

मिसिल स.- 8(84)/2021/डी.पी/एनपीपीए-डीवी-II
F. No. 8(84)/2021/DP/NPPA-Div. II

कार्यवाही स. : 216/84/2021/F
Proceeding No: 216/84/2021/F

Minutes of the 216th (overall) and 84th meeting of the Authority under DPCO, 2013 held on 10.03.2021 at 11:30 AM

The 216th meeting of the Authority (overall), which is the 84th meeting under the DPCO, 2013, was held on 10th of March 2021 at 11:30 AM under the Chairmanship of Ms. Shubhra Singh, Chairman, NPPA. The following Authority members of the NPPA were present during the meeting:

- (i) Dr. Vinod Kotwal, Member Secretary, NPPA
- (ii) Shri A. K. Saha, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure
- (iii) Ms. A. Srija, Economic Advisor, Department of Economic Affairs
- (iv) Dr. V. G. Somani, DCG(I), CDSCO, Ministry of Health & Family Welfare

Shri A. K. Pradhan, Deputy Drug Controller, CDSCO, was also present.

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

- (i) Shri N. I. Chowdhury, Advisor
- (ii) Shri S. S. Ojha, Jt. Director (Pricing)
- (iii) Shri Prasenjit Das, Deputy Director (Pricing)
- (iv) Shri Prakash Hemani, Asstt. Director (Enforcement/ Pricing)

II. Agenda items

1. Agenda item no. 1 - Confirmation of the Minutes of the 83rd meeting held on 27.01.2021.

1.1 The Authority confirmed the minutes without any change.

2. Agenda item no. 2 - Action Taken Report on decisions taken by NPPA in its 83rd meeting dated 27.01.2021

2.1 The Authority noted that due action has been taken.

2.2 The Authority noted that the ceiling price of Pheniramine Maleate Injection 22.75 mg/ ml in 33 ml and 100 ml pack was not notified since Central Drugs Standard Control Organisation (CDSCO) informed that the pack size details of Pheniramine Maleate Injection

22.75 mg/ ml is not available. The Authority also noted the license submitted by M/s Intervet India Pvt. Ltd and observed that the license of Pheniramine Maleate Injection 22.75 mg/ ml is for veterinary use. The Authority deliberated upon the matter in detail and decided that since the license is for veterinary use, clarification be obtained from Department of Pharmaceuticals as to whether ceiling price is to be notified for scheduled formulation which are used for veterinary purpose.

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

3.1 It was noted by the Authority that all cases are being processed in a time-bound manner.

3.2 The Authority recalled the discussion regarding 'prescription audit' in the 83rd meeting held on 27.01.2021. The Authority was apprised that Indian Council of Medical Research (ICMR), has implemented a Nation wide programme by opening 15 virtual centers at leading government hospitals that look into the rational use of medicines amongst other things. Discussions have been held and efforts would be made to dovetail Authority concerns with the on-going work of ICMR.

4. Agenda item no. 4 - New Drug application 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(lxxx) (total 80 Form I applications containing retail price fixation of 80 new drugs) falling under the purview of Para 2(u) of DPCO, 2013 and approved the retail prices of 76 (seventy six) new drugs [except 3 formulation as per agenda no. 4(xvi), 4(lxxvii), 4(lxxiii) and 4(lxxix)] 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 + Amlodipine + Hydrochlorothiazide Tablet	Each film coated tablet contains: Telmisartan IP 40mg, Amlodipine Besylate IP eq. to Amlodipine 5mg Hydrochlorothiazide IP	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s Jagsonpal Pharmaceuticals Ltd.	9.02

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		12.5mg			
4 (ii)	Dexamethasone +Chloramphenicol Eye Drops	Each ml contains: Dexamethasone Sodium Phosphate IP eq. to Dexamethasone 0.1%w/v, Chloramphenicol IP 1% w/v,	1 ML	M/s Skymap Healthcare Pvt. Ltd. / M/s Albert David Limited	4.09 (Note 2)
4(iii)	Dexamethasone +Chloramphenicol Eye Drops	Each ml contains: Dexamethasone Sodium Phosphate IP eq. to Dexamethasone 0.1%w/v, Chloramphenicol IP 1% w/v,	1 ML	M/s Skymap Healthcare Pvt. Ltd.	4.09 (Note 2)
4(iv)	Telmisartan & Metoprolol Succinate (ER) Tablet	Each uncoated bilayered tablet contains: Telmisartan IP 40mg, Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate 25mg (As Extended Release form)	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s Jagsonpal Pharmaceuticals Ltd.	11.22
4(v)	Telmisartan & Metoprolol Succinate (ER) Tablet	Each uncoated bilayered tablet contains: Telmisartan IP 40mg, Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate 25mg (As Extended Release form)	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s Glensmith Labs Pvt. Ltd.	11.22
4(vi)	Telmisartan, Amlodipine & Hydrochlorothiazide Tablet	Each film coated tablet contains: Telmisartan IP 40mg, Amlodipine Besylate IP eq. to Amlodipine 5mg, Hydrochlorothiazide IP 12.50 mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s Glensmith Labs Pvt. Ltd.	9.02
4(vii)	Paracetamol, Phenylephrine Hydrochloride, Caffeine & Diphenhydramine Tablet	Each film coated tablet contains: Paracetamol IP 500mg, Phenylephrine Hydrochloride IP 5mg, Caffeine (Anhydrous) IP	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd.	2.99

