मिसिल स.- 8(97)/2022/डी.पी/एनपीपीए-डीवी-II
F. No. 8(97)/2022/DP/NPPA-Div. II

कार्यवाही स. : 229/97/2022/F
Proceeding No: 229/97/2022/F

Minutes of the 229th (overall) and 97th meeting of the Authority under DPCO, 2013 held on 06.05.2022 at 11:30 AM

The 229th meeting of the Authority (overall), which is the 97th meeting under the DPCO, 2013, was held on 06th of May 2022 at 11:30 AM under the Chairmanship of Shri Kamlesh Kumar Pant, Chairman, NPPA. 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

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 Sanjay Kumar, Advisor (Cost-II)
(ii) Ms. Rashmi Tahiliani, Jt. Director (Pricing)
(iii) Shri Prasenjit Das, Deputy Director (Pricing)
(iv) Shri Mahaveer Saini, Deputy Director (Pricing)

II. Agenda items

1. Agenda item no. 1 - Confirmation of the Minutes of the 96th Meeting held on 24.03.2022

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 96th Meeting held on 24.03.2022

2.1 The Authority noted that due action has been taken.

2.2 The Authority was apprised that the retail prices of 18 new drugs [10 new drugs comprising FDC of Sitagliptin + Metformin tablet and 8 new drugs comprising FDC of Linagliptin+ Metformin tablet] that was fixed in its 96th Authority dated 24.03.2022 meeting could not be notified since representations had been received. Accordingly, the matter was placed in the present meeting for deliberation by the Authority.

2.3 The Authority was apprised that the ceiling price of (i) Foot and Mouth Disease (Trivalent) Oil adjuvant vaccine and (ii) Brucella Abortus (S19 strain) Vaccine, Live freeze dried which was fixed in its 96th Authority dated 24.03.2022 meeting could not be notified since representations had been received. Accordingly, the matter was placed in the present meeting for deliberation by the Authority.

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(xlv)(d) (total 68 Form I applications containing retail price fixation of 68 new drugs) falling under the purview of Para 2(u) of DPCO, 2013 and approved the retail prices of 66 (sixty six)[except agenda item no. 4(xxxv) and 4(xxxvi)] 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.)
	(2)	(3)	(4)	(5)	(6)
4(i)	Glimepiride and Metformin Hydrochloride sustained release tablets	**Each uncoated bilayer tablet contains:** Glimepiride IP 2mg Metformin Hydrochloride IP 500mg (As sustained release)	1 Tablet	M/s Indu Drugs Private Limited / M/s. Maxbien Pharma Private Limited	9.55
4(ii)	Glimepiride and Metformin Hydrochloride sustained release tablets	**Each uncoated bilayer tablet contains:** Glimepiride IP 1mg Metformin Hydrochloride IP 500mg (As sustained release)	1 Tablet	M/s Indu Drugs Private Limited / M/s. Maxbien Pharma Private Limited	6.78
4(iii)	Gastro-Resistant Omeprazole and Domperidone Sustained Release Capsules	**Each hard gelatin capsule contains:** Omeprazole IP 20mg (as gastro-resistant pellets) Domperidone IP 30mg (as sustained release pellets)	1 Capsule	M/s Indu Drugs Private Limited / M/s. Ma Lara Healthcare Pvt. Ltd.	9.53
4(iv)	Gastro-Resistant Pantoprazole and Domperidone Sustained Release Capsules	**Each hard gelatin capsule contains:** Pantoprazole Sodium IP eq. to Pantoprazole 40mg (as gastro-resistant pellets) Domperidone IP 30mg (as sustained release pellets)	1 Capsule	M/s Indu Drugs Private Limited / M/s. Ma Lara Healthcare Pvt. Ltd.	9.21
4(v)	Gastro-Resistant Rabeprazole and Domperidone	**Each hard gelatin capsule contains:** Rabeprazole Sodium	1 Capsule	M/s Indu Drugs Private Limited / M/s. Ma Lara	9.67

Agenda Item No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
	(2)	(3)	(4)	(5)	(6)
	Sustained Release Capsules	IP 20mg (as gastro-resistant pellets) Domperidone IP 30mg (as sustained release pellets)		Healthcare Pvt. Ltd.	
4(vi)	Gastro-Resistant Esomeprazole and Domperidone Sustained Release Capsules	**Each hard gelatin capsule contains:** Esomeprazole Magnesium Trihydrate IP eq. to Esomeprazole 40mg (As gastro-resistant pellets) Domperidone IP 30mg (As Sustained Release pellets)	1 Capsule	M/s Indu Drugs Private Limited / M/s. Ma Lara Healthcare Pvt. Ltd.	10.17
4(vii)	Thyroxine Sodium Tablets	**Each uncoated tablet contains:** Thyroxine Sodium IP eq. to anhydrous Thyroxine Sodium 200mcg (Synthetic Thyroid Hormone)	1 Tablet	M/s Abbott India Ltd.	1.98
4(viii)	Atorvastatin & Ezetimibe Tablets	**Each film coated tablet contains:** Atorvastatin Calcium IP eq. to Atorvastatin 10mg Ezetimibe IP 10mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. /M/s German Remedies Pharmaceuticals Private Limited	16.23
4(ix)	Atorvastatin & Clopidogrel Tablets	**Each Uncoated Bilayered tablet contains:** Atorvastatin Calcium IP eq. to Atorvastatin 10mg Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. /M/s German Remedies Pharmaceuticals Private Limited	11.62
4(x)	Dextromethorphan hydrobromide, Chlorpheniramine Maleate & Phenylephrine Hydrochloride Syrup	**Each 5 ml contains:** Dextromethorphan hydrobromide IP 10mg Chlorpheniramine Maleate IP 2mg Phenylephrine Hydrochloride IP 5mg	1 ML	M/s Akums Drugs & Pharmaceuticals Ltd. /M/s German Remedies Pharmaceuticals Private Limited	0.86
4(xi)	Atorvastatin, Clopidogrel & Aspirin Capsules	**Each hard gelatin capsule contains:** Atorvastatin Calcium IP eq. to Atorvastatin 10mg (As film coated	1 Capsule	M/s Safetab Life Science / M/s Ajanta Pharma Ltd.	4.68

