

Minutes of the 244th (overall) and 112th meeting of the Authority under DPCO, 2013 held on 01.05.2023 at 03:00 PM.

The 244th meeting of the Authority (overall), which is the 112th meeting under the DPCO, 2013, was held on 1st May, 2023 at 03:00 PM under the Chairmanship of Shri Kamlesh Kumar Pant, Chairman, NPPA. The following Authority members of NPPA were present during the meeting:

- (i) Dr. Vinod Kotwal, Member Secretary, NPPA
- (ii) Shri G. Venkatesh, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure
- (iii) Shri Antony Cyriac, Economic Advisor, Department of Economic Affairs through video conferencing

Shri A. K. Pradhan, Jt. Drug Controller, CDSCO, Ministry of Health & Family Welfare also was present.

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

- (i) Shri Manmohan Sachdeva, Advisor (Cost-I)
- (ii) Ms. Rashmi Tahiliani, Jt. Director (Pricing)
- (iii) Shri Mahaveer Saini, Deputy Director (Pricing)

II. Agenda items

1. Agenda item no. 1 - Confirmation of Minutes of the 111th Meeting held on 29.03.2023.

1.1 The Authority confirmed the minutes without any change.

2. Agenda item no. 2 - (a) Action Taken Report (ATR) on decisions taken by NPPA in its 111th Meeting held on 29.03.2023.

2.1 Noted.

3. Agenda item no. 3 - Status of New Drug applications

3.1 Noted.

4. Agenda item no. 4 – New Drug applications for Price fixation under Para 5 and Para 15 of DPCO, 2013

4.1 The Authority discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 4 (i) to 4 (xv) (total 15 Form I applications containing retail price fixation of 15 new drug) falling under the purview of Para 2(1)(u) of DPCO, 2013 and approved the retail prices of 15 (Fifteen) new drugs under Para 5 and 15 of the DPCO 2013, as detailed in **Table 1:**

Table No. 1: Retail price fixation of new drugs

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (i)	Amoxycillin and Potassium Clavulanate Oral Suspension (Combi pack with Sterile Water for Reconstitution of Dry Syrup)	Each combi pack contains: A. Amoxycillin and Potassium Clavulanate Oral suspension IP Composition: Each 5ml of reconstituted suspension contains: Amoxycillin Trihydrate IP eq. to Amoxycillin 600mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 42.9mg B. 2 Ampoules of sterile water for reconstitution of dry syrup each ampoule contains: sterile water for injection IP 25ml	Each Combi Pack	M/s Malik Lifesciences Pvt. Ltd. / M/s Dr. Reddy's Laboratories Limited	162.11
4 (ii)	Paracetamol, Phenylephrine Hydrochloride & Chlorpheniramine maleate Tablets	Each uncoated tablet contains: Paracetamol IP 500mg Phenylephrine Hydrochloride IP 10mg Chlorpheniramine maleate IP 2mg	1 Tablet	M/s East African (India) Overseas / M/s Alkem Laboratories Ltd.	4.42
4 (iii)	Amoxycillin & Potassium Clavulanate Tablets IP	Each film coated tablet contains: Amoxycillin Trihydrate IP eq. to Amoxycillin 875mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 125mg	1 Tablet	M/s Theon Pharmaceuticals Limited / M/s FDC Limited	33.92
4 (iv)	Ofloxacin and	Each 5ml contains:	1 ml	M/s Skymap	1.45

