authority deliberated upon the matter and observed while fixing the ceiling price of Tiotropium Inhalation (MDI) 9 mcg/dose, data had been called for from all the manufacturers of the said formulations. Despite request, M/s Zydus Healthcare Ltd did not provide the data to NPPA. The Authority desired that the company may be asked to explain the same.

**7. Agenda item no. 7 - Recommendation of Standing National Committee of Medicines (SNCM) against ceiling price fixation of Paclitaxel Injection based on representation made by M/s Fresenius Kabi India Pvt. Ltd – regarding nano based formulation.**

7.1 The Authority deliberated upon the matter in detail and noted that in the review petition, M/s Fresenius Kabi India Pvt. Ltd contended that their formulation 'nanoxel' is not a conventional paclitaxel but a polymer based nano particle paclitaxel drug. Hence, it is not a scheduled drug and is not to be considered in the price calculation of paclitaxel. As per the review order of Department of Pharmaceuticals dated 19.09.2016 NPPA was directed to revise

the price in the light of para 11(3) of DPCO 2013. The matter was sent to Standing National Committee on Medicines (SNCM) for its examination and the recommendation of the Committee received vide its letter dated 10.07.2019, read as under:

“1. Chemically the nano formulation of any drug (eg. Pegylated liposomal doxorubicin, nanoparticle albumin bound paclitaxel, etirinotecan pegol etc) are considered separate from their conventional counterparts (examples: doxorubicin, paclitaxel and irinotecan respectively)  
2. NLEM Oncology expert group has not found sufficient evidence to categorise the nano formulations of paclitaxel as ‘essential’. However, nano formulation is an innovative product.”

Accordingly, the Authority decided that the matter may be referred to Department of Pharmaceuticals for guidance in this matter on whether amendment in DPCO, 2013 is required for exclusion of all Nano based formulations or DoP will issue clarification if the nano formulations is to be treated under para 2(u) f DPCO 2013 relating to new drugs.

**8. Agenda item no. 8 – Ceiling Price notified by the NPPA for Oxygen Gas being supplied to the various Hospitals through composite contract**

8.1 The Agenda was deferred.

**9. Agenda item no. 9 – Revision of ceiling price of scheduled formulation Silver Sulphadiazine Cream 1% – Communication from Rajasthan Medical Services Corporation Limited showing inability to procure the same at ceiling price notified by NPPA.**

9.1 The Authority deliberated the matter in detail and approved the revised ceiling price of Silver Sulphadiazine cream 1% at Rs. 0.50 per gm excluding GST.

**10. Agenda item no. 10 – Representations regarding classification of Coronary Stents**

10.1 The Authority was appraised that the Secretariat of Standing National Committee on Medicines (SNCM) vide their letter dated 06.08.2019 requested to await the recommendation of the SNCM in view of the representations from manufacturers to present new evidence in support of their innovation which was under the consideration of the SNCM. The same was noted.

**11. Agenda item no. 11 - Intimation of Minutes of 12th meeting of Multidisciplinary Committee of Experts held on 30.07.2019.**

11.1 Noted.

**12. Agenda item no. 12 - Overcharging cases pertaining to eight (8) medical devices which are regulated as 'Drugs' under D&C Act, 1940**

12.1 The matter was discussed and it was informed by DCGI that the eight medical devices are regulated as drugs under the Drugs & Cosmetics Act, 1940. The Authority requested DCGI to forward a clarificatory note in the matter.

**13. Agenda item no. 13 - Review application against ceiling price fixation of Ringer lactate Injection fixed vide S.O. 2401(E) dated 28.07.2017 filed by**

**(i) M/s Albert David Ltd**

**(ii) M/s Aculife healthcare Pvt. Ltd**

**(iii) M/s B. Braun Medical (india) Pvt. Ltd**

**(iv) M/s Fresenius Kabi India Pvt. Ltd**

**(v) M/s Ostuka Pharmaceuticals India Pvt. Ltd.**

13.1 The Authority deliberated upon the matter in detail and noted that the DCGI had not given a separate license for these products for having special features. Since the drug remained the same, the price increase due to special packaging may distort market price. However, it is also important to acknowledge R&D efforts for improved drug delivery systems. Para 4 of DPCO 2013 does not prescribe the formula for price revision in such cases. Department of Pharmaceuticals be requested for clear directions in such cases.

Accordingly, the Authority directed that the matter may be referred to Department of Pharmaceuticals for further guidance in this regard.

**14. Agenda item No. 14 - Presentation of Data for price fixation of Liposomal Amphotericin B as per "Working sheet related to price notified on 28<sup>th</sup> June 2013 under DPCO, 2013**

14.1 The Authority deliberated the matter in detail and decided to implement the directions of the Hon'ble High Court of Delhi. Accordingly, the Authority approved the ceiling price of Amphotericin B (Lipid) 50 mg injection and Amphotericin B (Liposomal) 50 mg injection at Rs. 3136.81 and Rs. 7306.60 per pack excluding GST respectively.

**15. Agenda item No. 15 – Ceiling prices of Orthopaedic Knee Implants for Knee Replacement System**

15.1 The Authority deliberated upon the matter in detail and noted the following requests made by various industry associations:

- (i) consideration of 20% increase in the ceiling price of orthopaedic knee implants for all categories due to currency depreciation.
- (ii) No price increase (even WVPI adjustment) was given in the year 2018.
- (iii) Separate ceiling price for knee implants components like Bone cement and components required for revision surgery.

15.2 The Authority observed that there is more than 30% increase in sale of knee implants during the period of July 18 to June 19 in comparison to that of previous year. It may be inferred that fixation of ceiling prices of orthopaedic knee implants under Para 19 of the DPCO, 2013 has contributed to increased access to affordable healthcare to general public.

15.3 The Authority noted that the non scheduled devices/drugs are monitored under para 20(1) of DPCO, 2013. Knee Implants are non-scheduled devices/ drugs. No annual increase was allowed in year 2018.

15.4 After taking all the above into consideration, the Authority decided that in continuation to the notifications S.O. 2668(E) dated 16th August, 2017 and S.O. 298(E) dated 13th August, 2018, regarding fixation of ceiling prices of orthopaedics knee implants under para 19 of DPCO, 2013, the ceiling prices shall continue and be further monitored as per the provisions of paragraph 20(1) of DPCO, 2013 for a period of one year. Further, the ceiling price of orthopaedics knee implants will be reviewed after a period of one year.

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

Sd/-  
(Ritu Dhillon)  
Member Secretary