Agenda Item No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
	(2)	(3)	(4)	(5)	(6)
		tablet IP) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg Aspirin IP 75mg (As Gastro-Resistant Tablet IP)			
4(xii)	Atorvastatin, Clopidogrel & Aspirin Capsules	**Each hard gelatin capsule contains:** Atorvastatin Calcium IP eq. to Atorvastatin 20mg (As film coated tablet IP) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg Aspirin IP 75mg (As Gastro-Resistant Tablet IP)	1 Capsule	M/s Safetab Life Science / M/s Ajanta Pharma Ltd.	6.32
4(xiii)	Paracetamol Infusion IP	**Each 100ml contains:** Paracetamol IP 1000mg water for Injection IP	1 ML	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Mankind Life Sciences Pvt. Ltd.	2.88
4(xiv)	Norethisterone Acetate controlled release Tablets	**Each film coated controlled release tablet contains:** Norethisterone Acetate BP 15mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Obsurge Biotech Ltd.	19.20
4(xv)	Atorvastatin & Clopidogrel Capsules	**Each Hard Gelatin Capsule Contains:** Atorvastatin Calcium IP eq to Atorvastatin 40mg (As green coloured spherical pellets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As two brown coloured film coated tablets Each containing 37.5mg Clopidogrel Tablets)	1 Capsule	M/s Windlas Biotech Limited. / M/s Mankind Pharma Ltd.	30.74
4(xvi)	Ivermectin & Albendazole Tablets	**Each uncoated Chewable tablet contains:** Ivermectin IP 6mg Albendazole IP 400mg	1 Tablet	M/s Next Wave (India) / M/s Mankind Prime Labs Pvt. Ltd.	22.52
4(xvii)	Aceclofenac, Paracetamol & Thiocolchicoside	**Each film coated tablet contains:** Aceclofenac IP 100mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s	16.27

Agenda Item No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
	(2)	(3)	(4)	(5)	(6)
	tablets	Paracetamol IP 325mg Thiocolchicoside IP 4mg		Troikaa Pharmaceuticals Ltd.	
4(xviii)	Etoricoxib & Paracetamol Tablets	**Each Film Coated tablet contains:** Etoricoxib IP 60 mg Paracetamol IP 325 mg	1 Tablet	M/s Haelwood Laboratories Pvt. Ltd. / M/s Eris Healthcare Pvt. Ltd.	7.67
4(xix)	Metformin Hydrochloride prolonged-release and Glimepiride Tablets	**Each uncoated bilayered tablet contains:** Glimepiride IP 1 mg Metformin Hydrochloride IP 500 mg (as prolonged-release form)	1 Tablet	M/s Akum Drugs & Pharmaceuticals Limited/M/s German Remedies Pharmaceuticals Pvt. Ltd.	6.93
4(xx)	Ivermectin & Albendazole Oral Suspension	**Each 5 ml contains:** Ivermectin IP 1.5 mg Albendazole IP 200 mg	1 ML	M/s Next Wave (India) / M/s Mankind Prime Labs Pvt. Ltd.	2.20
4(xxi)	Cilnidipine & Telmisartan tablets	**Each film coated tablet contains:** Cilnidipine IP 10mg Telmisartan IP 40 mg	1 Tablet	M/s Mediforce Healthcare Pvt. Ltd./ M/s Mankind Prime Labs Pvt. Ltd.	9.92
4(xxii)	Nimesulide & Paracetamol tablets	**Each uncoated tablet contains:** Nimesulide BP 100mg Paracetamol IP 325 mg	1 Tablet	M/s Softdeal Pharmaceutical Private Limited	4.27
4(xxiii)	Travoprost & Timolol Maleate Eye Drops	**Each ml contains:** Travoprost IP 40 mcg Timolol Maleate eq. to Timolol IP 5 mg	1 ML	M/s East African (India) Overseas/ M/s Alkem Laboratories Limited	123.68
4(xxiv)	Dorzolamide & Timolol Eye Drops	**Composition:** Dorzolamide Hydrochloride IP eq. to Dorzolamide 2% w/v Timolol Maleate eq. to Timolol IP 0.5 % w/v Water for injection	1 ML	M/s East African (India) Overseas/ M/s Alkem Laboratories Limited	63.67
4(xxv)	Brimonidine Tartrate & Timolol Maleate Ophthalmic Solution	**Each ml contains:** Brimonidine Tartrate IP 2 mg Timolol Maleate eq. to Timolol IP 5 mg	1ML	M/s East African (India) Overseas/ M/s Alkem Laboratories Limited	49.04
4(xxvi)	Atorvastatin & Clopidogrel Tablets	**Each uncoated bilayered tablet contains:**	1 Tablet	M/s Pure and Cure Healthcare Pvt.	