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		30mg Diphenhydramine Hydrochloride IP 25mg			
4(viii)	Telmisartan + Cilnidipine + Metoprolol (ER) Tablet	Each film coated Bilayered tablet contains: Telmisartan IP 40mg, Cilnidipine IP 10mg Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate (as extended release) 25mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Glenmark Pharmaceutical s Ltd.	10.16
4(ix)	Telmisartan + Cilnidipine + Metoprolol (ER) Tablet	Each film coated Bilayered tablet contains: Telmisartan IP 40mg, Cilnidipine IP 10mg Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate (as extended release) 50mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Glenmark Pharmaceutical s Ltd.	12.41
4(x)	Telmisartan + Hydrochlorothiazide Tablet (MACSART H 80 & TELMIDUCE H 80)	Each uncoated bilayered tablet contains: Telmisartan IP 80mg, Hydrochlorothiazide IP 12.50mg	1 Tablet	M/s Macleods Pharmaceutical s Ltd.	14.00
4(xi)	Telmisartan + Amlodipine Tablet (MACSART AM 80 & TELMIDUCE AM 80)	Each uncoated bilayered tablet contains: Telmisartan IP 80mg, Amlodipine Besylate IP eq. to Amlodipine 5mg	1 Tablet	M/s Macleods Pharmaceutical s Ltd.	12.50
4(xii)	Metformin + Gliclazide Tablet (MEFOMIN-GZ 60)	Each uncoated bilayered tablet contains: Metformin Hydrochloride IP 500mg (as Extended Release form), Gliclazide IP 60mg (as Extended Release form),	1 Tablet	M/s Macleods Pharmaceutical s Ltd.	9.74

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(xiii)	Telmisartan + Cilnidipine + Metoprolol (ER) Tablet (NEXOVAS TM 25)	Each film coated Bilayered tablet contains: Telmisartan IP 40mg, Cilnidipine IP 10mg Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate (as extended release) 25mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Macleods Pharmaceuticals Ltd.	10.16
4(xiv)	Atorvastatin + Clopidogrel + Aspirin Capsule	Each Hard gelatine capsule contains: Atorvastatin calcium IP eq. to Atorvastatin 10mg (As Pellets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As Pellets), Aspirin IP 75mg (As enteric coated pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Aristo Pharmaceuticals Private Limited.	4.16
4(xv)	Atorvastatin + Clopidogrel + Aspirin Capsule	Each Hard gelatine capsule contains: Atorvastatin calcium IP eq. to Atorvastatin 20mg (As Pellets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As Pellets), Aspirin IP 75mg (As enteric coated pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Aristo Pharmaceuticals Private Limited.	5.61
4(xvi)	Aceclofenac + Paracetamol Tablet	Each film coated tablet contains: Aceclofenac IP 100mg Paracetamol IP 325mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Mylan Pharmaceuticals Private Limited.	Closed (Note 7)
4(xvii)	Cefixime & Ofloxacin Tablet	Each film coated tablet contains: Cefixime IP as Trihydrate eq. to Anhydrous Cefixime 200mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Mylan	11.47

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Ofloxacin IP 200mg		Pharmaceuticals Private Limited.	
4(xviii)	Azelnidipine + Telmisartan Tablets	Each film coated bilayered tablet contains: Azelnidipine IP 8mg, Telmisartan IP 40mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Cipla Limited.	11.02
4(xix)	Azelnidipine + Telmisartan Tablets	Each film coated bilayered tablet contains: Azelnidipine IP 8mg, Telmisartan IP 80mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Cipla Limited.	13.22
4(xx)	Glimepiride + Metformin Hydrochloride prolonged release tablets	Each uncoated bilayered tablet contains: Glimepiride IP 4mg Metformin Hydrochloride IP 500mg (In prolonged release form)	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd.	10.25 (Note 2)
4(xxi)	Glimepiride + Metformin Hydrochloride prolonged release tablets	Each uncoated bilayered tablet contains: Glimepiride IP 4mg Metformin Hydrochloride IP 1000mg (In prolonged release form)	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd.	9.76 (Note 2)
4(xxii)	Glimepiride + Metformin Hydrochloride prolonged release tablets	Each uncoated bilayered tablet contains: Glimepiride IP 3mg Metformin Hydrochloride IP 500mg (In prolonged release form)	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd.	8.41 (Note 2)
4(xxiii)	Glimepiride + Metformin Hydrochloride prolonged release tablets	Each uncoated bilayered tablet contains: Glimepiride IP 3mg Metformin Hydrochloride IP 1000mg (In prolonged release form)	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd.	9.35 (Note 2)
	Telmisartan + Cilnidipine +	Each film coated bilayered tablet	1 Tablet	M/s Ravenbhel Healthcare Pvt.	12.41

