मिसिल स.- 8(96)/2022/डी.पी/एनपीपीए-डीवी-II
F. No. 8(96)/2022/DP/NPPA-Div. II

कार्यवाही स. : 228/96/2022/F
Proceeding No: 228/96/2022/F

Minutes of the 228th (overall) and 96th meeting of the Authority under DPCO, 2013 held on 24.03.2022 at 3:00 PM

The 228th meeting of the Authority (overall), which is the 96th meeting under the DPCO, 2013, was held on 24th of March 2022 at 3:00 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) Dr. V. G. Somani, Drug Controller General of India through Video Conferencing
(iii) Shri Amardeep Singh Chowdhary, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure
(iv) Shri A. K. Pradhan, Jt. Drug Controller, CDSCO, Ministry of Health & Family Welfare was also present during the meeting through Video Conferencing

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 the Minutes of the 95th Meeting held on 28.01.2022

1.1 The Authority confirmed the minutes without any change.

2. Agenda item no. 2 – Action Taken Report (ATR) on decisions taken by NPPA in its 95th Meeting held on 28.01.2022

2.1 The Authority noted that due action has been taken.

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(xxxiv) (total 58 Form I applications containing retail price fixation of 58 new drugs) falling under the purview of Para 2(u) of DPCO, 2013 and approved the retail prices of 56(fifty six)[except agenda item no. 4(viii) and 4(xvi)] new drugs under Para 5 and 15 of the DPCO 2013, as detailed below:

A. Retail price fixed under Para 5 and 15 of DPCO, 2013

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(i)	Telmisartan + Cilnidipine + Chlorthalidone Tablet	**Each film coated tablet contains:** Telmisartan IP 40 mg Cilnidipine IP 10 mg Chlorthalidone IP 6.25 mg	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	11.61 (Note 2)
4(ii)	Paracetamol Bilayer Tablets 1000 mg	**Each uncoated bilayered tablet contains:** Paracetamol IP 300 mg (as immediate release) Paracetamol IP 700 mg (as sustained release)	1 Tablet	M/s Sterling Labs / M/s Micro Labs Limited	4.07
4(iii)	Levetiracetam Tablet	**Each film coated tablet contains:** Levetiracetam IP 1000 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Zydus Healthcare Ltd.	30.38
4(iv)	Torsemide and Spironolactone Tablets	**Each film coated tablet contains:** Torsemide IP 10mg Spironolactone IP 25mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s J. B. Chemicals & Pharmaceuticals Limited	2.71 (Note 2)
4(v)	Paracetamol, Phenylephrine Hydrochloride, Caffeine and Diphenhydramine Hydrochloride tablet	**Each film coated tablet contains:** Paracetamol IP 500mg Phenylephrine Hydrochloride IP 5mg Caffeine (anhydrous) IP 30mg Diphenhydramine Hydrochloride IP 25mg	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd. / Dr. Reddy's Laboratories Limited	3.21
4(vi)	Metformin Hydrochloride (as Prolonged-Release)+	**Each Uncoated bilayered tablet contains:** Metformin Hydrochloride	1 Tablet	M/s East African (India) Overseas / M/s La-Medica Life Sciences Pvt.	8.24

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Glimepiride Tablet IP	IP 500mg (as Prolonged-Release) Glimepiride IP 2mg		Ltd.	
4(vii)	Metformin Hydrochloride (as Prolonged-Release)+ Glimepiride Tablet IP	**Each uncoated bilayered tablet contains:** Metformin Hydrochloride IP 500mg (as Prolonged-Release) Glimepiride IP 1mg	1 Tablet	M/s East African (India) Overseas / M/s La-Medica Life Sciences Pvt. Ltd.	5.63
4(viii)	Diclofenac Diethylamine + Virgin Linseed Oil+ Methyl Salicylate +Menthol gel	**Gel Composition:** Diclofenac Diethylamine IP 1.16% w/w eq. to 1% w/w + Virgin Linseed Oil(Oleum Lini) 3% + Methyl Salicylate IP 10% w/w + Menthol IP 5% w/w	1 gm	M/s Nanz Med Science Pharma Pvt. Ltd./M/s Zuventus Healthcare Ltd.	(Note 2) (Note 3)
4(ix)	Cefixime, Cloxacillin & Lactic Acid Bacillus Tablets	**Each film coated tablet contains:** Cefixime IP as Trihydrate eq. to Anhydrous Cefixime 200mg, Cloxacillin Sodium IP eq. to Cloxacillin 500mg (in extended release form), Lactic Acid Bacillus 90 Million Spores.	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Abbott Healthcare Pvt. Ltd.	14.65
4(x)	Diclofenac Transdermal Patch	**Each 75Sq cm Transdermal Patch contains:** Diclofenac Diethylamine IP 200mg	1 Patch	M/s Azista Industries Pvt. Ltd. / M/s Hetero Healthcare Ltd.	40.18
4(xi)	Efonidipine Hydrochloride Ethanolate + Telmisartan Tablet	**Each uncoated bilayered tablet contains:** Efonidipine Hydrochloride Ethanolate 20mg, Telmisartan IP 40mg	1 Tablet	M/s Zuventus Healthcare Limited	9.94
4(xii)	Gliclazide ER + Metformin ER Tablet	**Each uncoated bilayered tablet contains:** Gliclazide IP (as extended release form) 60mg Metformin Hydrochloride IP (as extended release form) 1000mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Lupin Limited	8.53