Agenda Item No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
	(2)	(3)	(4)	(5)	(6)
		Atorvastatin Calcium IP eq. to Atorvastatin 20 mg Clopidogrel Bisulphate eq. to Clopidogrel IP 75 mg		Limited/M/s German Remedies Pharmaceuticals Pvt. Ltd.	17.17
4 (xxvii)	Telmisartan & Chlorthalidone Tablets	**Each film coated tablet contains:** Telmisartan IP 80mg Chlorthalidone IP 12.5mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Limited/M/s Abbott Healthcare Pvt. Ltd.	10.55
4 (xxviii)	Voglibose, Glimepiride and Metformin Hydrochloride (sustained release)Tablets	**Each uncoated bilayered tablet contains:** Voglibose IP 0.2mg Glimepiride IP 2mg Metformin Hydrochloride IP 1000mg (as sustained release form)	1 Tablet	M/s Swiss Garnier Genexiaa Sciences Pvt Ltd. / M/s Mankind Pharma Ltd.	13.31
4 (xxix)	Vitamin D3 Oral Solution	**Each 5ml contains:** Cholecalciferol IP (In nano Droplet form) 60000IU	1 ML	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Mankind Pharma Limited	13.94
4 (xxx)	Vitamin D3 Oral Solution	**Each 5ml contains:** Cholecalciferol IP (In nano Droplet form) 60000IU	1 ML	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Mankind Prime Labs Pvt. Ltd.	13.94
4 (xxxi)	Calcium & Vitamin D3 Suspension	**Each 5ml contains:** 625mg Calcium Carbonate from an Organic Source (Oyster Shell) eq. to Elemental Calcium 250mg Vitamin D3 IP 125IU	1 ML	M/s Shivalik Remedies Pvt. Ltd. / M/s Mankind Prime Labs Pvt. Ltd.	0.51
4 (xxxii)	Voglibose, Glimepiride and Metformin Hydrochloride (sustained release) Tablets	**Each uncoated bilayered tablet contains:** Voglibose IP 0.2mg Glimepiride IP 1mg Metformin Hydrochloride IP 1000mg (as sustained release form)	1 Tablet	M/s Swiss Garnier Genexiaa Sciences Pvt Ltd. / M/s Mankind Pharma Ltd.	11.43
4 (xxxv)	Diclofenac Sodium and Paracetamol	**Each uncoated tablet contains:** Diclofenac Sodium IP	1 Tablet	M/s Akums Drugs & Pharmaceuticals	Deferred

Agenda Item No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
	(2)	(3)	(4)	(5)	(6)
	Tablets	50mg, Paracetamol IP 325mg		Ltd. / M/s Emcure Pharmaceuticals Ltd.	
4(xxxvi)	Tacrolimus Capsule	**Each hard gelatin capsule s contains:** Tacrolimus IP 3mg	1 Capsule	M/s Cadila Healthcare Limited	Rejected (Note 1)
4(xxxvii)	Diclofenac Diethylamine, Methyl Salicylate, Linseed Oil and Menthol Tropical Spray	**Composition:** Diclofenac Diethylamine IP 1.16% w/w eq. to Diclofenac Sodium 1% w/w Virgin Linseed Oil BP 3% w/w Methyl Salicylate IP 10% w/w Menthol IP 5% w/w	1 gm	M/s Pontika Aerotech Ltd./M/s Zuventus Healthcare Ltd.	2.69 (Note 2) (Note 3)
4 (xxxviii)	Diclofenac Diethylamine, Linseed Oil, Methyl Salicylate and Menthol Gel	**Composition:** Diclofenac Diethylamine IP 1.16% w/w eq. to Diclofenac Sodium 1% w/w Virgin Linseed Oil(Oleum Lini) BP 3% Methyl Salicylate IP 10% w/w Menthol IP 5% w/w	1GM	M/s Nanz Med Science Pharma Pvt. Ltd./M/s Zuventus Healthcare Ltd.	2.83 (Note 2) (Note 3)
4 (xxxix)	Tramadol & Paracetamol Tablets	**Each film coated tablet contains:** Tramadol Hydrochloride IP37.5mg Paracetamol IP 325mg	1 Tablet	M/s Hab Pharmaceuticals & Research Limited /M/s German Remedies Pharmaceuticals Private Limited	8.35
4 (xl)	Telmisartan & Amlodipine Tablets	**Each uncoated bilayered tablet contains:** Telmisartan IP 40mg Amlodipine Besylate IP eq. to Amlodipine 5mg	1 Tablet	M/s Indchemie Health Specialities Pvt. Ltd.	9.49
4 (xli)	Telmisartan & Metoprolol Succinate ER Tablets	**Each film coated bilayered tablet contains:** Telmisartan IP 40mg Metoprolol Succinate IP eq. to Metoprolol Tartrate 50mg (as Extended Release form)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Limited/M/s German Remedies Pharmaceuticals Pvt. Ltd.	13.66
4 (xlii)	Telmisartan +	**Each uncoated**	1	M/s Indchemie	9.95

Agenda Item No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
	(2)	(3)	(4)	(5)	(6)
	Hydrochlorothiazide Tablets	**bilayered tablet contains:** Telmisartan IP 40mg Hydrochlorothiazide IP 12.50mg	Tablet	Health Specialities Pvt. Ltd.	
4 (xliii)	Paracetamol & Chlorzoxazone Tablets	**Each uncoated tablet contains:** Paracetamol IP 500mg Chlorzoxazone USP 250mg	1 Tablet	M/s The Madras Pharmaceuticals /M/s Sun Pharmaceutical Industries Ltd.	10.31
4 (xliv)	Diclofenac Diethylamine, Methyl Salicylate, Menthol & Absolute Alcohol Topical Spray	**Composition:** Diclofenac Diethylamine IP 2.32% w/v eq. to Diclofenac Sodium IP 2% w/v Methyl Salicylate IP 10% w/v Menthol IP 5% w/v Absolute Alcohol IP 10% v/v	1 GM	M/s Pontika Aerotrch Limited / M/s Mankind Pharma Ltd.	3.22
4 (xxxiii)a	Sitagliptin Phosphate & Metformin Hydrochloride Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Aristo Pharmaceuticals Pvt. Ltd.	18.34 (Note 4)
4 (xxxiii)b	Sitagliptin Phosphate & Metformin Hydrochloride Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Aristo Pharmaceuticals Pvt. Ltd.	20.02 (Note 4)
4 (xxxiii)c	Sitagliptin Phosphate & 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 Lupin Limited	18.34 (Note 4)
4 (xxxiii)d	Sitagliptin Phosphate & Metformin Hydrochloride Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP 64.25mg eq. to Sitagliptin 50mg Metformin	1 Tablet	M/s Bajaj Healthcare Ltd. / M/s Lupin Limited	20.02 (Note 4)