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(xxiv)	Metoprolol Tablet (NEXOVAS TM 50)	contains: Telmisartan IP 40mg, Cilnidipine IP 10mg Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate (as extended release) 50mg		Ltd. / M/s Macleods Pharmaceuticals Ltd.	
4(xxv)	Glimepiride + Metformin Hydrochloride prolonged release tablets	Each uncoated bi-layered tablet contains: Glimepiride IP 4mg Metformin Hydrochloride IP 1000mg (In prolonged release form)	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s Jagsonpal Pharmaceuticals Ltd.	9.76 (Note 2)
4(xxvi)	Glimepiride + Metformin Hydrochloride prolonged release tablets	Each uncoated bi-layered tablet contains: Glimepiride IP 4mg Metformin Hydrochloride IP 500mg (In prolonged release form)	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s Jagsonpal Pharmaceuticals Ltd.	10.25 (Note 2)
4(xxvii)	Glimepiride + Metformin Hydrochloride prolonged release tablets	Each uncoated bi-layered tablet contains: Glimepiride IP 3mg Metformin Hydrochloride IP 500mg (In prolonged release form)	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s Jagsonpal Pharmaceuticals Ltd.	8.41 (Note 2)
4(xxviii)	Glimepiride + Metformin Hydrochloride prolonged release tablets	Each uncoated bi-layered tablet contains: Glimepiride IP 3mg Metformin Hydrochloride IP 1000mg (In prolonged release form)	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s Jagsonpal Pharmaceuticals Ltd.	9.35 (Note 2)
4(xxix)	Escitalopram Oxalate + Clonazepam Tablets IP	Each film coated tablet contains: Escitalopram Oxalate IP Eq. to Escitalopram 5mg, Clonazepam IP 0.25mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Aristo Pharmaceutical	6.73

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
				s Private Limited.	
4(xxx)	Escitalopram Oxalate + Clonazepam Tablets IP	Each film coated tablet contains: Escitalopram Oxalate IP Eq. to Escitalopram 5mg, Clonazepam IP 0.5mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Aristo Pharmaceuticals Private Limited.	7.40
4(xxxi)	Escitalopram Oxalate + Clonazepam Tablets IP	Each film coated tablet contains: Escitalopram Oxalate IP Eq. to Escitalopram 10mg, Clonazepam IP 0.25mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Aristo Pharmaceuticals Private Limited.	8.93 (Note 2)
4(xxxii)	Escitalopram Oxalate + Clonazepam Tablets IP	Each film coated tablet contains: Escitalopram Oxalate IP Eq. to Escitalopram 10mg, Clonazepam IP 0.5mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Aristo Pharmaceuticals Private Limited.	10.79
4(xxxiii)	Ceftriaxone & Tazobactam for Injection 1125mg	Each vial contains: Ceftriaxone Sodium IP (Sterile) eq. to Ceftriaxone 1g Tazobactam Sodium (Sterile) eq. to Tazobactam 125mg	Each Pack	M/s Nitin Lifesciences Limited / M/s Mylan Pharmaceuticals Private Limited	146.32
4(xxxiv)	Moxifloxacin 0.5% w/v + Dexamethasone Phosphate 0.1% w/v Ophthalmic Solution	Each ml contains: Moxifloxacin Hydrochloride IP eq. to Moxifloxacin 5.0mg Dexamethasone Sodium Phosphate IP eq. to Dexamethasone Phosphate 1.0mg	1 ML	M/s Micro Labs Limited	19.10

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Water for Injections IP q. s. to 1ml			
4(xxxv)	Metformin Hydrochloride prolonged release + Glimepiride tablet IP	Each uncoated bilayered tablet contains: Metformin Hydrochloride IP (in prolonged release form) 500mg Glimepiride IP 1mg	1 Tablet	M/s Inventia Healthcare Limited	5.95
4(xxxvi)	Metformin Hydrochloride prolonged release + Glimepiride tablet IP	Each uncoated bilayered tablet contains: Metformin Hydrochloride IP (in prolonged release form) 500mg Glimepiride IP 2mg	1 Tablet	M/s Inventia Healthcare Limited	7.73
4(xxxvii)	Metformin Hydrochloride prolonged release + Glimepiride tablet IP	Each uncoated bilayered tablet contains: Metformin Hydrochloride IP (in prolonged release form) 1000mg Glimepiride IP 1mg	1 Tablet	M/s Inventia Healthcare Limited	6.55
4(xxxviii)	Metformin Hydrochloride prolonged release + Glimepiride tablet IP	Each uncoated bilayered tablet contains: Metformin Hydrochloride IP (in prolonged release form) 1000mg Glimepiride IP 2mg	1 Tablet	M/s Inventia Healthcare Limited	8.33
4(xxxix)	Norethisterone Acetate Controlled release Tablets	Each film coated controlled release tablet contains: Norethisterone Acetate BP 10 mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Mankind Pharma Limited	15.09
4(xl)	Norethisterone Acetate Controlled release Tablets	Each film coated controlled release tablet contains: Norethisterone Acetate BP 15 mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Mankind Pharma Limited	18.00