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Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Betamethasone Sodium Phosphate Eye / Ear Drops	Ofloxacin IP 0.3% w/v Betamethasone Sodium Phosphate IP 0.1% w/v Benzalkonium Chloride Solution IP 0.02% v/v (As preservative)		Pharmaceuticals Pvt. Ltd. / M/s German Remedies Pharmaceuticals Pvt. Ltd.	
4 (v)	Tranexamic Acid and Etamsylate Tablets	Each film coated tablet contains: Etamsylate BP 250mg Tranexamic Acid IP 500mg.	1 Tablet	M/s Windlas Biotech Pvt. Ltd. / M/s Torrent Pharmaceuticals Ltd.	23.37
4 (vi)	Aceclofenac and Paracetamol Tablets	Each film coated tablet contains: Aceclofenac IP 100mg Paracetamol IP 325mg	1 Tablet	M/s Aagya Biotech Pvt. Ltd. / M/s German Remedies Pharmaceuticals Pvt. Ltd.	4.83
4 (vii)	Calcium, Vitamin D3, Mecobalamin, L-Methylfolate Calcium & Pyridoxal-5-Phosphate Tablets	Each film coated tablet contains: Calcium Carbonate IP 1250mg eq. to Elemental Calcium 500mg Vitamin D3 IP 2000 IU Mecobalamin IP 1500mcg L-Methylfolate Calcium 1mg Pyridoxal-5-Phosphate 20mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Emcure Pharmaceuticals Ltd.	18.36
4 (viii)	Itraconazole Capsules 65mg (Supra-Bioavailable Formulation)	Each hard gelatin capsule contains: Itraconazole BP 65mg	1 Capsule	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	11.94
4 (ix)	Chlorhexidine gluconate, Metronidazole and Lignocaine Hydrochloride Gel	Composition: Chlorhexidine gluconate solution IP eq. to Chlorhexidine 1 % w/w, Metronidazole Bezoate IP eq. to Metronidazole 1% w/w Lignocaine	1Gm	M/s Alaina Healthcare Pvt. Ltd. / M/s Abbott Healthcare Pvt. Ltd.	3.75

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Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Hydrochloride IP 2% w/w			
4 (x)	Itraconazole Capsules 65mg (Supra-Bioavailable Formulation)	Each hard gelatin capsule contains: Itraconazole BP 65mg	1 Capsule	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Emcure Pharmaceuticals Limited	11.94
4 (xi)	Itraconazole Capsules 130mg (Supra-Bioavailable Formulation)	Each hard gelatin capsule contains: Itraconazole BP 130mg	1 Capsule	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Emcure Pharmaceuticals Limited	20.72
4 (xii)	Pantoprazole (EC) and Levosulpiride (SR) Capsules	Each hard gelatin capsule contains: Pantoprazole Sodium eq. to Pantoprazole IP 40mg (as enteric coated pellets) Levosulpiride 75mg (As sustained release pellets)	1 Capsule	M/s Theon Pharmaceuticals Ltd. / M/s Cadila Pharmaceuticals Ltd.	16.15
4 (xii)	Linezolid Infusion	Each 100ml contains: Linezolid IP 200mg Dextrose Anhydrous IP 5mg water for Injection	1 ml	M/s AXA Parenterals Ltd. / M/s Themis Medicare Limited	1.36
4 (xiv)	Bisoprolol Fumarate and Amlodipine Tablets	Each film coated tablet contains: Bisoprolol Fumarate IP 5mg Amlodipine Besylate IP Eq. to Amlodipine 5mg	1 Tablet	M/s Swiss Garaniers Biotech Pvt. Ltd. / M/s Zydus Healthcare Limited	8.34
4 (xv)	Alpha Lipoic Acid + Mecobalamin + Myo-Inositol + Folic Acid + Pyridoxine Hydrochloride + Chromium Picolinate and Benfortiamine Tablets	Each film coated table contains: Alpha Lipoic Acid IP 200mg Mecobalamin IP 1500mcg Myo-Inositol IP 100mg Folic Acid IP 1.5mg Pyridoxine Hydrochloride IP 3mg Chromium Picolinate IP eq. to Elemental chromium 200mcg Benfortiamine 200mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Zydus Healthcare Limited	22.86

5. Agenda item no. 5 – Status of implementation of Review cases

5.1 Noted.



6. Agenda item no. 6 -Retail Price fixation of formulation "Formoterol Fumarate Dihydrate 6mcg + Beclomethasone Dipropionate IP 100mcg Inhaler (MDI) for M/s Cipla Limited in view of DoP's Review Order dated 03.10.2022.

6.1 The Authority noted that no clear recommendation about closure of the matter have been received from Multi Disciplinary Committee of Experts on non receipt of requisite details from M/S Cipla Limited. Hence, the Authority referred the matter back to MDC to provide clear recommendations in the matter.