Agenda Item No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
	(2)	(3)	(4)	(5)	(6)
		Hydrochloride IP 1000mg			
4 (xxxiii)e	Sitagliptin & Metformin Hydrochloride Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Intas Pharmaceuticals Ltd.	18.34 (Note 4)
4 (xxxiii)f	Sitagliptin & Metformin Hydrochloride Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Intas Pharmaceuticals Ltd.	20.00 (Note 4)
4 (xxxiii)g	Sitagliptin & Metformin Hydrochloride Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Optimus Pharma Pvt. Ltd. / M/s Mankind Pharma Ltd.	18.34 (Note 4)
4 (xxxiii)h	Sitagliptin & Metformin Hydrochloride Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Optimus Pharma Pvt. Ltd. / M/s Mankind Pharma Ltd.	20.02 (Note 4)
4 (xxxiii)i	Sitagliptin & Metformin Hydrochloride Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 850mg	1 Tablet	M/s Optimus Pharma Pvt. Ltd. / M/s Mankind Pharma Ltd.	19.14 (Note 4)
4 (xxxiii)j	Sitagliptin Phosphate & 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 Windlas Biotech Limited / Wockhardt Limited	8.92 (Note 4)

Agenda Item No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
	(2)	(3)	(4)	(5)	(6)
4 (xxxiii)k	Sitagliptin Phosphate & 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 Windlas Biotech Limited / Wockhardt Limited	9.82 (Note 4)
4 (xxxiii)l	Sitagliptin Phosphate & Metformin Hydrochloride Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Sun Pharma Laboratories Limited	18.34 (Note 4)
4 (xxxiii)m	Sitagliptin Phosphate & Metformin Hydrochloride Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Sun Pharma Laboratories Limited	20.02 (Note 4)
4 (xxxiii)n	Sitagliptin Phosphate & Metformin Hydrochloride Extended Release Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (As Extended Release form)	1 Tablet	M/s Sun Pharma Laboratories Limited	19.81 (Note 4)
4 (xxxiii)o	Sitagliptin Phosphate & Metformin Hydrochloride Tablets	**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 Eris Life Sciences Limited	18.34 (Note 4)
4 (xxxiii)p	Sitagliptin Phosphate & Metformin Hydrochloride Tablets	**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 Eris Life Sciences Limited	20.02 (Note 4)
4	Sitagliptin	**Each film coated**		M/s Exemed	

Agenda Item No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
	(2)	(3)	(4)	(5)	(6)
(xxxiii)q	Phosphate & Metformin Hydrochloride Tablets	**tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 850mg	1 Tablet	Pharmaceuticals / M/s Eris Life Sciences Limited	19.14 (Note 4)
4 (xxxiv)a	Linagliptin & Metformin Hydrochloride Tablets	**Each Film coated tablet contains:** Linagliptin 2.5 mg Metformin Hydrochloride 500 mg	1 Tablet	M/s Mediforce Healthcare Pvt. Ltd. / M/s Mankind Pharma Ltd.	14.65 (Note 5)
4 (xxxiv)b	Linagliptin & Metformin Hydrochloride Tablets	**Each film coated tablet contains:** Linagliptin 2.5mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Alkem Healthscience (A unit of Alkem Laboratories Ltd.) /M/s Alkem Laboratories Ltd.	14.65 (Note 5)
4 (xxxiv)c	Linagliptin & Metformin Hydrochloride Tablets	**Each film coated tablet contains:** Linagliptin 2.5mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Alkem Healthscience (A unit of Alkem Laboratories Ltd.) /M/s Alkem Laboratories Ltd.	16.33 (Note 5)
4 (xxxiv)d	Linagliptin & Metformin Hydrochloride Tablets	**Each Film Coated tablet contains:** Linagliptin 2.5 mg Metformin Hydrochloride IP 1000 mg	1 Tablet	M/s Mediforce Healthcare Pvt. Ltd. / M/s Mankind Pharma Ltd.	16.33 (Note 5)
4 (xxxiv)e	Linagliptin & Metformin Hydrochloride Tablets	**Each Film Coated tablet contains:** Linagliptin 2.5 mg Metformin Hydrochloride IP 850 mg	1 Tablet	M/s Mediforce Healthcare Pvt. Ltd. / M/s Mankind Pharma Ltd.	15.45 (Note 5)
4 (xlv) a	Vildagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Vildagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Associated Biotech / M/s Unistretch Pharmaceuticals Pvt. Ltd.	6.75 (Note 6)
4 (xlv) b	Vildagliptin + Metformin Hydrochloride Tablet	**Each film-coated tablet contains:** Vildagliptin IP 50mg Metformin Hydrochloride IP	1 Tablet	M/s Windlas Biotech Limited / M/s Mankind Prime Labs Pvt. Lttd.	7.60 (Note 6)

Agenda Item No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
	(2)	(3)	(4)	(5)	(6)
		1000mg			
4 (xlv) c	Vildagliptin (as Immediate release) and Metformin Hydrochloride (as sustained release) Tablets	**Each uncoated bilayer tablets contains:** Vildagliptin IP (as Immediate release) 50mg Metformin Hydrochloride IP (as sustained release) 1000mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. M/s German Remedies Pharmaceuticals Pvt. Ltd.	8.06 (Note 7)
4 (xlv) d	Vildagliptin (as Immediate release) and Metformin Hydrochloride (as sustained release) Tablets	**Each uncoated bilayer tablets contains:** Vildagliptin IP (as Immediate release) 50mg Metformin Hydrochloride IP (as sustained release) 500mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. M/s German Remedies Pharmaceuticals Pvt. Ltd.	7.21 (Note 7)