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(xli)	Metformin + Vildagliptin (SR)Tablet (VILDAMAC M SR 50/500)	Each uncoated bilayered tablet contains: Metformin Hydrochloride IP 500mg (As sustained release form) Vildagliptin 50mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Macleods Pharmaceuticals Ltd.	6.86 (Note 3)
4(xlii)	Metformin + Vildagliptin (SR) Tablet (VILDAMAC M SR 50/1000)	Each uncoated bilayered tablet contains: Metformin Hydrochloride IP 1000mg (As sustained release form) Vildagliptin 50mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Macleods Pharmaceuticals Ltd.	7.51 (Note 3)
4(xliii)	Ciprofloxacin + Dexamethasone Eye Drops	Each ml contains: Ciprofloxacin Hydrochloride IP Eq. to Ciprofloxacin 0.3% w/v, Dexamethasone IP 0.1% w/v,	1 ML	M/s AXA Parenterals Ltd. /M/s Sun Pharmaceutical Industries Limited	1.69
4(xliv)	Esomeprazole & sustained release Domperidone Capsule	Each hard Gelatin Capsule contains: Esomeprazole Magnesium Trihydrate IP eq. to Esomeprazole 40mg (as enteric coated pellets) Domperidone IP 30mg (as sustained release pellets)	1 Capsule	M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Alembic Pharmaceuticals Limited	6.00
4(xlv)	Levetiracetam Infusion 500mg/100ml	Each 100ml contains: Levetiracetam IP 500mg Sodium Chloride IP 820mg Water for Injections IP q. s.	Each Pack	M/s Akums Drugs & Pharmaceuticals Limited / M/s Abbott Healthcare Pvt. Ltd.	91.56
4(xlvi)	Levetiracetam Infusion 1000mg/100ml	Each 100ml contains: Levetiracetam IP 1000mg Sodium Chloride IP 750mg Water for Injections IP q. s.	Each Pack	M/s Akums Drugs & Pharmaceuticals Limited / M/s Abbott Healthcare Pvt.	148.72

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
				Ltd.	
4(xlvii)	Telmisartan + Cilnidipine + Metoprolol (ER) Tablet	Each film coated bilayered tablet contains: Telmisartan IP 40mg, Cilnidipine IP 10mg Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate (as extended release) 50mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Mankind Pharma Limited	11.96
4(xlviii)	Telmisartan + Cilnidipine + Metoprolol (ER) Tablet	Each film coated bilayered tablet contains: Telmisartan IP 40mg, Cilnidipine IP 10mg Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate (as extended release) 25mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Mankind Pharma Limited	9.64
4(xlix)	Labetalol Tablet	Each film coated tablet contains: Labetalol Hydrochloride IP 200mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Sun Pharma Laboratories Limited	22.38
4(l)	Rabeprazole + Domperidone capsule	Each hard gelatin capsule contains: Rabeprazole Sodium IP 20mg (as enteric coated pellets) Domperidone IP 30mg (As sustained release pellets)	1 Capsule	M/s Theon Pharmaceuticals Ltd. / M/s Eris Healthcare Private Limited	9.11 (Note 2)
4(li)	Paracetamol + Nimesulide Tablet	Each uncoated tablet contains: Paracetamol IP 325mg, Nimesulide BP 100mg	1 Tablet	M/s Shivalik Remedies Pvt. Ltd. / M/s Eris Healthcare Private Limited	3.98 (Note 2)
	Telmisartan +	Each uncoated tablet	1 Tablet	M/s Macleods	8.63

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(lii)	Chlorthalidone Tablet (TELMIDUCE CH 6.25 & MACSART CH 6.25)	contains: Telmisartan IP 40mg, Chlorthalidone IP 6.25mg		Pharmaceuticals Limited	(Note 2)
4 (liii)	Calcium Carbonate + Vitamin D3 + Methylcobalamin + L-Methylfolate Calcium + Pyridoxal -5-Phosphate Tablets	Each Film coated tablet contains: Calcium Carbonate IP 1250mg, Vitamin D3 IP 2000 IU, Methylcobalamin IP 1500mcg, Calcium L-5-Methyltetrahydrofolate (L-Methylfolate Calcium) USP 1mg Pyridoxal -5- Phosphate 20mg	1 Tablet	M/s Tirupati Medicare Limited / M/s Intas Pharmaceuticals Ltd.	18.02 (Note 2)
4 (liv)	Vildagliptin + Metformin Hydrochloride (as sustained release) Tablet	Each uncoated bilayered tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 500mg (As sustained release form)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Mankind Pharma Ltd.	6.58 (Note 3)
4 (lv)	Vildagliptin + Metformin Hydrochloride (as sustained release) Tablet	Each uncoated bilayered tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 1000mg (As sustained release form)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Mankind Pharma Ltd.	7.07 (Note 3)
4 (lvi)	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 Zydus Healthcare Limited	11.81 (Note 4)