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(xiii)	Bisoprolol Fumarate & Amlodipine tablet	**Each film coated tablet contains:** Bisoprolol Fumarate IP 5mg Amlodipine Besylate IP Eq. to Amlodipine 5mg	1 Tablet	M/s Swiss Garnier Biotech Ltd. / Dr. Reddy's Laboratories Limited	6.69
4(xiv)	Bisoprolol Fumarate & Amlodipine tablet	**Each film coated tablet contains:** Bisoprolol Fumarate IP 2.5mg Amlodipine Besylate IP Eq. to Amlodipine 5mg	1 Tablet	M/s Swiss Garnier Biotech Ltd. / Dr. Reddy's Laboratories Limited	4.46
4(xv)	Paracetamol & Mefenamic Acid tablet	**Each Uncoated Tablet contains:** Paracetamol IP 325mg Mefenamic Acid IP 500mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Alkem Laboratories Limited	3.27 (Note 2)
4(xvi)	Diclofenac Diethylamine + Methyl Salicylate + Linseed Oil+ Menthol topical spray	**Spray Composition:** Diclofenac Diethylamine IP 1.16% w/w eq. to 1% w/w Virgin Linseed Oil 3% Methyl Salicylate IP 10% w/w Menthol IP 5% w/w	1 gm	M/s Pontika Aerotech Ltd./M/s Zuventus Healthcare Ltd.	(Note 2) (Note 3)
4(xvii)	Levofloxacin Infusion IP (0.5% w/v)	**Each 100 ml contains:** Levofloxacin Hemihydrate IP eq. to Levofloxacin 500 mg Sodium Chloride IP 900 mg , Water for Injection IP q. s.	1 ml	M/s Akums Drugs & Pharmaceuticals Ltd./M/s Emcure Pharmaceuticals Ltd.	1.32
4(xviii)	Paracetamol & Tramadol HCl tablet USP	**Each uncoated Tablet contains:** Paracetamol IP 325mg Tramadol HCL IP 37.5mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Hetero Healthcare Ltd.	8.35
4(xix)	Ceftriaxone & Tazobactam for Injection 1125mg	**Each vial contains:** Sterile Ceftriaxone Sodium IP eq. to Ceftriaxone 1000mg Sterile Tazobactam Sodium IP eq. to Tazobactam 125mg Each ampoule contains: 10ml Sterile water for Injection IP	1 Vial	M/s Prosperity Six Pharmaceuticals / M/s Torrent Pharmaceuticals Limited	167.87
4(xx)	Telmisartan + Cilnidipine + Chlorthalidone	**Each film coated tablet contains:** Telmisartan IP 40 mg +	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	12.94

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Tablet	Cilnidipine IP 10 mg + Chlorthalidone IP 12.50 mg			
4(xxi)	Amoxycillin + Potassium Clavulanate Oral Suspension	**Each ml of constituted suspension contains:** Amoxycillin Trihydrate IP eq. to Amoxycillin 80mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 11.4mg	1 ml	M/s Copmed Pharmaceuticals Pvt. Ltd. / M/s Mankind Prime Labs Pvt. Ltd.	7.42
4(xxii)	Tramadol HCl + Acetaminophen (Paracetamol)Tablet	**Each uncoated tablet contains:** Tramadol HCl 37.5mg Acetaminophen (Paracetamol) 325mg	1 Tablet	M/s Penta Kraft / M/s Mankind Prime Labs Pvt. Ltd.	8.35
4(xxiii)	Metformin (extended-release) + Teneligliptin Tablet	**Each uncoated bilayered tablet contains:** Metformin Hydrochloride IP 500mg (as Extended-Release) Teneligliptin Hydrobromide hydrate eq. to Teneligliptin 20mg	1 Tablet	M/s Associated Biotech / M/s Dales Laboratories	7.14 (Note 4)
4(xxiv)	Clonazepam mouth dissolving Tablet	**Each uncoated mouth dissolving tablet contains:** Clonazepam IP 2mg	1 Tablet	M/s Lifecare Neuro Products Ltd./ M/s Mankind Pharma Ltd.	8.60
4(xxv)a	Dapagliflozin + Metformin Hydrochloride Extended release Tablet	**Each film-coated tablet contains:** Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 1000mg (As Extended release form)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Emcure Pharmaceuticals Limited	10.70 (Note 5)
4(xxv)b	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	**Each film-coated bilayered tablet contains:** Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 1000mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Natco Pharma Ltd.	7.97 (Note 5)