Note1*. The Authority noted the application for retail price fixation of new drug "Tacrolimus Prolonged Release Capsules 3 mg" filed by M/s Cadila Healthcare Ltd that was placed before the Multidisciplinary Committee of Experts. The committee in its 41st meeting dated 08.04.2022 recommended that ".....since Tacrolimus Prolonged Release hard gelatine capsule 3 mg would continue to be new drugs after promulgation of New Drugs and Clinical Trials Rules, 2019, M/s Cadila Healthcare Ltd would require specific approval from CDSCO to import/ manufacture the formulation Tacrolimus Prolonged Release hard gelatine capsule 3 mg in India. Accordingly, the Committee decided to reject the application of M/s Cadila Healthcare Ltd for retail price fixation of Tacrolimus Prolonged Release hard gelatine capsules 3 mg since CDSCO has not given approval to M/s Cadila Healthcare Ltd to import/ manufacture the formulation Tacrolimus Prolonged Release hard gelatine capsule 3 mg." The Authority deliberated upon the matter in detail and accepted the recommendation of the Multidisciplinary Committee of Experts. Accordingly, the Authority rejected the application of M/s Cadila Healthcare Ltd for retail price fixation of Tacrolimus Prolonged Release hard gelatine capsule 3 mg.*

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

Note 3*. The representation received from M/s Zuventus Healthcare Ltd on the draft calculation sheet uploaded on NPPA website was sent to Pharmatrac for verification/confirmation. Pharmatrac sent the revised data. Accordingly, based on the revised data provided by Pharmatrac, the retail price is calculated.*

Note 4. *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 5. *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 6. *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 84th Authority meeting dated 10.03.2021.*

Note 7. *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 92nd Authority meeting dated 08.09.2021. However, the incremental difference of Rs.0.46 has been allowed based on the latest applicable SO. 1499(E) dated 30.03.2022.*

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

5.1 Noted.

6. Agenda item no. 6 – Review application of M/s Emcure Pharmaceuticals Ltd against retail price fixation of Darunavir 800mg + Ritonavir 100 mg tablet vide S.O. 4062(E) dated 08.11.2019

6.1 The Authority deliberated upon the matter in detail and decided to revise the retail price of 'Each film coated tablet containing Darunavir Ethanolate eq. To Darunavir 800mg + Ritonavir IP 100mg Tablet' fixed vide SO. 4062(E) dated 08.11.2019 to Rs. 212.91 per tablet excluding GST towards implementation of Department of Pharmaceuticals' (DoP) review order no. 31015/16/2019-Pricing dated 25.06.2021 read with DoP' letter no. F. No. 31015/16/2019-Pricing (E-14046) dated 05.04.2022.

7. Agenda item no. 7 - Application filed by M/s Bharat Serums & Vaccines Ltd for exemption under Para 32(i) of DPCO 2013 for the formulation "Recombinant Anti Rho-D Immunoglobulin Injection 300mcg (liquid injection) in (i) 2 ml vial and (ii) 1 ml graduated pre-filled syringe.

7.1 The Authority noted the application filed by M/s Bharat Serums & Vaccines Ltd for exemption under Para 32(i) of DPCO 2013 for the formulations (i) Recombinant Anti Rho-D Immunoglobulin Injection 300mcg (liquid injection) in 2 ml vial and (ii) Recombinant Anti Rho-D Immunoglobulin Injection 300mcg (liquid injection) in 1 ml graduated pre-filled syringe.

7.2 The Authority further noted that M/s Bharat Serums & Vaccines Ltd submitted the following documents:

a. Copy of the Patent certificate issued by the Patent Office, Government of India to M/s Bharat Serums & Vaccines Ltd for the invention entitled "ANTI-RHD MONOCLONAL ANTIBODY" [Patent No: 254428, Date of grant: 02.11.2012, Period of grant: 20 years from 31.12.2008]

b. Copy of the new drug approval given by Central Drugs Standard Control Organisation (CDSCO) dated 24.12.2020 to M/s Bharat Serums and vaccines Ltd for the formulations

(i) Recombinant Anti Rho-D Immunoglobulin Injection 300mcg (liquid injection) in 2 ml vial and (ii) Recombinant Anti Rho-D Immunoglobulin Injection 300mcg (liquid injection) in 1 ml graduated pre-filled syringe.

7.3 The Authority noted the Patent Office, Government of India Report titled "*Report on Scope of Patent claims with respect to a new drug formulations approval granted by CDSCO to M/s Bharat Serums & Vaccines Ltd in respect of following three products namely: (i) Recombinant Anti Rho-D Immunoglobulin Injection 300mcg (liquid injection) in 2 ml vial (ii) Recombinant Anti Rho-D Immunoglobulin Injection 300mcg (liquid injection) in 1 ml graduated pre-filled syringe; and (iii) Anti Rho-D Immunoglobulin (r-DNA origin) 150mcg liquid injection in 2 ml vial*" sent vide e-mail dated 08.04.2022. The Report stated as follows:

> *"The above said three products (i) to (iii) applied for DPCO exemption as such are not covered within the scope of granted claims 1-16 in Patent No. 254428. The applied products relating to: (i) recombinant anti-Rho-D immunoglobulin injection 300 mcg (liquid injection) in 2 ml vial; (ii) recombinant anti-Rho-D immunoglobulin injection 300 mcg (liquid injection) in 1 ml graduated pre-filled syringe; and (iii) anti-Rho-D immunoglobulin (r-DNA origin) 150 mcg liquid injection in 2 ml vial are compared with the granted claims 1-16 as well as description and examples. As a result, it is found that said products as such are not covered within the scope of the granted claims and also, there is no full and particular disclosure in the patent specification with respect to said products."*

