

Minutes of the 235th(overall) and 103rdmeeting of the Authority under DPCO, 2013 held on 10.11.2022 at 11:00 AM

The 235thmeeting of the Authority (overall), which is the 103rdmeeting under the DPCO, 2013, was held on 10thof November at 11:00AM 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 Saikat Sarkar, Economic Adviser, Department of Economic Affairs

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

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

- (i) Shri Sanjay Kumar, Advisor (Cost-II)
- (ii) Ms. Rashmi Tahiliani, Joint Director (Pricing)
- (iii) Shri Mahaveer Saini, Deputy Director (Pricing)

1.2 Chairman, NPPA and other Authority members welcomed Shri Saikat Sarkar, Economic Adviser, Department of Economic Affairs, the new Authority member who has joined in place of Ms. Manisha Sensarma, Economic Adviser. The contribution made by Ms. Manisha Sensarma, Adviser during her tenure as Authority member was also appreciated.

II. Agenda items

1. Agenda item no. 1 - Confirmation of Minutes of the 102ndMeeting held on 27.09.2022

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 102ndMeeting held on 27.09.2022

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 pricefixation of new drugs as presented in Agenda no. 4 (i) to 4(xxxv) (c) (total 43 Form I applications containing retail price fixation of 43 new drugs) falling under the purview of Para 2(1)(u) of DPCO, 2013 and approved the retail prices of 40(Forty) new drugs under Para 5 and 15 of the DPCO 2013, as detailed below:

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
1.	Telmisartan and Hydrochlorothiazide Tablet IP	Each Uncoated Bilayered Tablet Contains: Telmisartan IP 40mg Hydrochlorothiazide IP 12.5mg	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Sun Pharmaceuticals Industries Limited	10.32
2.	Trastuzumab 375mg Injection	Lyophilized powder for intravenous infusion (to be supplied with bacteriostatic water for injection 20ml for reconstitution), Multi-use vial Each Lyophilized vial contains: Trastuzumab 375mg Excipients: L-Histidine Hydrochloride monohydrate EP 8.44mg L-Histidine USP 5.45mg α , α -Trehalose dihydrate NF 340.90mg Polysorbate 20 NF 1.53mg pH 6.0 Diluent: Bacteriostatic water for injection 20ml for reconstitution	Per Vial	M/s Zydus Lifesciences Ltd.	12420.28
3.	Glimepiride, Voglibose & Metformin (Extended-release) tablet	Each uncoated bilayered tablet contains: Glimepiride IP 1mg, Voglibose IP 0.2mg Metformin	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Apex Laboratories Pvt. Ltd.	10.00

Handwritten signature/initials

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Hydrochloride IP 500mg (As Extended-release)			
4.	Cholecalciferol (Vitamin D3) Oral Solution	Each 5ml contain: Cholecalciferol IP 60000 IU (In nano Droplet form)	1 ML	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Cadila Pharmaceuticals Ltd.	12.03
5.	Ibuprofen and Paracetamol Tablet IP	Each uncoated tablet contains: Ibuprofen IP 400mg Paracetamol IP 325mg	1 Tablet	M/s Shiva Biogenetic Pharmaceuticals Pvt. Ltd. / M/s Mankind Prime Labs Ltd.	1.45
6.	Myo-Inositol, Melatonin & Folic Acid Tablet	Each film coated tablet contains: Myo-Inositol USP 1gm Melatonin BP 1.5mg Folic Acid IP 1000mcg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Mankind Pharma Ltd.	20.93
7.	Ibuprofen & Paracetamol Tablet	Each uncoated tablet contains: Ibuprofen IP 400mg Paracetamol IP 325mg	1 Tablet	M/s Innova Captab Limited / M/s Abbott India Limited	1.45
8.	Olmesartan Medoxomil & Amlodipine Tablet	Each Film Coated Tablet contains: Olmesartan Medoxomil IP 20mg Amlodipine Besilate IP eq. to Amlodipine 5mg	1 Tablet	M/s Hetero Labs Ltd. / M/s Mankind Prime Labs Pvt. Ltd.	11.41
9.	Ibuprofen and Paracetamol Suspension	Each 5ml contains: Ibuprofen IP 100mg Paracetamol IP 162.5mg	1 ml	M/s Innova Captab Limited / M/s Abbott India Limited	0.41
10.	Olmesartan Medoxomil, Amlodipine & Hydrochlorothiazide Tablet	Each Film Coated Tablet contains: Olmesartan Medoxomil IP 20mg Amlodipine Besilate IP eq. to Amlodipine 5mg Hydrochlorothiazide IP 12.50mg	1 Tablet	M/s Pharma Force Lab. / M/s Mankind Prime Labs Pvt. Ltd.	13.24
11.	Olmesartan Medoxomil & Amlodipine Tablet	Each Film Coated Tablet contains: Olmesartan Medoxomil IP 40mg Amlodipine Besilate IP eq. to Amlodipine 5mg	1 Tablet	M/s Hetero Labs Ltd. / M/s Mankind Prime Labs Pvt. Ltd.	18.77