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (lvii)	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 Pharmaceutical / M/s Zydus Healthcare Limited	10.22 (Note 4)
4 (lviii)	Dapagliflozin + Metformin Hydrochloride Extended Release Tablet	Each film-coated bilayered tablet contains: Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin 5mg, Metformin Hydrochloride IP 500mg (As Extended release form)	1 Tablet	M/s Alkem Healthscience /M/s Alkem Laboratories Ltd.	6.74 (Note 5)
4 (lix)	Dapagliflozin + Metformin Hydrochloride Extended Release Tablet	Each film-coated bilayered tablet contains: Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin 5mg, Metformin Hydrochloride IP 1000mg (As Extended release form)	1 Tablet	M/s Alkem Healthscience /M/s Alkem Laboratories Ltd.	8.12 (Note 5)
4 (lx)	Dapagliflozin + Metformin Hydrochloride Extended Release 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 Alkem Healthscience /M/s Alkem Laboratories Ltd.	10.22 (Note 4)
4 (lxi)	Dapagliflozin + Metformin Hydrochloride Extended	Each film-coated bilayered tablet contains: Dapagliflozin Propanediol	1 Tablet	M/s Alkem Healthscience /M/s Alkem Laboratories	11.81 (Note 4)

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Release Tablet	monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 1000mg (As Extended release form)		Ltd.	
4 (lxii)	Vildagliptin + Metformin Hydrochloride Tablet	Each film coated tablet contains: Metformin Hydrochloride IP 500mg Vildagliptin 50mg,	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Blue Cross Laboratories Pvt. Ltd.	5.90 (Note 6)
4 (lxiii)	Vildagliptin + Metformin Hydrochloride Tablet	Each film coated tablet contains: Metformin Hydrochloride IP 1000mg Vildagliptin 50mg,	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Blue Cross Laboratories Pvt. Ltd.	6.90 (Note 6)
4 (lxiv)	Dapagliflozin + Metformin Hydrochloride Extended Release Tablet	Each film-coated tablet contains: Dapagliflozin 10mg, Metformin Hydrochloride IP / USP 1000mg (As Extended release form)	1 Tablet	M/s MSN Laboratories Pvt. Ltd. / M/s USV Pvt. Limited	11.81 (Note 4)
4 (lxv)	Dapagliflozin + Metformin Hydrochloride Extended Release Tablet	Each film-coated tablet contains: Dapagliflozin 10mg, Metformin Hydrochloride IP / USP 500mg (As Extended release form)	1 Tablet	M/s MSN Laboratories Pvt. Ltd. / M/s USV Pvt. Limited	10.22 (Note 4)
4 (lxvi)	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 Intas Pharmaceuticals Limited	6.74 (Note 5)
4 (lxvii)	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 Intas Pharmaceutical	8.12 (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)		s Limited	
4 (lxviii)	Dapagliflozin + Metformin Hydrochloride Extended Release Tablet	Each film-coated tablet contains: Dapagliflozin 10mg, Metformin Hydrochloride IP / USP 1000mg (As Extended release form)	1 Tablet	M/s MSN Laboratories Pvt. Ltd. / M/s Intas Pharmaceuticals Limited	11.81 (Note 4)
4 (lxix)	Dapagliflozin + Metformin Hydrochloride Extended Release Tablet	Each film-coated tablet contains: Dapagliflozin 10mg, Metformin Hydrochloride IP / USP 500mg (As Extended release form)	1 Tablet	M/s MSN Laboratories Pvt. Ltd. / M/s Intas Pharmaceuticals Limited	10.22 (Note 4)
4 (lxx)	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 Pharmaceutical / M/s Zydus Healthcare Limited	8.12 (Note 5)
4 (lxxi)	Dapagliflozin + Metformin Hydrochloride (Extended Release) Tablet	Each film-coated tablet contains: Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin 5mg, Metformin Hydrochloride IP 500mg (As Extended release form)	1 Tablet	M/s Exemed Pharmaceutical / M/s Zydus Healthcare Limited	6.74 (Note 5)
4 (lxxii)	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 Eris Lifesciences Limited	6.74 (Note 5)
4 (lxxiii)	Dapagliflozin + Metformin Hydrochloride Extended Release Tablet	Each film-coated tablet contains: Dapagliflozin 5mg, Metformin Hydrochloride IP / USP 1000mg (As Extended release form)	1 Tablet	M/s MSN Laboratories Pvt. Ltd. / M/s Eris Lifesciences Limited	8.12 (Note 5)
4 (lxxiv)	Dapagliflozin +	Each film-coated tablet	1 Tablet	M/s MSN	10.22