7.4 The Authority deliberated upon the matter in detail and observed that Report of the Patent Office, Government of India has noted that the formulations (i) Recombinant anti-Rho-D immunoglobulin injection 300 mcg (liquid injection) in 2 ml vial (ii) Recombinant anti-Rho-D immunoglobulin injection 300 mcg (liquid injection) in 1 ml graduated pre-filled syringe of M/s Bharat Serums and Vaccines Ltd are not covered within the scope of granted claims 1-16 in Patent No. 254428 and also, there is no full and particular disclosure in the patent specification with respect to the said products. Hence, the Authority is of the opinion that the formulations (i) Recombinant anti-Rho-D immunoglobulin injection 300 mcg (liquid injection) in 2 ml vial and (ii) Recombinant anti-Rho-D immunoglobulin injection 300 mcg (liquid injection) in 1 ml graduated pre-filled syringe of M/s Bharat Serums and Vaccines Ltd is not qualified for exemption under Para 32(i) of DPCO 2013.

7.5 Accordingly, the Authority decided that no exemption be granted to M/s Bharat Serums and Vaccines Ltd under Para 32(i) of DPCO 2013 for their formulations (i) Recombinant anti-Rho-D immunoglobulin injection 300 mcg (liquid injection) in 2 ml vial and (ii) Recombinant anti-Rho-D immunoglobulin injection 300 mcg (liquid injection) in 1 ml graduated pre-filled syringe and the application be treated as closed.

8. Agenda item no. 8 – Application filed by M/s Bharat Serums & Vaccines Ltd for exemption under Para 32(i) of DPCO 2013 for the formulation "Anti Rho-D Immunoglobulin (r-DNA origin) 150mcg liquid injection in 2 ml vial"

8.1 The Authority noted the application filed by M/s Bharat Serums & Vaccines Ltd for exemption under Para 32(i) of DPCO 2013 for the formulation "Anti Rho-D Immunoglobulin (r-DNA origin) 150mcg liquid injection in 2 ml vial."

8.2 The Authority further noted that M/s Bharat Serums & Vaccines Ltd submitted the following documents:

a. Copy of the Patent certificate issued by the Patent Office, Government of India to M/s Bharat Serums & Vaccines Ltd for the invention entitled "ANTI-RHD MONOCLONAL ANTIBODY" [Patent No: 254428, Date of grant: 02.11.2012, Period of grant: 20 years from 31.12.2008]

b. Copy of the new drug approval given by Central Drugs Standard Control Organisation (CDSCO) dated 24.08.2021 to M/s Bharat Serums and vaccines Ltd for the formulation "Anti Rho-D Immunoglobulin (r-DNA origin) 150mcg liquid injection in 2 ml vial"

8.3 The Authority noted the Patent Office, Government of India Report titled "*Report on Scope of Patent claims with respect to a new drug formulations approval granted by CDSCO to M/s Bharat Serums & Vaccines Ltd in respect of following three products namely: (i) Recombinant Anti Rho-D Immunoglobulin Injection 300mcg (liquid injection) in 2 ml vial (ii) Recombinant Anti Rho-D Immunoglobulin Injection 300mcg (liquid injection) in 1 ml graduated pre-filled syringe; and (iii) Anti Rho-D Immunoglobulin (r-DNA origin) 150mcg liquid injection in 2 ml vial*" sent vide e-mail dated 08.04.2022. The Report stated as follows:

> *"The above said three products (i) to (iii) applied for DPCO exemption as such are not covered within the scope of granted claims 1-16 in Patent No. 254428. The applied products relating to: (i) recombinant anti-Rho-D immunoglobulin injection 300 mcg (liquid injection) in 2 ml vial; (ii) recombinant anti-Rho-D immunoglobulin injection 300 mcg (liquid injection) in 1 ml graduated pre-filled syringe; and (iii) anti-Rho-D immunoglobulin (r-DNA origin) 150 mcg liquid injection in 2 ml vial are compared with the granted claims 1-16 as well as description and examples. As a result, it is found that said products as such are not covered within the scope of the granted claims and also, there is no full and particular disclosure in the patent specification with respect to said products.""*

8.4 The Authority deliberated upon the matter in detail and observed that the Report of the Patent Office, Government of India has noted that the formulation "Anti Rho-D Immunoglobulin (r-DNA origin) 150mcg liquid injection in 2 ml vial" of M/s Bharat Serums and Vaccines Ltd are not covered within the scope of granted claims 1-16 in Patent No. 254428 and also, there is no full and particular disclosure in the patent specification with respect to the said product. Hence, the Authority is of the opinion that the formulation "Anti Rho-D Immunoglobulin (r-DNA origin) 150mcg liquid injection in 2 ml vial" of M/s Bharat Serums and Vaccines Ltd is not qualified for exemption under Para 32(i) of DPCO 2013.

8.5 Accordingly, the Authority decided that no exemption be granted to M/s Bharat Serums and Vaccines Ltd under Para 32(i) of DPCO 2013 for their formulation "Anti Rho-D Immunoglobulin (r-DNA origin) 150mcg liquid injection in 2 ml vial" and the application be treated as closed.

9. Agenda item no. 9 - Application of M/s Neon Laboratories Ltd for exemption under Para 32 of DPCO 2013 for the formulation "FDC of Ropivacaine Hydrochloride IP eq. to anhydrous Ropivacaine Hydrochloride 7.5 mg + Dextrose (Monohydrate) IP 80mg per ml Injection".