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
12.	Paracetamol & Mefenamic Acid Suspension	Each 5ml contains: Paracetamol IP 250mg Mefenamic Acid 100mg	1 ml	M/s Pharma Force Lab. / M/s Mankind Prime Labs Pvt. Ltd.	0.75
13.	Telmisartan, Chlorthalidone & Metoprolol ER Tablet	Each film coated bilayered tablet contains: Telmisartan IP 40mg Chlorthalidone IP 6.25mg Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate (as Extended release) 25mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Abbott Healthcare Pvt. Ltd.	9.51
14.	Telmisartan, Chlorthalidone & Metoprolol ER Tablet	Each film coated bilayered tablet contains: Telmisartan IP 40mg Chlorthalidone IP 6.25mg Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate (as Extended release) 50mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Abbott Healthcare Pvt. Ltd.	10.88
15.	Paracetamol Bilayered Sustained Release Tablet	Each uncoated bilayered sustained release tablet contains: Paracetamol IP (as Immediate release) 300mg Paracetamol IP (as Sustained release) 700mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Zydus Healthcare Limited	4.15
16.	Glimepiride and Metformin Hydrochloride (ER) Tablet	Each uncoated bilayered tablet contains: Glimepiride IP 4mg Metformin Hydrochloride IP 1000mg (In extended-release form)	1 Tablet	M/s Innova Captab Ltd. / M/s Cipla Ltd.	10.87
17.	Glimepiride and Metformin Hydrochloride (ER) Tablet	Each uncoated bilayered tablet contains: Glimepiride IP 3mg Metformin Hydrochloride IP 1000mg (In extended-	1 Tablet	M/s Innova Captab Ltd. / M/s Cipla Ltd.	10.18

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		release form)			
18.	Glimepiride and Metformin Hydrochloride (ER) Tablet	Each uncoated bilayered tablet contains: Glimepiride IP 3mg Metformin Hydrochloride IP 500mg (In extended-release form)	1 Tablet	M/s Innova Captab Ltd. / M/s Cipla Ltd.	9.66
19.	Glimepiride and Metformin Hydrochloride (ER) Tablet	Each uncoated bilayered tablet contains: Glimepiride IP 4mg Metformin Hydrochloride IP 500mg (In extended-release form)	1 Tablet	M/s Innova Captab Ltd. / M/s Cipla Ltd.	10.36
20.	Amoxicillin and Potassium Clavulanate Oral Suspension IP	Each Combipack contains: (A) Amoxicillin and Potassium Clavulanate Oral Suspension IP Composition: Each 5ml of reconstituted suspension contains: Amoxicillin Trihydrate IP eq. to Amoxicillin 600mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 42.9mg (B) 2 Ampoules of sterile water for reconstitution of Dry syrup Each 25ml ampoule contains: Sterile water for injection IP	Each combi Pack	M/s Malik Life Sciences Pvt. Ltd. / M/s Cipla Limited	168.43
21.	Olmesartan Medoxomil, Amlodipine & Hydrochlorothiazide Tablet	Each film coated tablet contains: Olmesartan Medoxomil IP 40mg Amlodipine Besilate IP eq. to Amlodipine 5mg Hydrochlorothiazide IP 12.5mg	1 Tablet	M/s Pharma Force Lab. / M/s Mankind Prime Labs Pvt. Ltd.	17.59
22.	Diclofenac Sodium &	Each ml contains:	1 ml	M/s Niche	Note 1