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Metformin Hydrochloride Extended Release Tablet	contains: Dapagliflozin 10mg, Metformin Hydrochloride IP / USP 500mg (As Extended release form)		Laboratories Pvt. Ltd. / M/s Eris Lifesciences Limited	(Note 4)
4 (lxxv)	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 MSN Laboratories Pvt. Ltd. / M/s Eris Lifesciences Limited	11.81 (Note 4)
4 (lxxvi)	Atorvastatin and Aspirin Capsule	Each Hard gelatin capsule contains: Atorvastatin calcium IP eq. to Atorvastatin 40mg, Aspirin IP 75mg (As Gastro-resistant tablet IP)	1 Capsule	M/s USV Private Limited.	20.22
4(lxxx)	Aceclofenac + Paracetamol + Thiocolchicoside Tablet	Each film coated tablet contains: Aceclofenac IP 100mg, Paracetamol IP 325mg Thiocolchicoside IP 4mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. /M/s Mylan Pharmaceuticals Private Limited.	15.18 (Note 2)

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. The representative of DCGI present in the meeting confirmed that the formulations are approved by DCGI

Note 3. 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 80th Authority meeting dated 26.10.2020, based on the recommendation of Multidisciplinary Committee of Experts.

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 2 of Para 4.1 of the Minutes of the 82nd

Authority meeting dated 23.12.2020, based on the recommendation of Multidisciplinary Committee of Experts.

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 10 of Para 4.1 of the Minutes of the 82nd Authority meeting dated 23.12.2020, based on the recommendation of Multidisciplinary Committee of Experts.*

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 E of Para 4.1 of the Minutes of the 72nd Authority meeting dated 20.01.2020, based on the recommendation of Multidisciplinary Committee of Experts.*

Note 7. *M/s Mylan Pharmaceuticals Pvt. Ltd made a representation stated for withdrawal of the Form-I application. Accordingly, the Authority decided to close the application.*

4.2 Agenda item no. 4(lxxvii): The Authority noted the application for retail price fixation of Thyroxine 112mcg. The Authority further noted the recommendation of the Multidisciplinary Committee of Experts made in its 28th meeting held on 04.03.2021 to close the retail price application and to direct the company to follow the ceiling price of Levothyroxine 112mcg already notified since there is negligible therapeutic difference between “thyroxine” and “levothyroxine” and both the formulations are used synonymously. The Authority deliberated upon the matter in detail and approved the recommendations of the Committee.

4.3 Agenda item no. 4(lxxix): The Authority noted the application for retail price fixation of Thyroxine 37.5 mcg tablet. The Authority further noted the recommendation of the Multidisciplinary Committee of Experts made in its 28th meeting held on 04.03.2021 to close the retail price application and to direct the company to follow the ceiling price of Levothyroxine 37.5 mcg tablet, after its fixation by the Authority, being a scheduled formulation, because there is negligible therapeutic difference between “Thyroxine” and “Levothyroxine” and both the formulations are used synonymously. The Authority deliberated upon the matter in detail and approved the recommendations of the Committee.

4.4 Agenda item no. 4(lxxviii): The Authority deliberated upon the matter in detail with respect to application of M/s Sun Pharma Laboratories Ltd towards retail price fixation of Budesonide IP 9 mg tablet and directed that the matter be placed before the Multidisciplinary Committee of Experts for recommendation of retail price and place the same in the next Authority meeting.

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

5.1 It was noted that only one review case is pending with NPPA which is listed as agenda item no. 18.

6. Agenda item no. 6 - Representation of M/s Glenmark Pharmaceuticals Ltd regarding allowing WPI to separate price fixed for Digihaler FB 100/200/400 (Fixed Dose Combination) of Budesonide/Formoterol (100/6/200/6 and 400/6 mcg) of M/s Glenmark Pharmaceuticals Ltd vide SO. 4539(E) dated 18.12.2019.

6.1 The Authority deliberated upon the matter in detail and approved that Wholesale Price Index (WPI), as applicable for scheduled formulation be allowed from the next year on the additional price of 'Digital Dose Counter" with respect to the formulation (a) Budesonide 100mcg+ Formeterol 6mcg per dose Inhaler 120 MDI (b) Budesonide 200mcg+ Formeterol 6mcg per dose Inhaler 120 MDI and (c) Budesonide 400mcg+ Formeterol 6mcg per dose Inhaler 120 MDI fixed for M/s Glenmark Pharmaceuticals Ltd vide S.O. 4539(E) dated 18.12.2019.

7. Agenda item no. 7 - Intimation of Minutes of 27th & 28th meeting of Multidisciplinary Committee of Experts held on 10.02.2021 & 04.03.2021 .

7.1 Noted.

8. Agenda item no. 8 - Upward revision of Ceiling Price of Enoxaparin Inj. 40mg & 60mg under para 19 of DPCO, 2013.

8.1 The Authority noted the comments of the Committee constituted to monitor Export /import trends of API's, Formulation and Medical Devices needed for COVID-19. The Committee opined that the price of Enoxaparin API is stable and hence the request for increase of ceiling price of Enoxaparin may not be considered at this stage.

8.2 The Authority deliberated upon the matter in detail and accepted the opinion of the Committee. Accordingly, the Authority decided that the representation for upward revision of ceiling price of Enoxaparin Inj. 40mg & 60mg under para 19 of DPCO, 2013 cannot be considered and the representation be treated as closed.