9.1 The Authority noted the application filed by M/s Neon Laboratories Ltd for exemption under Para 32 of DPCO 2013 for the formulation "FDC of Ropivacaine Hydrochloride IP eq. to anhydrous Ropivacaine Hydrochloride 7.5 mg + Dextrose (Monohydrate) IP 80mg per ml Injection".

9.2 The Authority further noted that M/s Neon Laboratories Ltd submitted the following documents:
a. Copy of the Patent certificate issued by the Patent Office, Government of India to M/s Neon Laboratories Ltd for the invention entitled "HYPERBARIC INJECTION SOLUTION OF ROPIVACAINE HYDROCHLORIDE AND PROCESS FOR PREPARATION THEREOF "[Patent No: 304288, Date of grant: 11.12.2018, Period of grant: 20 years from 13.07.2015]
b. Copy of the new drug approval given by Central Drugs Standard Control Organisation (CDSCO) dated 01.10.2021 to M/s Neon Laboratories Ltd for the formulation "FDC of Ropivacaine Hydrochloride IP eq. to anhydrous Ropivacaine Hydrochloride 7.5 mg + Dextrose (Monohydrate) IP 80mg per ml Injection".

9.3 The Authority noted the Patent Office, Government of India Report titled "*Report on Scope of Patent claims with respect to application filed by M/s Neon Laboratories Ltd. for exemption under Para 32 of DPCO 2013 for drug formulation "FDC of Ropivacaine Hydrochloride IP eq. to anhydrous Ropivacaine Hydrochloride 7.5 mg + Dextrose (Monohydrate) IP 80 mg per ml Injection"* sent vide e-mail dated 13.04.2022. The Report stated as follows:

- *Formulation approved by CDSCO contains in each ml, 7.5 mg Ropivacaine Hydrochloride IP eq. to anhydrous Ropivacaine Hydrochloride; 80 mg Dextrose (Monohydrate) IP; and Q.S. water for injection IP;*
- *Claims of granted Patent No. 304288 cover within the scope a formulation comprising 5 mg Ropivacaine Hydrochloride; 4-15% w/v Dextrose; base/acid (as stated in claim 1 above) to adjust pH between 3.5 to 6.0 and water as a vehicle (copy of granted claims 1-8 is also enclosed).*
- *Amount of drug Ropivacaine Hydrochloride is different in both the formulations, i.e. one that is approved by CDSCO and other that is allowed in said granted patent.*
- *What has been approved by CDSCO as a formulation (of 1 ml) containing 7.5 mg of Ropivacaine Hydrochloride is not within the scope of claims of granted patent in terms of amount of drug Ropivacaine Hydrochloride, whereas the formulation also contains 80 mg of dextrose ,which is within the scope of granted patent.*
- *Further, the formulation approved by CDSCO also differs in respect of base/acid included to adjust the pH between 3.5 to 6.0 as per claim 1 of granted patent, which is not mentioned in the approved formulation of CDSCO.*

9.4 The Authority deliberated upon the matter in detail and observed that the Report of the Patent Office, Government of India has noted that (i) the formulation containing 7.5 mg of Ropivacaine Hydrochloride, as approved by CDSCO is not within the scope of claims of granted patent in terms of amount of drug Ropivacaine Hydrochloride, and (ii) the formulation approved by CDSCO also differs in respect of base/acid included to adjust the pH between 3.5 to 6.0 as per claim 1 of granted patent, which is not mentioned in the approved formulation of CDSCO. Thus, as per the Report furnished by the Patent Office, the formulation "FDC of Ropivacaine Hydrochloride IP eq. to anhydrous Ropivacaine Hydrochloride 7.5 mg + Dextrose (Monohydrate) IP 80mg per ml Injection" of M/s Neon Laboratories Ltd, as approved by CDSCO is not within the

scope of the Patent No. 304288 claimed by the company. Hence, the Authority is of the opinion that the formulation "FDC of Ropivacaine Hydrochloride IP eq. to anhydrous Ropivacaine Hydrochloride 7.5 mg + Dextrose (Monohydrate) IP 80mg per ml Injection" of M/s Neon Laboratories Ltd is not qualified for exemption under Para 32 of DPCO 2013.

9.5 Accordingly, the Authority decided that no exemption be granted to M/s Neon Laboratories Ltd under Para 32 of DPCO 2013 for their formulation "FDC of Ropivacaine Hydrochloride IP eq. to anhydrous Ropivacaine Hydrochloride 7.5 mg + Dextrose (Monohydrate) IP 80mg per ml Injection" and the application be treated as closed.

10. Agenda item no. 10 - Fixation of Ceiling Price of Clotrimazole 1% mouth paint under DPCO 2013 (NLEM 2015)

10.1 The Authority noted that the matter was referred to the Multidisciplinary Committee of Experts, which in its 41st meeting dated 08.04.2022 decided as follows:

> *"...the clarification dated 07.04.2022 received from the Office of the Central Drugs Standard Control Organisation (CDSCO) that the formulation Clotrimazole 1% mouth paint is not approved by CDSCO. The Committee deliberated upon the matter in detail and is of the opinion that since Clotrimazole 1% mouth paint is not approved by CDSCO, it cannot be categorised as scheduled formulation as per Explanation-I of DPCO 2013. Accordingly, the Committee decided that Clotrimazole 1% mouth paint is not a scheduled formulation as per Explanation-I of DPCO 2013 and hence its ceiling price not to be fixed."*

10.2 The Authority deliberated upon the matter in detail and accepted the recommendations of the Multidisciplinary Committee of Experts and decided that Clotrimazole 1% mouth paint is not a schedule formulation as per Explanation-I of DPCO 2013 as it is not approved by CDSCO.