7. Agenda item no. 7 - Fixation of Ceiling Prices of 20 Scheduled formulation under Revised Schedule-I (NLEM, 2022).

1. The Authority noted that prices of 651 formulations have been notified under NLEM 2022 based on the methodology for fixation of ceiling price of scheduled formulations under revised Schedule-I (NLEM, 2022) that was deliberated in the 104th meeting of the Authority held on 23.11.2022.
2. Authority also noted that change in WPI index w.e.f. 01.04.2023 is 12.1218% and that the ceiling prices of 651 formulations fixed under NLEM 2022 till 31.03.2023 have already been revised and notified on 31.03.2023 after applying WPI increase of 12.1218%.
3. The remaining scheduled formulations for which ceiling prices are yet to be re-fixed under NLEM 2022 have also been revised and notified on 31.03.2023 after applying WPI increase of 12.1218%.
4. For such formulations for which ceiling prices under NLEM, 2022 are yet to be fixed, the Authority decided to follow the following methodology:
 - a. The prices shall first be computed on the basis of market database for the month of July, 2022 by following the methodology agreed upon by the Authority in its 104th and 111th meetings; and
 - b. For arriving at the ceiling price, the WPI increase of 12.1218% shall be applied on the prices as computed as per (a) above.
5. The Authority noted that similar methodology was applied while fixing the ceiling prices under NLEM, 2015. The Authority took note of methodology decided in 27th Authority meeting held on 29.03.2016 regarding ceiling price fixations considering Pharmatrac data for August 2015 after giving effect of WPI which was reduction @ 2.7015%, with effect from 01.04.2016. It was also noted in the 27th Authority meeting that such principle i.e. giving effect of WPI was being followed consistently for fixation of ceiling price under original schedule-I of DPCO 2013 and hence would be followed uniformly while fixing the ceiling price of schedule formulation under revised Schedule-I.
6. The Authority noted that based on the above methodology (as per 4 above), ceiling prices for 20 scheduled formulations were uploaded on the NPPA website for 10 working days to invite comments in compliance to O.M. No. F. NO. 31015/44/2016-PI.I dated 11.07.2016 issued by Department of Pharmaceuticals.

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7. The Authority noted that no representation has been received in respect of following 12 scheduled formulations. Hence, Authority deliberated and approved the ceiling prices of following 12 formulations under Para 4 (1) of DPCO 2013.

Table 1: Ceiling Price fixation under Para 4(1) of DPCO, 2013

S.No	Section	Formulation	Dosage form(s) and strength(s)	Prevailing Ceiling Prices		New Ceiling Price	Unit
				(Rs./ Unit)	SO No.& dated		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
1	6.2.2.8	Gentamicin (Note 1)	Injection 40mg/ml. (2ml)	10.48 per pack OR 5.24/ML	(S.O. 1573(E) dated 31.03.2023)	4.85	1 ML
2	6.2.2.8	Gentamicin (Note 1)	Injection 40mg/ml. (1.5 ml)	Not fixed	Not fixed	2.9	1 ML
3	3.3	Dexamethasone (Note 1)	Injection 4mg/ml. (5 ML)	Not Fixed	Not Fixed	2.57	1 ML
4	2.1.5	Paracetamol	Injection 150mg/ml. (2ML)	8.02 per pack OR 4.01/ML	(S.O. 1573(E) dated 31.03.2023)	3.97	1 ML
5	3.3	Dexamethasone (Note 1)	Injection 4mg/ml. (2 ML)	11.60 per pack OR 5.80/ML	(S.O. 1573(E) dated 31.03.2023)	5.09	1 ML
6	19.3.5	Japanese encephalitis vaccine	As licensed (4mcg to 6 mcg)	868.4	(S.O. 1573(E) dated 31.03.2023)	677.13	1 Vial
7	18.4.1	Clomiphencitrate	Capsule 50mg	38.11	(S.O. 1573(E) dated 31.03.2023)	27.37	1 Capsule
8	2.1.5	Paracetamol	Injection 150mg/ml. (100 ML)	Not fixed	Not fixed	1.6	1 ML
9	23.2.1.3	Fluoxetine	Tablet 10 mg	3.1	(S.O. 1573(E) dated 31.03.2023)	2.78	1 Tablet
10	23.2.1.3	Fluoxetine	Tablet 40 mg	6.64	(S.O. 1573(E) dated 31.03.2023)	5.56	1 Tablet
11	23.2.1.3	Fluoxetine	Tablet 60 mg	9.21	(S.O. 1573(E) dated 31.03.2023)	8.25	1 Tablet
12	7.4.6	Fluoxetine	Tablet 20 mg	4.93	(S.O. 1573(E) dated 31.03.2023)	4.15	1 Tablet