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(xxv)c	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	**Each film-coated bilayered tablet contains:** Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 1000mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Apex Laboratories Private Limited	10.70 (Note 5)
4(xxv)d	Dapagliflozin + Metformin Hydrochloride Extended release Tablet	**Each film-coated tablet contains:** Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 500mg (As Extended release form)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Emcure Pharmaceuticals Limited	9.18 (Note 5)
4(xxv)e	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	**Each film-coated bilayered tablet contains:** Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 500mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Natco Pharma Ltd.	7.30 (Note 5)
4(xxv)f	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	**Each film-coated bilayer tablet contains:** Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 500mg (As extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Apex Laboratories Private Limited	9.18 (Note 5)
4(xxv)g	Dapagliflozin + Metformin Hydrochloride Extended release Tablet	**Each film-coated tablet contains:** Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg, Metformin Hydrochloride IP 1000mg (As extended release form)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Emcure Pharmaceuticals Limited	7.29 (Note 5)
4(xxv)h	Dapagliflozin + Metformin Hydrochloride Extended release Tablet	**Each film-coated tablet contains:** Dapagliflozin 5mg, Metformin Hydrochloride IP/USP 1000mg (As	1 Tablet	M/s MSN Laboratories Pvt. Ltd. / M/s USV Limited	7.29 (Note 5)

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		extended release form)			
4(xxv)i	Dapagliflozin + Metformin Hydrochloride Extended release Tablet	**Each film-coated tablet contains:** Dapagliflozin 5mg, Metformin Hydrochloride IP/USP 500mg (As extended release form)	1 Tablet	M/s MSN Laboratories Pvt. Ltd. / M/s USV Limited	6.16 (Note 5)
4(xxvi)	Cefixime, Dicloxacillin MR & Lactic Acid Bacillus Tablets	**Each modified release tablet contains:** Cefixime IP as Trihydrate eq. to Anhydrous Cefixime 200mg (in immediate release form), Dicloxacillin Sodium IP eq. to Dicloxacillin 500mg (in modified release form), Lactic Acid Bacillus 2.5 Billion Spores.	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Abbott Healthcare Pvt. Ltd.	18.24
4(xxvii)	Efonidipine Hydrochloride Ethanolate + Telmisartan Tablet	**Each uncoated bilayered tablet contains:** Efonidipine Hydrochloride Ethanolate 40mg, Telmisartan IP 40mg	1 Tablet	M/s Zuventus Healthcare Limited	15.67
4(xxviii)	Human Normal Immunoglobuli n for Intravenous use IP 5% (Ig M Enriched)	**Each vial contains:** Total Protein 50 g/L, Immunoglobulin M 6g/L, Immunoglobulin A 6g/L, Immunoglobulin G 38g/L, Glucose Monohydrate (as stabilizer) 27.5g/L, Sodium Chloride 4.56g/L, Water for injection q. s. Distribution of Ig G subclass is approx. 62%IgG1,27%IgG2,1%Ig G3,10%IgG4	Per 1 ml (for 10 ml vial)	M/s Intas Pharmaceuticals Ltd	177.85
4(xxix)a	Linagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Linagliptin 2.5mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Optimus Pharma Pvt. Ltd. / M/s Natco Pharma Ltd.	8.04 (Note 6)
4(xxix)b	Linagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Linagliptin 2.5mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s MSN Laboratories Private Limited / M/s Emcure Pharmaceuticals Limited	14.65 (Note 6)

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(xxix)c	Linagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Linagliptin 2.5mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s MSN Laboratories Private Limited / M/s Eris Lifesciences Limited	14.65 (Note 6)
4(xxix)d	Linagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Linagliptin 2.5mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Micro Labs Limited	10.63 (Note 6)
4(xxix)e	Linagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Linagliptin 2.5mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Optimus Pharma Pvt. Ltd. / M/s Natco Pharma Ltd.	8.37 (Note 6)
4(xxix)f	Linagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Linagliptin 2.5mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s MSN Laboratories Private Limited / M/s Emcure Pharmaceuticals Limited	16.33 (Note 6)
4(xxix)g	Linagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Linagliptin 2.5mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Micro labs Limited	11.52 (Note 6)
4(xxix)h	Linagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Linagliptin 2.5mg Metformin Hydrochloride IP 850mg	1 Tablet	M/s MSN Laboratories Private Limited / M/s Emcure Pharmaceuticals Limited	15.45 (Note 6)
4(xxx)a	Sitagliptin Phosphate + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP 64.25mg is eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Alkem Healthsciences (A Unit of Alkem Laboratories Ltd.) / M/s Alkem Laboratories Limited	20.02 (Note 7)
4(xxx)b	Sitagliptin Phosphate + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP 64.25mg is eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Alkem Healthsciences (A Unit of Alkem Laboratories Ltd.) / M/s Alkem Laboratories Limited	18.34 (Note 7)
4(xxx)c	Sitagliptin	**Each film coated**	1 Tablet	M/s Alkem	