9. Agenda item no. 9 - Representation of M/s Cipla Ltd regarding annual WPI in Foracort Synchrobreathe.

9.1 The Authority deliberated upon the matter in detail and approved that Wholesale Price Index (WPI) as applicable for scheduled formulation be allowed from the next year on the additional price of 'Synchrobreathe Inhaler Device" with respect to the formulation (a)

Budesonide 200mcg+ Formeterol 6mcg per dose Inhaler 120 MDI and (b) Budesonide 400mcg+ Formeterol 6mcg per dose Inhaler 120 MDII fixed for M/s Cipla Ltd vide S.O. 4538(E) dated 18.12.2019.

10. Agenda item no. 10 - Revised Ceiling price of Heparin Injection 1000IU/ml and 5000IU/ml

10.1 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 are applicable up to 31.12.2020 and the same was extended up to 31.03.2021 vide SO. 4333(E) dated 03.12.2020. The Authority further noted the report of the API monitoring Committee dated 10.03.2021. The Committee, based on the movement in API prices, opined that *“NPPA may continue with the increased ceiling price for Heparin Injection 1000IU/ml and 5000IU/ml, to ensure continuous availability of this essential drug. The ceiling price of Heparin may be reviewed after the COVID-19 situation become normal or earlier as deemed fit.”*

10.2 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 pandemic situation of COVID-19. Therefore, due to extraordinary situation, the Authority 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 upto 31.03.2021 vide SO. 4333(E) to be further extended up to 30.09.2021 or until further order, whichever is earlier, in public interest.

10.3 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 30.09.2021 or until further order, whichever is earlier.

11. Agenda item no. 11 - Price fixation of Medical Oxygen

11. 1 The Authority noted that inputs/comments from DPIIT have not been received and decided to defer the Agenda.

12. Agenda item no. 12 - Issues relating to Para 18(i) of DPCO 2013

12.1 It was noted that guidance in the matter has been sought from Department of Pharmaceuticals..

13. Agenda item no. 13 - Wholesale Price Index for the year 2021 (To be applicable from 01.04.2021)

13.1 The Authority noted that the confirmation about Wholesale Price Index (WPI) is yet to be received from the Department for Promotion of Industry and Internal Trade (DPIIT), Ministry of Commerce and Industry, Government of India. The Authority deliberated upon the matter in detail and decided that an Office Memorandum on WPI applicable from 01.04.2021 to be issued and the revised ceiling price of scheduled formulations to be notified after getting confirmation from DPIIT.

14. Agenda item no. 14 - Fixation of Ceiling Price of Povidone Iodine 7.5% Scrub

14.1 The Authority deliberated upon the matter in detail and approved the ceiling price of Povidone Iodine 7.5% Scrub at Rs. 1.60 per ml excluding GST.

15. Agenda item no. 15 - Ceiling price fixation of Levothyroxine 37.5 mcg tablet

15.1 The Authority deliberated upon the matter in detail and approved the ceiling price of Levothyroxine 37.5 mcg tablet at Rs. 0.98 per tablet excluding GST.

16. Agenda item no. 16 - Policy for recovery of Overcharged amount by NPPA

16.1 Noted.

17. Agenda item no. 17 - Retail price fixation for companies in respect of formulations to which exemption granted under para 32 of DPCO 2013 has been expired.

17.1 Matters relating to M/s Torrent Pharmaceuticals Ltd

17.1.1 The Authority noted that the exemption granted under para 32 of DPCO 2013 to M/s Torrent Pharmaceuticals Ltd for Fixed Dose Combination (FDC) of Prasugrel Hydrochloride 10 mg (as film coated) plus Aspirin 75 mg (as enteric coated) vide SO 2110(E) dated 21.08.2014 and for Olanzapine Pamoate Prolong Release Powder for suspension for IM Injection (Olanzapine Pamoate Monohydrate eq. to Olanzapine 210mg/ vial, 300 mg/vial and 405 mg/vial) vide SO 856(E) dated 25.03.2015 has expired.

17.1.2 The Authority further noted that Acetylsalicylic (Aspirin) 75mg tablet is a scheduled formulation, included in revised schedule I of DPCO'13. Accordingly, FDC of Prasugrel Hydrochloride 10 mg (as film coated) plus Aspirin 75 mg is a New Drug for the existing companies as per the provisions of DPCO 2013. Further, Olanzapine Pamoate Prolong Release Powder for suspension for IM Injection (Olanzapine Pamoate Monohydrate eq. to Olanzapine 210mg/ vial, 300 mg/vial and 405 mg/vial) is a non-scheduled formulation under DPCO 2013.

17.1.3 The Authority deliberated upon the matter in detail and observed that M/s Torrent Pharmaceuticals Ltd, being an existing manufacturer/ marketer is required to apply for retail price fixation of “Fixed Dose Combination (FDC) of Prasugrel Hydrochloride 10 mg (as film coated) plus Aspirin 75 mg (as enteric coated)” after the expiry of the exemption granted under para 32(iii) of DPCO 2013. Accordingly, the Authority decided that the retail price for the new drug “Fixed Dose Combination (FDC) of Prasugrel Hydrochloride 10 mg (as film coated) plus Aspirin 75 mg (as enteric coated)” is to be fixed for M/s Torrent Pharmaceuticals Ltd.