Note 1: Gentamicin 40mg/ml and Dexamethasone 4mg/ml: As decided in the 111th meeting, the prices have been recalculated for Gentamycin Injection 40mg/ml in 2 ML pack and in 1.5 ML pack and Dexamethasone Injection 4mg/ml in 2 ML pack and in 5 ML pack. The draft working sheets were re-uploaded for 10 working days to invite comments. However, no comments were received and accordingly, the Authority approved the prices on per pack basis.

8. The Authority deliberated and approved the ceiling prices of following 8 scheduled formulations under Para 6 (1) of DPCO 2013

Table 2: Ceiling Price fixation under Para 6(1) of DPCO, 2013

S.N	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Prices		New Ceiling Price	Unit
				(Rs./Unit)	SO & dated		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
1	14.1.5	Povidone iodine (Note 1)	Solution (4%)	2.16	(S.O. 1573(E) dated 31.03.2023)	1.74	1 ML
2	23.1.4	Risperidone (Note 2)	Injection (Longacting) 25mg	New added	New added	1930.19	1 ML
3	23.1.4	Risperidone	Injection (Longacting) 37.5 mg	New added	New added	2649.26	1 ML
4	19.3.5	Japanese encephalitis vaccine	As licensed (upto 3 mcg)	661.59	(S.O. 1573(E) dated 31.03.2023)	518.63	1 Vial
5	18.4.1	Clomiphene citrate	Capsule 100 mg	69.3	(S.O. 1573(E) dated 31.03.2023)	51.14	1 Capsule
6	6.2.2.1	Azithromycin	Capsule 500mg	20.64	(S.O. 1573(E) dated 31.03.2023)	19.03	1 Capsule
7	6.7.2.1	Efavirenz	Capsule 200 mg	29.97	(S.O. 1573(E) dated 31.03.2023)	21.98	1 Capsule
8	6.5.3	Fluconazole	Capsule 100mg	31.46	(S.O. 1573(E) dated 31.03.2023)	21.4	1 Capsule

Note 1: Povidone iodine (4%): Authority noted the representation dated 24.04.2022 received from M/s Win Medicare for revision of PTR from Rs.69.60 per 50 ml to Rs.77.20 per 50 ml and that the manufacturing company had filed Form V on 11.05.2022. Accordingly, the Authority noted that ceiling price considering the revised PTR is Rs.1.74 per ml instead of Rs.1.57 as uploaded. The same was approved by the Authority.

Note 2: Risperidone (Long Acting) 25mg Injection: The Authority recalled that ceiling price of Risperidone (Long Acting) 25mg Injection was deferred in 108th meeting held on 27.01.2023 based on representation of M/S Johnson & Johnson Private Ltd and it

was directed that clarification may be sought from DCGI with respect to the approval status of RESTONORM marketed by M/s Aleteus Biogenics Ltd and manufactured by M/s HFA Formulations Pvt Ltd. Accordingly, letter was sent to the office of DCGI on 02.02.2023 Office. DCGI vide letter dated 22.03.2023 informed that no permission has been issued to M/s HFA Formulations Pvt Ltd. for Risperidone Long Acting injection 25mg/ml. Further, DCGI has initiated an investigation in this respect.

Accordingly, the Authority noted that the ceiling price of Rs.1930.19 per ml is calculated only one the basis of one line item (i.e. excluding M/s HFA Formulations Pvt Ltd) after applying monopoly clause as per Para 6(1) of DPCO, 2013.

8. Agenda item no. 8 - Guidelines for application received from the marketers for change in manufacturer for the formulations for which retail price already notified and product launched in the market.

8.1 The agenda item could not be deliberated in detail due to paucity of time and hence deferred for detailed deliberations in the next Authority meeting.

The meeting ended with a vote of thanks to the Chair and all the participants in the meeting.

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4/5/2023
(Dr. Vinod Kotwal)
Member Secretary