मिसिलस.- 8(100)/2022/डी.पी/एनपीपीए-डीवी-II F. No. 8(100)/2022/DP/NPPA-Div. II

<u>कार्यवाहीस. : 232/100/2022/F</u> Proceeding No: 232/100/2022/F

Minutes of the 232nd(overall) and 100th meeting of the Authority under DPCO, 2013 held on 05.08.2022 at 3:30 PM

The 232ndmeeting of the Authority (overall), which is the 100thmeeting under the DPCO, 2013, was held on 05th of August 2022 at 3:30 PM under the Chairmanship of Shri Kamlesh Kumar Pant, Chairman, NPPA. The Chairman, NPPA complimented the Authority and NPPA officers on achieving the milestone of 100 meetings under DPCO,2013 and reiterated the resolve to keep working assiduously. Following Authority members of NPPA were present during the meeting:

- (i) Dr. Vinod Kotwal, Member Secretary, NPPA
- (ii) Shri Amardeep Singh Chowdhary, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure

Ms. Manisha Sensarma, Advisor, Department of Economic Affairs had requested for leave of absence as she was on leave,.

Shri A. K. Pradhan, Jt. Drug Controller, CDSCO, Ministry of Health & Family Welfare was also 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) Shri Sanjay Kumar, Advisor (Cost-II)
 - (iii) Ms. Rashmi Tahiliani, Jt. Director (Pricing)
 - (iv) Shri Prasenjit Das, Deputy Director (Pricing)
 - (v) Shri Mahaveer Saini, Deputy Director (Pricing)

II. Agenda items

- 1. Agenda item no. 1 Confirmation of Minutes of the 99^{th} Meeting held on 28.06.2022
- 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 99th Meeting held on 28.06.2022
- 2.1 Noted.
- 2.2 The Authority further noted that the notification on extension of price regulation of 5 medical devices namely (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer & (v) Glucometer has been issued vide SO. 3534 (E) dated 29.07.2022.



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

4.1The Authority discussed the following cases of retail pricefixation of new drugs as presented in Agenda no. 4 (i) to 4(xix)(total 45 Form I applications containing retail price fixation of 45 new drugs) falling under the purview of Para 2(u) of DPCO, 2013 and approved the retail prices of 45(forty five) new drugs under Para 5 and 15 of the DPCO 2013, as detailed below:

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)	Cyclosporine Eye Drop	Each ml contains: Cyclosporine IP 0.5mg	1 ml	M/s Indiana Opthalmics / M/s Intas Pharmaceuticals Ltd.	96.15
4(ii)	Omeprazole (GR) & Domperidone (SR) Capsules	Each Hard Gelatin Capsule Contains: Omeprazole IP 20mg (As Gastro Resistant Pellets) Domperidone IP 30mg (As Sustained Release Pellets)	1 Capsule	M/s Pure and Cure Healthcare Pvt. Ltd./M/s Cadila Pharmaceuticals Ltd.	9.53
4(iii)	Pantoprazole Dual Release Gastro Resistant Tablets	Each dual-release gastro resistant tablet contains: Pantoprazole Sodium IP eq. to Pantoprazole 80mg	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Hetero Healthcare Ltd.	11.16
4(iv)	Gastro-Resistant Esomeprazole and Domperidone Sustained Release Capsule	Each hard gelatin Capsule Contains: Esomeprazole Magnesium Trihydrate eq. to Esomeprazole IP 40mg (As Gastro- resistant pellets) Domperidone IP 30mg (As sustained release pellets)	1 Capsule	M/s Acme Generics Private Limited / M/s Mankind Prime Labs Pvt. Ltd.	11.32
4(v)	Amlodipine and Atenolol tablets	Each uncoated tablet contains: Amlodipine Besilate IP eq. to Amlodipine 5mg Atenolol IP 50mg	1 Tablet	M/s East African (India) Overseas / M/s Softdeal Pharmaceuticals Pvt. Ltd.	5.21



Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(vi)	Etamsylate& Tranexamic Acid Tablets	Each film coated tablet contains: Etamsylate BP 250mg, Tranexamic Acid IP 250mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Torrent Pharmaceuticals Ltd.	17.82
4(vii)	Paracetamol, Phenylephrine Hydrochloride, Caffeine & Diphenhydrami ne Hydrochloride Tablets	Each uncoated tablet contains: Paracetamol IP 500mg Phenylephrine Hydrochloride IP 5mg Caffeine (Anhydrous) IP 30mg Diphenhydramine Hydrochloride IP 25mg	1 Tablet	M/s Aagya Biotech Pvt. Ltd. / M/s German Remedies Pharmaceuticals Pvt. Ltd.	3.73
4(viii)	Amoxycillin and Potassium Clavulanate Oral Suspension IP	Each Composite Pack Contains: A & B Each 5ml of reconstituted suspension contains: A. Amoxycillin Trihydrate IP eq. to Amoxycillin 600mg, Potassium Clavulanate IP (as Potassium Clavulanate Diluted IP) eq. to Clavulanic Acid 42.9mg B. 2x30ml Sterile water for reconstitution of Dry syrup Each ampoule containing 30ml sterile water for reconstitution of Dry Syrup (as sterile water for Injection IP)	Per Combi Pack	M/s Micro Labs Limited	168.43
4(ix)	Diclofenac, Methyl Salicylate & Menthol Gel	Composition: Diclofenac Diethylamine IP 2.32%w/w (eq. to Diclofenac Sodium 2.00% w/w) Methyl Salicylate IP 10.00%w/w Menthol IP 5.00%w/w	1 gm	M/s Sirmour Remedies Pvt. Ltd. / M/s Mankind Pharma Ltd.	3.93
4(x)a	Sitagliptin and Metformin Hydrochloride (Sustained release) Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride (as an	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Cadila Pharmaceuticals Ltd.	18.67 (Note 1)



Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		sustained release form) IP 500mg			
4(x)b	Sitagliptin and Metformin Hydrochloride (Sustained release) Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride (as sustained release form) IP 1000mg	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Cadila Pharmaceuticals Ltd.	20.06 (Note 1)
4(x)c	Sitagliptin and Metformin Hydrochloride (Sustained release) Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride (as an sustained release form) IP 1000mg	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Cadila Pharmaceuticals Ltd.	21.56 (Note 1)
4(x)d	Sitagliptin and Metformin Hydrochloride (Extended release) Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride (as an Extended release form) IP 500mg	1 Tablet	M/s Torrent Pharmaceuticals Ltd.	18.00 (Note 1)
4(x)e	Sitagliptin and Metformin Hydrochloride (Extended release) Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride (as an Extended release form) IP 1000mg	1 Tablet	M/s Torrent Pharmaceuticals Ltd.	20.00 (Note 1)
4(x)f	Sitagliptin and Metformin Hydrochloride (Extended release) Tablets	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride (as Extended release form) IP 1000mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Micro Labs Ltd.	20.06 (Note 1)
4(x)g	Sitagliptin and Metformin Hydrochloride (Extended	Each film coated bilayered tablet contains: Sitagliptin Phosphate	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Micro Labs Ltd.	18.67 (Note 1)



Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	release) Tablets	Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride (as Extended release form) IP 500mg	(4)	(5)	(6)
4(x)h	Sitagliptin and Metformin Hydrochloride (Extended release) Tablets	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride (as an Extended release form) IP 500mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Micro Labs Ltd.	20.00 (Note 1)
4(x)i	Sitagliptin and Metformin Hydrochloride (Extended release) Tablets	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride (as an Extended release form) IP 1000mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Micro Labs Ltd.	21.00 (Note 1)
4(x)j	Sitagliptin and Metformin Hydrochloride Tablet	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Sai Primus Life Biotech Private Limited / M/s Primus Remedies Pvt. Ltd.	18.34 (Note 1)
4(x)k	Sitagliptin and Metformin Hydrochloride Tablet	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 850mg	1 Tablet	M/s Sai Primus Life Biotech Private Limited / M/s Primus Remedies Pvt. Ltd.	19.26 (Note 1)
4(x)l	Sitagliptin and Metformin Hydrochloride Tablet	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Sai Primus Life Biotech Private Limited / M/s Primus Remedies Pvt. Ltd.	20.02 (Note 1)
4(x)m	Sitagliptin and Metformin	Each film coated bilayered tablet	1 Tablet	M/s Ravenbhel Healthcare Pvt.	20.00 (Note 1)



Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	Hydrochloride (Extended release) Tablets	contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride (as an Extended release form)	(4)	Ltd. / M/s Torrent Pharmaceuticals Ltd.	(6)
4(x)n	Sitagliptin and Metformin Hydrochloride (Extended release) Tablets	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride (as an Extended release form) IP 500mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Torrent Pharmaceuticals Ltd.	18.00 (Note 1)
4(x)o	Sitagliptin and Metformin Hydrochloride (Sustained Release) Tablets	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg Metformin Hydrochloride IP 500 mg (as Sustained Release form)	1 Tablet	M/sMascot Health Series Private Limited / M/s Alembic Pharmaceuticals Ltd.	16.07 (Note 1)
4(x)p	Sitagliptin and Metformin Hydrochloride (Sustained Release) Tablets	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg Metformin Hydrochloride IP 1000 mg (as Sustained Release form)	1 Tablet	M/s Mascot Health Series Private Limited / M/s Alembic Pharmaceuticals Ltd.	17.85 (Note 1)
4(x)q	Sitagliptin and Metformin Hydrochloride (Extended release) Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg Metformin Hydrochloride IP (as Extended Release form) 1000 mg	1 Tablet	M/s Intas Pharmaceuticals Ltd.	21.56 (Note 1)
4(x)r	Sitagliptin and Metformin Hydrochloride (ER) Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg	1 Tablet	M/s Intas Pharmaceuticals Ltd.	18.67 (Note 1)



Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	Metformin Hydrochloride IP (as Extended Release form) 500 mg	(4)	(5)	(6)
4(x)s	Sitagliptin and Metformin Hydrochloride (ER) Tablets	Each filmcoatedtabletcontains:SitagliptinPhosphateMonohydrateIP eq. toSitagliptin50 mgMetforminHydrochlorideIP (asextendedReleaseform) 1000 mg	1 Tablet	M/s Intas Pharmaceuticals Ltd.	20.06 (Note 1)
4(x)t	Sitagliptin and Metformin Hydrochloride (ER) Tablets	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg Metformin Hydrochloride IP (as extended Release form) 500 mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Intas Pharmaceuticals Ltd.	20.17 (Note 1)
4(x)u	Sitagliptin and Metformin Hydrochloride (Extended release) Tablets	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride (as an extended release form) IP 500mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Cipla Ltd.	18.67 (Note 1)
4(x)v	Sitagliptin and Metformin Hydrochloride (Extended release) Tablets	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride (as an extended release form) IP 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Cipla Ltd.	20.06 (Note 1)
4(x)w	Sitagliptin and Metformin Hydrochloride (Extended release) Tablets	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride (as an extended release form)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Cipla Ltd.	20.00 (Note 1)



Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
(-)		IP 500mg			
4(x)x	Sitagliptin and Metformin Hydrochloride (Extended release) Tablets	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride (as an extended release form) IP 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Cipla Ltd.	21.56 (Note 1)
4(x)y	Sitagliptin Phosphate and Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP 64.25mg eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Bajaj Healthcare Ltd. / M/s J.B. Chemicals & Pharmaceuticals Ltd.	18.34 (Note 1)
4(x)z	Sitagliptin Phosphate and Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP 64.25mg eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Bajaj Healthcare Ltd. / M/s J.B. Chemicals & Pharmaceuticals Ltd.	20.02 (Note 1)
4(xi)	Purified Freeze- Dried Human Coagulation Factor VIII, Virus Inactivated IP (Immunate)	Composition: Purified Freeze-Dried Human Coagulation Factor VIII, Virus Inactivated IP 1000IU 1 vial with 10ml Sterilized Water for Injection	Per pack	M/s Baxalta Bioscience India Pvt. Ltd.	11,606.67
4(xii)a	Linagliptin and Metformin Hydrochloride extended- release Tablet	Each film coated tablet contains: Linagliptin 2.5mg Metformin Hydrochloride IP (as extended release) 1000mg	1 Tablet	M/s MSN Laboratories Pvt. Ltd. / M/s Eris Lifesciences Limited	16.37 (Note 2)
4(xii)b	Linagliptin and Metformin Hydrochloride extended- release Tablet		1 Tablet	M/s MSN Laboratories Pvt. Ltd. / M/s Eris Lifesciences Limited	25.33 (Note 2)



Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(xiii)	Acetazolamide Extended- Release Capsules	Each capsule contains: Acetazolamide IP 500mg	1 Capsule	M/s Sidmak Laboratories (India) Pvt. Ltd. / M/s Sun Pharma Laboratories Limited	8.15 (Note 3)
4(xiv)	Beclomethasone Dipropionate, Clotrimazole & Neomycin Sulphate Cream	Composition: Beclomethasone Dipropionate IP 0.025% w/w, Clotrimazole IP 1.005% w/w, Neomycin Sulphate IP 0.50% w/w	1 Gram	M/s Pharma Force Lab / M/s Torrent Pharmaceuticals Ltd.	6.33
4(xv)	Pantoprazole Dual Release Gastro Resistant Tablets	Each Dual Release Gastro Resistant Tablet Contains: Pantoprazole Sodium Eq. to Pantoprazole 80mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Intas Pharmaceuticals Limited	15.49
4(xvi)	Benidipine& Telmisartan Tablets	Each film coated tablet contains: Benidipine Hydrochloride JP 4mg Telmisartan IP 40mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Mankind Pharma Ltd.	12.70
4(xvii)	Benidipine& Telmisartan Tablets	Each film coated tablet contains: Benidipine Hydrochloride JP 4mg Telmisartan IP 80mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Mankind Pharma Ltd.	9.94
4(xviii)	Cilnidipine, Telmisartan &Chlorthalidone Tablets	Each Film Coated Tablet contains: Cilnidipine 10mg Telmisartan 40mg Chlorthalidone 6.25 mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Primus Remedies Pvt. Ltd.	12.50
4(xix)	Budesonide & Formoterol Fumarate Respirator Suspension	Each 2ml contains: Budesonide IP 0.5mg Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate 20mcg	1 ml	M/s AxaParenterals Limited / M/s Mankind Pharma Ltd.	22.75