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Phosphate + Metformin Hydrochloride(Extended release) Tablet	**bilayered tablet contains:** Sitagliptin Phosphate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (As an Extended release form)		Healthsciences (A Unit of Alkem Laboratories Ltd.) / M/s Alkem Laboratories Limited	20.17 (Note 7)
4(xxx)d	Sitagliptin Phosphate + Metformin Hydrochloride (Extended release) Tablet	**Each film coated bilayered tablet contains:** Sitagliptin Phosphate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (As an Extended release form)	1 Tablet	M/s Alkem Healthsciences (A Unit of Alkem Laboratories Ltd.) / M/s Alkem Laboratories Limited	19.81 (Note 7)
4(xxx)e	Sitagliptin Phosphate + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Emcure Pharmaceuticals Limited	18.34 (Note 7)
4(xxx)f	Sitagliptin Phosphate + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Emcure Pharmaceuticals Limited	20.02 (Note 7)
4(xxx)g	Sitagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Zydus Healthcare Limited	18.34 (Note 7)
4(xxx)h	Sitagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Zydus Healthcare Limited	20.02 (Note 7)
4(xxx)i	Sitagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Morepen Laboratories Limited	18.34 (Note 7)

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(xxx)j	Sitagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Morepen Laboratories Limited	20.02 (Note 7)
4(xxxi)	Medroxyprogesterone Acetate sustained release Tablet	**Each uncoated sustained release tablet contains:** Medroxyprogesterone Acetate IP 30mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Serum Institute of India Pvt. Ltd.	14.04
4(xxxii)	Medroxyprogesterone Acetate SR Tablet	**Each uncoated sustained release tablet contains:** Medroxyprogesterone Acetate IP 30mg	1 Tablet	M/s Synokem Pharmaceuticals Limited / M/s Torrent Pharmaceuticals Ltd.	14.04
4(xxxiii)	Glycopyrrolate + Formoterol Fumarate + Budesonide Inhalation	**Each actuation delivers:** Glycopyrrolate IP 9mcg Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate 4.8mcg Budesonide IP 160mcg	1 MDI	M/s Zydus Healthcare Ltd.	8.63
4(xxxiv)	Folic Acid, Pyridoxine Hydrochloride, Methylcobalamin & Vitamin D3 Tablet	**Each uncoated mouth dissolving tablet contains:** Folic Acid IP 5mg Pyridoxine Hydrochloride IP 3mg Methylcobalamin IP 1500mcg Vitamin D3 IP 1000 IU	1 tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	6.70

Note 1. *The retail prices are to be notified after 10 working days from uploading of draft working sheet/Minutes of the Multidisciplinary Committee of Experts/ Minutes of the Authority Meeting on NPPA's website, as applicable.*

Note 2. *DCGI present in the meeting confirmed that the formulations are approved..*

Note 3. *The Authority noted that representation has been received from M/s Zuventus Healthcare Ltd on the draft calculation sheet uploaded on NPPA website and decided to place the matter in the next meeting after examination of the representations.*

Note 4. *The Authority noted the representation received from M/s Associated Biotech dated 02.02.2022 in which the company stated that due to typographical error in pack size in Form-I application(which was submitted on 22.12.2021) '15' instead of '10' has been*

written. However, in the forwarding e-mail it was written as pack of 10 tablets. The Authority observed that the company has made the representation about the typographical error after more than one month from the submission of the application and after retail price was approved by the Authority in its 95th meeting held on 28.01.2022. The Authority further noted that in the earlier application made by M/s Associated Biotech vide e-mail dated 30.11.2021 for retail price fixation of the same formulation was rejected due to being incomplete in nature, the Form-I in rejected application also mentioned it as pack of '15". The Authority deliberated upon the matter in detail and is of the opinion that the requisite details as provided in Form-I is to be considered for fixation of retail price and according decided to approve the retail price for the formulation at Rs. 7.14 per tablet excluding GST.