S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Dicyclomine Hydrochloride Injection	Diclofenac Sodium IP 50mg Dicyclomine Hydrochloride IP 20mg Benzalkonium Chloride Solution IP 0.05% w/v Water for Injections q.s.		pharmLifesciences Pvt. Ltd. / M/s Seagull Pharmaceuticals Pvt, Ltd.	
23.	Diclofenac Diethylamine, Methyl Salicylate & Menthol Topical Spray	Composition: Diclofenac Diethylamine IP 2.32% w/w (eq. to Diclofenac Sodium 2% w/w) Methyl Salicylate IP 10% w/w Menthol IP 5% w/w	1 Gram	M/s Pontika Aerotech Limited / M/s Zydus Healthcare Limited	3.14
24.	Acetylcysteine & Acebrophylline Tablet	Each film coated tablet contains: Acetylcysteine BP 600mg Acebrophylline 100mg	1 Tablet	M/s Pure and Care Healthcare Pvt. Ltd. / M/s Cadila Pharmaceuticals Limited	Note 2
25.	Methylcobalamin, Alpha Lipoic Acid, Inositol, Folic Acid, Chromium Polynicotinate, Selenium Dioxide & Benfotiamine Capsule	Each soft Gelatin Capsule contains: Methylcobalamin IP 1500mcg Alpha Lipoic Acid USP 100mg Inositol USP NF 100mg Folic Acid IP 1.5mg Chromium Polynicotinate 200mcg Selenium Dioxide USP 55mcg Benfotiamine 150mg	1 Capsule	M/s Olive Healthcare / M/s Intas Pharmaceuticals Limited	Note 3
26.	Glycopyrrolate + Neostigmine Methylsulphate Injection	Each 5ml contains: Glycopyrrolate IP 0.5mg Neostigmine Methylsulphate IP 2.5mg Water for Injection IP q.s.	5 ml Ampoule	M/s Samarth Life Sciences Pvt. Ltd.	51.19
27.	Pantoprazole Dual Release Gastro Resistant Tablet	Each Dual Release Gastro Resistant Tablet Contains: Pantoprazole Sodium	1 Tablet	M/s Pure and Care Healthcare Pvt. Ltd. / M/s Cipla Limited	15.58

M.

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Eq. to Pantoprazole 80mg			
28.	Olmesartan Medoxomil and Amlodipine Besylate Tablet	Each film coated tablet contains: Olmesartan Medoxomil BP 20mg Amlodipine Besylate IP eq. to Amlodipine 5mg	1 Tablet	M/s Cadila Pharmaceuticals Limited	11.61
29.	Pantoprazole Dual-Release Gastro-Resistant Tablet	Each Dual-release Gastro-resistant tablet contains: Pantoprazole Sodium IP eq. to Pantoprazole 80mg	1 Tablet	M/s Zydus Healthcare Limited	15.58
30.	Pantoprazole powder for Oral Suspension (Sodium Bicarbonate as buffer)	Each sachet contains: Pantoprazole Sodium IP eq. to Pantoprazole 40mg (Sodium Bicarbonate as buffer)	1 Sachet of 5gm	M/s Alkem Laboratories Ltd.	9.05 (Note 4)
31.	Atorvastatin & Bempedoic Acid Tablet	Each film coated tablet contains: Atorvastatin Calcium IP eq. to Atorvastatin 80mg Bempedoic Acid 180mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Zydus Healthcare Limited	50.71
32.	Atorvastatin & Bempedoic Acid Tablet	Each film coated tablet contains: Atorvastatin Calcium IP eq. to Atorvastatin 80mg Bempedoic Acid 180mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Sun Pharma Laboratories Limited	50.71
33.	Telmisartan and Bisoprolol Tablet	Each film coated tablet contains: Telmisartan IP 40mg Bisoprolol Fumarate IP 5mg	1 Tablet	M/s Micro labs Ltd.	11.81
34.	Sitagliptin and Metformin Hydrochloride (ER) Tablet	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (as Extended Release)	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Lupin Limited	21.56
35.	Sitagliptin and	Each film coated	1 Tablet	M/s Ravenbhel	18.67

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Metformin Hydrochloride (ER) Tablet	bilayered tablet contains: Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg (as Extended Release)		Healthcare Pvt. Ltd. / M/s Unison Pharmaceuticals Pvt. Ltd.	
36.	Sitagliptin and Metformin Hydrochloride Tablet	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Mediforce Healthcare Pvt. Ltd. / M/s Mankind Prime Labs Pvt. Ltd.	18.34
37.	Sitagliptin and Metformin Hydrochloride Tablet	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Mediforce Healthcare Pvt. Ltd. / M/s Mankind Prime Labs Pvt. Ltd.	20.02
38.	Sitagliptin and Metformin Hydrochloride (ER)Tablets	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg (as Extended Release)	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Unison Pharmaceuticals Pvt. Ltd.	20.06
39.	Sitagliptin and Metformin Hydrochloride (ER)Tablets	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (as Extended Release)	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Unison Pharmaceuticals Pvt. Ltd.	20.17
40.	Sitagliptin and Metformin Hydrochloride (ER)Tablet	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Unison Pharmaceuticals Pvt.Ltd.	21.56

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Hydrochloride IP 1000mg (as Extended Release)			
41.	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablet	Each film coated tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (as Extended Release)	1 Tablet	M/s Sun Pharma Laboratories Limited	22.32
42.	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablet	Each film coated tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (as Extended Release)	1 Tablet	M/s Alkem Laboratories Limited	29.31
43.	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablet	Each film coated tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (as Extended Release)	1 Tablet	M/s Alkem Laboratories Limited	30.70

Note 1. The Authority observed that M/s Seagull Pharmaceuticals Private limited made representation vide email dated 21.10.2022 on the price uploaded on NPPA's website. The Authority deliberated upon the matter in detail and decided that the representation of the applicant may be examined and hence agenda item was deferred.