Note 1. The Authority deliberated upon the matter in detail and decided to approve the retail price in line with the decision as recorded in Note 7 of Para 4.1 of the Minutes of the 96th Authority meeting dated 24.03.2022.

- **Note 2.** The Authority deliberated upon the matter in detail and decided to approve the retail price in line with the decision as recorded in Note 6 of Para 4.1 of the Minutes of the 96th Authority meeting dated 24.03.2022.
- Note 3. The Authority noted the representation dated 20.7.2022 filed by M/s Sun Pharma Laboratories Ltd stating that recommendation of the retail price by the Multidisciplinary Committee of Experts in its 43rd meeting dated 04.07.2022 should be based on the ceiling price of Acetazolamide 250mg capsule as per SO. 1499(E) dated 30.03.2022 (which is applicable from 1st April 2022) instead of ceiling price based on SO. 1330(E) dated 25.03.2021 (which is applicable in November 2021). The Authority deliberated upon the matter in detail and observed that the ceiling price of Acetazolamide 250 mg capsule, as applicable in November 2021, has been considered by the Multidisciplinary Committee of Experts since it is six month prior to date of application made by M/s Sun Pharma Laboratories Ltd and the same is in line with the provisions of DPCO 2013 regarding the data to be taken for calculation of retail price. Accordingly, the Authority accepted the recommendation of the Committee and approved the retail price of Acetazolamide 500mg (extended release) capsule for M/s Sidmak Laboratories (India) Pvt. Ltd. (manufacturer) and M/s Sun Pharma Laboratories Limited (marketer) at Rs. 8.15 per capsule excluding GST.
- 5. Agenda item no. 5 Status of implementation of Review cases
- 5.1 Noted.
- 6. Agenda item no. 6 -Minutes of 43rd meeting of Multidisciplinary Committee of Experts held on 04.07.2022.
- 6.1 Noted.
- 6.2 The Authority requested that in the next meeting it may be apprised of the list of pending applications, if any before the Committee. The Authority noted that endeavor should be to dispose of the applications expeditiously.
- 7. Agenda item no. 7 Revision of retail price of each hard gelatin capsule containing Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate 12 mcg + Budesonide IP 400 mcg for M/s. Biodeal Pharmaceuticals Pvt. Ltd. (manufacturer) and M/s. Mankind Pharma Ltd. (marketer)
- 7.1 The Authority noted the decision taken in its 99th meeting held on 28.06.2022 regarding revision of retail price of each hard gelatin capsule containing Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate 12mcg + Budesonide IP 400mcg for M/s Mankind Pharma Ltd (marketer)/ M/s Biodeal Pharmaceuticals Pvt. Ltd (manufacturer) at Rs. 9.35 per capsule excluding GST and also noted the representation dated 06.07.2022 and 28.07.2022 received in this regard.
- 7.2 The Authority deliberated upon the matter in detail based on the representations received on the Authority decision. It was observed that the revised retail price has been worked out to rectify an error of selection of the data that was used for calculation



of retail price. The data was available but under different drug type i.e., Transcap, Rotacap, Respicap etc. Based on the clarification from M/S Pharmatrac that Transcap, Rotacap and Respicap are also capsules; the data of these drug types has been considered to calculate the correct retail price. It was also noted that Authority cannot be prohibited from making any rectification in the notified retail price on account of an error that has occurred only due to nomenclature issue of the data. Also, such rectification of error does not take away the right of the applicant to file for a review application, if it desires so.

7.3 In view of the above, the Authority reiterated its earlier stand and decided to correct and revise the retail price of each hard gelatin capsule containing Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate 12mcg + Budesonide IP 400mcg for M/s Mankind Pharma Ltd (marketer)/ M/s Biodeal Pharmaceuticals Pvt. Ltd (manufacturer) at Rs. 9.35 per capsule excluding GST

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

(Dr. Vinod Kotwal) Member Secretary