Note 5. Agenda item no. 4 (xxv)(a) to 4(xxv)(i) *– The Authority decided to fix the retail price in line with the decision taken in its 82nd meeting held on 23.12.2020 as recorded in Note 2 of Para 4.1 of the Minutes of 82nd Authority meeting.*

Note 6. Agenda item no. 4(xxix)(a) to 4(xxix)(h)*(i) The Authority noted that the formulation "Linagliptin" has become/ is on the verge of becoming off-patent and observed that, in line with the decision taken in its 89th meeting dated 28.06.2021, if the calculation is based on six month prior market data, the price of the patented period would be taken into consideration and hence the price rationalisation due to expiry of the patent may not pass on to the patients.*

(ii) The Authority further noted that matter was placed before the 40th meeting of the Multidisciplinary Committee of Experts held on 14.03.2022 which in line with decision taken in the 89th Authority meeting dated 28.06.2021, recommended to fix the retail price as per the following methodology:

" ..... The Committee observed that the market data of the FDCs of Linagliptin and Metformin tablet is also available and noted that if the retail price is calculated based on six month prior market data, the price of patented period would be taken into consideration and benefit of price reduction due to medicines which has become/ is on the verge of becoming off-patent would not pass not on to the consumers. The Committee deliberated upon the matter in detail and is of the opinion that the price of drugs be reduced in respect of the drugs which has become/ on the verge of becoming off-patent so as to pass the benefit of price reduction to the consumers and that a reduction of 50% be allowed on the patented component of FDCs i.e. 'Linagliptin' to arrive at the retail price. Accordingly, the Committee recommended to allow retail price for the FDCs of Linagliptin and Metformin tablet in line with the decision taken in its 33rd meeting held on 21.06.2021. However, where the calculated retail price of the FDC of formulation based on six month prior market data as per the provisions of DPCO 2013 is lower than claimed price and the calculated price, the Committee recommended that the same would be allowed."

(iii) The Authority deliberated upon the matter in detail and accepted the recommendation of the Multidisciplinary Committee of Experts and approved the fixation of the new drugs as per the methodology stated by the Multidisciplinary Committee of Experts.

Note 7. Agenda item no. 4(xxx)(a) to 4(xxx)(j) *– (i) The Authority noted that the formulation "Sitagliptin" has become/ is on the verge of becoming off-patent and observed that, in line with the decision taken in its 89th meeting dated 28.06.2021, if the calculation is based on six month prior market data, the price of the patented period would be taken into consideration and hence the price rationalisation due to expiry of the patent may not pass on to the patients.*

(ii) The Authority further noted that matter was placed before the 40th meeting of the Multidisciplinary Committee of Experts held on 14.03.2022 which in line decision taken in the 89th Authority meeting dated 28.06.2021, recommended to fix the retail price as per the following methodology:

"....The Committee observed that the market data of the FDCs of Sitagliptin and Metformin tablet is also available and noted that if the retail price is calculated based on six month prior market data, the price of patented period would be taken into consideration and benefit of price reduction due to medicines which has become/ is on the verge of becoming off-patent would not pass not on to the consumers. The Committee deliberated upon the matter in detail and is of the opinion that the price of drugs be reduced in respect of the drugs which has become/ on the verge of becoming off-patent so as to pass the benefit of price reduction to the consumers and that a reduction of 50% be allowed on the patented component of FDCs i.e. 'Sitagliptin' to arrive at the retail price. Accordingly, the Committee recommended to allow retail price for the FDCs of Sitagliptin and Metformin tablet in line with the decision taken in its 33rd meeting held on 21.06.2021. However, where the calculated retail price of the FDC of formulation based on six month prior market data as per the provisions of DPCO 2013 is lower than claimed price and the calculated price, the Committee recommended that the same would be allowed."

(iii) The Authority deliberated upon the matter in detail and accepted the recommendation of the Multidisciplinary Committee of Experts and approved the fixation of the new drugs as per the methodology stated by the Multidisciplinary Committee of Experts.

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

5.1 Noted.

6. Agenda item no. 6 – Minutes of 39th & 40th meeting of Multidisciplinary Committee of Experts held on 25.02.2022 & 14.03.2022.

6.1 Noted.

7. Agenda item no. 7 - Application filed by M/s Serum Institute of India Pvt. Ltd for exemption under Para 32(ii) of DPCO 2013 for the formulation Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) IP (10-Valent).

7.1 The Authority noted the application filed by M/s Serum Institute of India Pvt. Ltd for exemption under Para 32(ii) of DPCO 2013 for the formulation Pneumococcal

Polysaccharide Conjugate Vaccine (Adsorbed) IP (10-Valent) in (i) 0.5 ml – 1 dose (Vial), (ii) 2.5 ml – 5 dose (Vial) and (iii) 0.5 ml – 1 dose (pre-filled syringes).