11. Agenda item no. 11 - Fixation of ceiling price of (i) Foot and Mouth Disease (Trivalent) Oil adjuvant vaccine and (ii) Brucella Abortus (S19 strain) vaccine, live freeze dried

11.1 The Authority noted that representation has been received regarding ceiling price fixation of (i) Foot and Mouth Disease (Trivalent) Oil adjuvant vaccine and (ii) Brucella Abortus (S19 strain) vaccine, live freeze dried. The Authority deliberated upon the matter in detail and decided to examine the representation and place it before the Authority again after examination of the same.

12. Agenda item no. 12 - Minutes of 41st meeting of Multidisciplinary Committee of Experts held on 08.04.2022.

12.1 Noted.

13. Agenda item no. 13 - Price fixation as per Pharmaceuticals Purchase Policy (PPP) for products of Pharma Central Public Sector Enterprises (CPSEs) and their subsidiaries.

Record note of Discussion to be circulated separately to the members

14. Agenda item no. 14 - Issue relating to retail price fixation of Fixed Dose Combinations (FDCs) of 'Linagliptin+ Metformin tablet' and 'Sitagliptin+ Metformin tablet'.

14.1 The Authority noted that for the i) Fixed Dose Combination (FDC) of 'Linagliptin+ Metformin tablet' and (ii) FDC of 'Sitagliptin+ Metformin tablet', retail prices of these new drugs were fixed in its 96th meeting dated 24.03.2022 in line with the decision taken in its 89th meeting dated 28.06.2021.

14.2 The Authority noted the representation dated 05.04.2022 received from M/s Boehringer Ingelheim, which was also forwarded by Department of Pharmaceuticals (DoP) vide letter dated 11.04.2022. The Authority also noted the representation received from Organisation of Pharmaceutical Producers of India (OPPI) vide e-mail dated 08.04.2022 against the retail price fixation of new drugs (i) Fixed Dose Combination (FDC) of 'Linagliptin+ Metformin tablet' and (ii) FDC of 'Sitagliptin+ Metformin tablet'.

14.3 The Authority also noted the representations received from M/s Boehringer Ingelheim vide e-mails dated 27.04.2022, 02.05.2022 and 05.05.2022. In these representations', the company has mentioned about the court orders dated 25.02.2022 and 21.04.2022 of the Hon'ble High Court of Himachal Pradesh regarding injunction obtained in favour of M/s Boehringer Ingelheim for Linagliptin molecule covered under Indian Patent No. 243301. In the said order, M/s Boehringer Ingelheim has been granted an injunction restraining M/s Macleods Pharmaceuticals Limited from manufacturing and selling the infringing product under the brand name of LINAMAC & LINAONE.

14.4 The Authority perused the opinion of the legal division that the case has been filed by M/s Boehringer Ingelheim against M/s Macleods Pharmaceuticals Limited and it is a civil suit between two private parties contesting their rights with regards to the patent of drug. Further, NPPA regulates/monitors the prices of drugs in the country and has a duty/responsibility to ensure the affordable medicines to the public at large within the compliance of extant DPCO. Para 15 of DPCO, 2013 provides the fixation of retail price of a new drug for existing manufacturers of scheduled formulation. When the existing manufacturer of a drug with dosages and strengths as specified in National List of Essential Medicines (NLEM) launches a new drug, such existing manufacturers shall apply for the price approval of such new drug from the Government in Form-I specified under Schedule-II of DPCO, 2013. Para 15(3) of DPCO, 2013 is mandatory provision and not the directory provision and Government is under obligation to give retail price to the existing manufactures on the receipt of the application for the price approval of new drug.

14.5 The Authority further observed the Office Memorandum dated 08.08.2019 issued by Department for Promotion of Industry and Internal Trade, Ministry of Commerce and Industry which state as follows:

"……

2.5) "The Indian Patents Act, 1970 does not contain any provision to link the patent rights to marketing approval for a product. Moreover, the Drugs and Cosmetics Act does not require the Drug Controller General of India(DGCI) to see whether a patent exists on a drug on which application for marketing approval has been received, nor is he empowered to do so. Further, the office of DGCI is not technically qualified to take a view on the existence and scope of a patent before granting market approvals. Any such attempt by the Drug Controller would be substantively ultra vires of delegated powers to him".

.....

2.8 Patents are private rights which are to be enforced by the patent owner. If any other infringes on their rights, the patent owner can initiate legal proceedings against them.

.....

2.10 NPPA takes a decision for fixation of retail prices of drug formulation as per the provisions of DPCO, 2013 and relevant laws, and may not be technically qualified to decide on the existence and scope of a patent in any proposed formulation"

14.6 The Authority deliberated upon the matter in detail and is of the opinion that the Authority is under obligation to give retail price if any existing manufacturer launches a new drug and makes an application in this regard to obtain the price approval from the NPPA by producing the relevant documents such as the valid license obtained from CDSCO. DPCO, 2013 does not provide any express demarcation between patented drug and non patented drug. Since, Para 15(3) of DPCO, 2013 is mandatory provision and not the directory provision, therefore the Government is under obligation to give retail price to the existing manufacturer on the receipt of the application for the price approval of new drug for the compliance of DPCO, 2013. Furthermore, patents are private rights which are to be enforced by the patent owner. If any other entity infringes on their rights, the patent owner can initiate legal proceedings against them. The Order of Hon'ble Court dated 21st April, 2022 is specific to M/s Macleods Pharma and its applicability restricted to the private parties of the suit in the present matter.

14.7 Accordingly, the Authority decided to fix and notify the retail price of new drugs (i) Fixed Dose Combination (FDC) of 'Linagliptin+ Metformin tablet' and (ii) FDC of 'Sitagliptin+ Metformin tablet'.

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

Kotwal

(Dr. Vinod Kotwal)
Member Secretary