Note 2. The Authority observed that PTR of items at line No. 31 and 32 of the draft working sheet are same for the pack size of 10 and 15 tablets for M/S Fourrts India

nk

Laboratories Pvt. Limited. Hence, the Authority directed to reconfirm the data from M/S Pharmatrac. Hence, the agenda item was deferred by the Authority.

Note 3. The Authority observed that M/s Intas Pharmaceuticals limited made representation vide email dated 20.10.2022 on the price uploaded on NPPA's website. The Authority deliberated upon the matter in detail and decided that the representation of the applicant may be examined and agenda item was deferred.

Note 4. The Authority observed that M/s Alkem Laboratories Limited requested for withdrawal of application vide email dated 04.11.2022 on the ground of price being too low. Hence, the company requested to withdraw the price application temporarily.

The Authority deliberated upon the matter in detail and decided to reject the request of the applicant and approved the prices as recommended by MDC at Rs. 9.05 per sachet of 5 gm finished formulation containing 40 mg Pantoprazole.

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

5.1 Noted.

6. Agenda item no. 6 –Minutes of 46thmeeting of Multidisciplinary Committee of Experts held on 19.10.2022.

6.1 Noted.

7. Agenda item no. 7 –Revision of retail prices notified for Vitamin D3 Oral Solution for 5ml containing Cholecalciferol IP (in nano Droplet Form) 60,000 IU vide S.O. 2164(E) dated 09.05.2022-reg.

7.1 The Authority noted that prices of each 5ml containing Cholecalciferol IP (in nano Droplet Form) 60,000 IU for M/s Mankind Pharma Limited/M/s Ravenbhel Healthcare Private Limited (Marketer/Manufacturer) and M/s Mankind Prime Labs Private Limited/M/s Ravenbhel Healthcare Private Limited (Marketer/Manufacturer) were fixed at Rs.13.94 per ml in the 97th Authority meeting held on 06.05.2022 and notified vide S.O. 2164(E) dated 09.05.2022.

7.2 An error was observed in the Pharmatrac database while fixing the price of same formulation for M/s Micro labs Limited (marketing company) and M/S Ravenbhel Healthcare for the application received in June 2022 with respect to one of the line item i.e. 'KIDRICH D3 60000IU DROPS 5 ML' of Dr. Reddy Laboratories as appearing in Pharmatrac database at Rs.198 per 5 ml pack against Rs.49.50 per 5 ml as per web sources. Hence, clarification was sought from Pharmatrac and from Dr. Reddy laboratories. Pharmatrac vide its e-mail dated 2.9.2022 confirmed that the correct price of said SKU is 49.50 per ML. Dr. Reddy Lab also confirmed that the price of Rs. 198 is for the pack size of (4 x5ml) of 'KIDRICH D3 60000IU DROPS 5 ML'

The Authority observed that if the data for the said line item is rectified, the corrected price for M/s Mankind Pharma Limited/M/s Ravenbhel Healthcare Private Limited


(Marketer/Manufacturer) and M/s Mankind Prime Labs Private Limited/M/s Ravenbhel Healthcare Private Limited (Marketer/Manufacturer) would be Rs. 11.70 per ml (as against Rs. 13.94/- per ml notified vide SO 2164(E) dated 09.05.2022).

7.3 The Authority deliberated upon the matter in detail and is of the view that:

- a. NPPA is mandated to fix the retail price of drugs. In execution of this function, the analysis of data is carried out and prices are fixed as per the methodology provided in the DPCO, 2013.
- b. While doing the analysis of the data, NPPA may come across data inconsistency/miscalculations/errors that might have occurred. If any such issues are discovered, the same may be corrected by the NPPA. There can be no bar on NPPA to take corrective measures and the DPCO also does not bar the same.

7.4 In view of the above, the Authority approved the revised prices for M/s Mankind Pharma Limited/M/s Ravenbhel Healthcare Private Limited (Marketer/Manufacturer) and M/s Mankind Prime Labs Private Limited/M/s Ravenbhel Healthcare Private Limited (Marketer/Manufacturer) at Rs. 11.70 per ml (as against Rs. 13.94/- per ml notified vide SO 2164(E) dated 09.05.2022) and also noted that the same shall be informed to DoP.

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


(Dr. Vinod Kotwal)
Member Secretary