7.2 The Authority further noted that M/s Serum Institute of India Pvt. Ltd submitted the following documents:

a. Patent No. 318780 granted on 22.08.2019 to M/s Serum Institute of India Pvt. Ltd for invention entitled "PURIFICATION OF CAPSULAR POLYSACCHARIDES" for the term of 20 years from 15.05.2010, issued by the Patent Office, Government of India.

b. Patent No. 284211 granted on 14.06.2017 to M/s Serum Institute of India Pvt. Ltd for invention entitled "METHOD FOR PREPARING BACTERIAL VACCINES" for the term of 20 years from 26.04.2010, issued by the Patent Office, Government of India.

c. Patent No. 276304 granted on 13.10.2016 to M/s Serum Institute of India Pvt. Ltd for invention entitled "METHOD FOR EVALUATION OF MULTIPLE ANTIGENS" for the term of 20 years from 26.03.2010, issued by the Patent Office, Government of India.

d. New Drug approval granted to M/s Serum Institute of India Pvt. Ltd from Central Drugs Standard Control Organisation (CDSCO), in form CT-23 to manufacture the new drug "Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) IP (10-Valent) (PCV 10V)" in (i) single dose (0.5 ml) vial, (ii) multi-dose (2.5 ml) vial) and (iii) single dose (0.5ml) pre-filled syringes

7.3 The Authority noted the Patent Office India Report titled "Report on scope of patent claims with respect to a new drug formulation approval granted by CDSCO vide FORM CT23 dated 14th July, 2020 to M/s Serum Institute of India Pvt. Ltd, Pune" sent vide e-mail dated 19.01.2022. The Report stated as follows:

> *".....II. Granted claims 1 to 9 of Patent No. 318780 are related to a process for purification of antigenic polysaccharides by removing protein contaminants and the said process of purification of polysaccharide antigens covers within its scope, the purification of Streptococcus pneumonia serotypes 1,5, 9V,14,19A,19F,23F,7F,6A and 6B included in the formulation approved by CDSCO in the permission dated 17.07.2020.*
>
> *III. Granted claims 1 to 10 of Patent No. 284211 are related t a method for preparing a size reduced polysaccharide or oligosaccharide by subjecting the polysaccharides or oligosaccharides to a high pressure cell disruption treatment and the said method for preparing polysaccharide or oligosaccharide covers within its scope, the preparation of Streptococcus pneumonia serotypes 1, 5, 9V, 14,19A,19F,23F,7F,6A and 6B included in the formulation approved by CDSCO in the permission dated 17.07.2020.*
>
> *IV. Granted claims 1-3 of Patent No. 276304 are related to a method for simultaneously detecting the presence of multiple Streptococcus pneumonia polysaccharide antigens in a single vaccine in –process and the said method for detecting the presence of polysaccharides covers within its scope, the detection of Streptococcus pneumonia serotypes 1, 5, 9V, 14, 19A, 19F, 23F, 7F, 6A and 6B included in the formulation approved by CDSCO in the permission dated 17.07.2020....."*

7.4 The Authority deliberated upon the matter in detail and observed that M/s Serum Institute of India Pvt. Ltd fulfills the conditions of para 32(ii) of DPCO 2013 with respect to the formulation "Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) IP (10-Valent) (PCV 10V)" in (i) single dose (0.5 ml) vial, (ii) multi-dose (2.5 ml) vial), and (iii) single dose (0.5ml) pre-filled syringes.

7.5 Accordingly, the Authority decided that exemption be granted to M/s Serum Institute of India Pvt. Ltd under Para 32(ii) of DPCO 2013 for their formulation "Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) IP (10-Valent) (PCV 10V)" in (i) single dose (0.5 ml) vial, (ii) multi-dose (2.5 ml) vial), and (iii) single dose (0.5ml) pre-filled syringes for a period of five years from the date of commencement of its commercial production in the country subject to it being co-terminus with the duration of Indian Patent.

7.6 The Authority further directed that M/s Serum Institute of India Pvt. Ltd be requested to intimate the date of commercial production of the formulation "Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) IP (10-Valent) (PCV 10V)" in (i) single dose (0.5 ml) vial, (ii) multi-dose (2.5 ml) vial) and (iii) single dose (0.5ml) pre-filled syringes in the country and the launch price of the product.

7.7 The Authority recalled the decision taken in its 84th meeting dated 10.03.2021 and also directed M/s Serum Institute of India Pvt. Ltd to seek retail price approval, if applicable, three month before the expiry of the exemption granted under Para 32(ii) of DPCO 2013.

8. Agenda item no. 8 – Extension of revised Ceiling price of Heparin Injection 1000IU/ml and 5000IU/ml.

8.1 The Authority noted that the revised ceiling price of Heparin Injection 5000IU/ml and 1000 IU/ml fixed vide SO. 2151(E) dated 30.06.2020 were applicable up to 31.12.2020 and the same were extended up to 31.03.2021 vide SO. 4333(E) dated 03.12.2020, and then upto 30.09.2021 vide SO. 1236(E) dated 17.03.2021 and again upto 31.03.2022 or until further orders, whichever is earlier, vide SO. 3935(E) dated 23.09.2021. The Authority further noted the opinion of the Committee constituted to monitor Export/Import trends of APIs, Formulations and Medical Devices needed for COVID-19 provided vide letter dated 15.03.2022 in which the Committee has stated that *"...NPPA may continue with the increased ceiling price for Heparin injection 1000 IU/ml and 5000 IU/ml, to ensure continuous availability of this essential drug in the current pandemic situation. This extension of ceiling price of Heparin may be considered for duration of six months or may be reviewed earlier as deemed fit.."*

8.2 The Authority deliberated upon the matter in detail and considered the aspect of availability of Heparin Injection 1000IU/ ml and Heparin Injection 5000IU/ ml, a scheduled formulation, especially during the COVID-19 pandemic. The Authority noted

the resurgence of COVID-19 pandemic in other countries and highlighted the necessity to remain vigilant against threat of COVID 19. Accordingly, it decided that the revised ceiling price of Heparin Injection 5000IU/ml and 1000 IU/ml fixed vide SO. 2151(E) dated 30.06.2020 and extended vide SO. 4333(E) dated 03.12.2020, SO. 1236(E) dated 17.03.2021 and SO. 3935(E) dated 23.09.2021 to be further extended upto 30.09.2022 or until further orders, whichever is earlier, in public interest.

8.3 The Authority further directed that the provisions of para 13(2) of DPCO 2013 would not be applicable on the revised ceiling price of Heparin 1000IU/ml Injection and Heparin 5000IU/ml Injection up to 30.09.2022 or until further order, whichever is earlier.

9. Agenda item no. 9 - Extension of revised price of Medical Oxygen

9.1 The Authority noted that the price fixed for Liquid Medical Oxygen (LMO) and Oxygen Inhalation (Medicinal gas) in cylinder vide SO. 3322(E) dated 25.09.2020 were applicable up to 31.03.2021 were extended upto 30.09.2021 vide SO. 1335(E) dated 25.03.2021, and then upto 31.12.2021 vide SO. 3936(E) dated 23.09.2021 and again extended upto 31.03.2022 or until further orders, whichever is earlier, vide SO. 5424(E) dated 28.12.2021.

9.2 The Authority further noted that Department for Promotion of Industry & Internal Trade (DPIIT), Ministry of Commerce and Industry, Government of India vide its Office Memorandum dated 24.03.2022 stated as follows:

> *"...the matter has been examined in this Department and in view of the necessity to remain vigilant against threat of COVID 19 and its new variant Omicron, it is recommended that the prices of above drugs may further be extended by another three months beyond 31.03.2022, after which the issue may be reviewed again."*

9.3 The Authority deliberated upon the matter in detail and in view of continuing extraordinary circumstances due to the COVID pandemic decided that the revised price of Liquid Medical Oxygen (LMO) and Oxygen Inhalation (Medicinal gas) in cylinder fixed vide SO. 3322(E) dated 25.09.2020 and extended vide SO. 1335(E) dated 25.03.2021, SO. 3936(E) dated 23.09.2021 and SO. 5424(E) dated 28.12.2021 be further extended up to 30.06.2022 or until further orders, whichever is earlier, in public interest

10. Agenda item no. 10 - Wholesale Price Index as per Para 16 of DPCO 2013 to be applicable from 01.04.2022

10.1 The Authority noted that DPIIT, Ministry of Commerce and Industry, Government of India has confirmed the monthly final Wholesale Price Indices (WPI) of all commodities for the year 2020 and 2021 vide O.M. OEA-11025(13)/18/2017-WPD-Part(256) dated 23.03.2022. The Authority deliberated upon the matter in detail and approved the WPI @ 10.76607% to be applicable on scheduled formulations w.e.f 01.04.2022. The Authority further decided to issue an Office Memorandum intimating the WPI to be applicable w.e.f. 01.04.2022 and to issue notification(s) for revised ceiling

price of scheduled formulations based on WPI @ 10.76607% to be effective from 01.04.2022.

11. Agenda item no. 11 - Fixation of ceiling price of Foot and Mouth Disease (Trivalent) Oil adjuvant vaccine

11.1 The Authority noted that Foot and Mouth Disease (Trivalent) Oil adjuvant vaccine became a scheduled formulation vide SO. 508(E) dated 01.02.2021 and its ceiling price is required to be fixed. The Authority further noted that the market based data of the formulation is not available in AIOCD-AWACS Pharmatrac database.

11.2 The Authority also noted that Foot and Mouth Disease (Trivalent) Oil adjuvant vaccine is procured by Department of Animal Husbandry and Dairying (DoAHD), Ministry of Fisheries, Animal Husbandry & Dairying through tender process and DoAHD also provided the latest price discovered through tender process.

11.3 The Authority deliberated upon the matter in detail and is of the opinion that the regulation of price of Foot and Mouth Disease (Trivalent) Oil adjuvant vaccine is essential in public interest so as to ensure availability of the vaccine in the country at affordable price. Accordingly, the Authority decided to fix the ceiling price of Foot and Mouth Disease (Trivalent) Oil adjuvant vaccine under Para 19 of DPCO 2013 at Rs. 14.82 per dose excluding GST (one dose is 2 ml), by adding 16% retailer margin on the tender price provided by DoAHD, as detailed below:

S. No.	Particulars	Unit	Amount
1.	L1 rate provided by DoAHD	Per dose (1 dose is 2 ml)	Rs. 13.42 (inclusive of all taxes)
2.	Less: GST@5%	Per dose (1 dose is 2 ml)	Rs. 12.78 excluding GST [Rs. 13.42 /1.05]
3.	L1 rate excluding GST	Per ml	Rs. 6.39 per ml excluding GST [Rs.12.78/2]
4.	Add: Retailer margin @ 16%	Per ml	Rs. 1.02
5.	Ceiling price under para 19 of DPCO 2013	Per ml	Rs. 7.41 excluding GST
6.	Ceiling price per dose excluding GST	1 dose (per dose is 2 ml)	Rs. 14.82 excluding GST

12. Agenda item no. 12 - Fixation of ceiling price of Brucella Abortus (S19 strain) Vaccine, Live freeze dried

12.1 The Authority noted that Brucella Abortus (S19 strain) Vaccine, Live freeze dried became a scheduled formulation vide SO. 508(E) dated 01.02.2021 and its ceiling price is required to be fixed. The Authority further noted that the market based data of the formulation is not available in AIOCD-AWACS Pharmatrac database.

12.2 The Authority also noted that Brucella Abortus (S19 strain) Vaccine, Live freeze dried is procured by DoAHD, Ministry of Fisheries, Animal Husbandry & Dairying through tender process and DoAHD provided the latest price discovered through tender process.

12.3 The Authority deliberated upon the matter in detail and is of the opinion that the regulation of price of Brucella Abortus (S19 strain) Vaccine, Live freeze dried is essential in public interest so as to ensure availability of the vaccine in the country at affordable price. Accordingly, the Authority decided to fix the ceiling price of Brucella Abortus (S19 strain) Vaccine, Live freeze dried under Para 19 of DPCO 2013 at Rs. 10.16 per dose excluding GST(one dose is 2ml after reconstitution), by adding 16% retailer margin on the tender price provided by DoAHD, as detailed below:

Per dose [one dose is 2ml after reconstitution]

S. No.	Particulars	Unit	Amount
1.	L1 rate provided by DoAHD	Per dose for 5 dose pack	Rs. 9.29 (inclusive of all taxes) i.e. Rs. 8.847 excluding GST [Rs.9.29/1.05] [GST is 5%]
2.	L1 rate provided by DoAHD	Per dose for 20 dose pack	Rs. 9.11 (inclusive of all taxes) i.e. Rs. 8.676 excluding GST [Rs.9.11/1.05] [GST@5%]
3.	Average of (1) and (2)	Per dose	Rs. 8.762 excluding GST [(Rs. 8.847+Rs.8.676)/2]
4.	Add: Retailer margin @ 16% on (3)	Per dose	Rs. 1.40
5.	Ceiling price per dose under para 19 of DPCO 2013	Per dose	Rs. 10.16 per dose excluding GST

13. Agenda item no. 13 - Fixation of Ceiling Price of Framycetin cream 0.5% under Para 4 and 6 of DPCO 2013

13.1 The Authority noted that 'Framycetin 0.5% cream is a scheduled formulation under DPCO 2013 and its ceiling price is required to be fixed. The Authority further noted that the ceiling price of 'Framycetin 0.5% ointment' was fixed under DPCO 1995. The Authority deliberated upon the matter in detail and is of the opinion that there is no significant difference between 'cream' and 'ointment' from the point of pharmacokinetics and pharmacodynamics and both are therapeutically the same. Accordingly, the Authority decided to fix the ceiling price of Framycetin cream 0.5% as per Para 4 of DPCO 2013 after considering Para 6(2) of DPCO 2013 and approved the ceiling price at Rs. 1.07 per gm excluding GST.

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

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25/3/2022

(Dr. Vinod Kotwal)
Member Secretary