The Authority also observed that as per the data submitted by M/s Torrent Pharmaceuticals Ltd, the present MRP of Fixed Dose Combination (FDC) of Prasugrel Hydrochloride 10 mg (as film coated) plus Aspirin 75 mg (as enteric coated) capsule is Rs. 27.26 per capsule.

17.1.4 The Authority further observed that the matter was placed before the Multidisciplinary Committee of Experts in its 27th meeting dated 10.02.2021 in which the Committee deliberated/ recommended as follows:

“.....The Committee observed that the representations of the companies are not tenable since on being granted exemption under Para 32 of DPCO 2013, none of the provisions of DPCO 2013 is applicable during the exemption period. However, on expiry of the period of exemption, the provisions of DPCO 2013 becomes applicable and accordingly the price approval is required for manufacturing/ marketing of “FDC of Prasugrel Hydrochloride 10 mg (as film coated) plus Aspirin 75 mg (as enteric coated) capsule” by M/s Torrent Pharmaceuticals Ltd being an existing manufacturer.”

“The Committee deliberated upon the matter in detail and is of the view that the retail price is to be fixed for “FDC of Prasugrel Hydrochloride 10 mg (as film coated) plus Aspirin 75 mg (as enteric coated) capsule”for M/s Torrent Pharmaceuticals Ltd”

“.....the Committee deliberated upon the matter relating to fixation of the retail price of the formulations and decided to fix the retail price as per Para 5 of DPCO 2013 by taking the data for the month which is six month prior to the month of the meeting in which the price is recommended i.e. the data for the month of July 2020”

Accordingly, the Committee recommended the retail price of ‘Prasugrel Hydrochloride 10 mg (as film coated) plus Aspirin 75 mg (as enteric coated) capsule’ for M/s Torrent Pharmaceutical Ltd at Rs. 20.16 per capsule excluding GST.

17.1.5 The Authority deliberated upon the matter in detail and accepted the recommendations of the Committee in its 27th meeting dated 10.02.2021 and decided to approve the retail price of ‘Prasugrel Hydrochloride 10 mg (as film coated) plus Aspirin 75

mg (as enteric coated) capsule' at Rs. 20.16 per capsule for M/s Torrent Pharmaceuticals Ltd. The Authority further decided that the price would be applicable prospectively.

17.2 Matters relating to M/s Wockhardt Ltd

17.2.1 The Authority noted that the exemption granted under para 32 of DPCO 2013 to M/s Wockhardt Ltd for (i) Insulin Human Injection, 200IU/ml (ii) Isophane Insulin Human Suspension 200IU/ml and (iii) 70% Isophane Insulin Human Suspension and 30% Insulin Human Injection 200IU/ml vide SO 3131(E) dated 20.11.2015 had expired.

17.2.2 The Authority further noted that Insulin 40IU/ml is a scheduled formulation, included in revised schedule I of DPCO'13. Accordingly, (i) Insulin Human Injection, 200IU/ml (ii) Isophane Insulin Human Suspension 200IU/ml and (iii) 70% Isophane Insulin Human Suspension and 30% Insulin Human Injection 200IU/ml are New Drugs for the existing companies as per the provisions of DPCO 2013.

17.2.3 The Authority deliberated upon the matter in detail and observed that M/s Wockhardt Ltd, being as existing manufacturer/ marketer is required to apply for retail price fixation of (i) Insulin Human Injection, 200IU/ml (ii) Isophane Insulin Human Suspension 200IU/ml and (iii) 70% Isophane Insulin Human Suspension and 30% Insulin Human Injection 200IU/ml, after the expiry of the exemption granted under para 32(iii) of DPCO 2013. Accordingly, the Authority decided that the retail price for the new drug (i) Insulin Human Injection, 200IU/ml (ii) Isophane Insulin Human Suspension 200IU/ml and (iii) 70% Isophane Insulin Human Suspension and 30% Insulin Human Injection 200IU/ml, is to be fixed for M/s Wockhardt Ltd.

The Authority also observed that as per the data submitted by M/s Wockhardt Ltd, the present MRP of (i) Insulin Human Injection, 200IU/ml is Rs. 132.67 per ml and (iii) 70% Isophane Insulin Human Suspension and 30% Insulin Human Injection 200IU/ml is Rs. 132.50 per ml.

17.2.4 The Authority further observed that the matter was placed before the Multidisciplinary Committee of Experts in its 27th meeting dated 10.02.2021 in which the Committee deliberated/ recommended as follows:

"...The Committee observed that the representations of the companies are not tenable since on being granted exemption under Para 32 of DPCO 2013, none of the provisions of DPCO 2013 is applicable during the exemption period. However, on expiry of the period of exemption, the provisions of DPCO 2013 becomes applicable and accordingly the price approval is required for manufacturing/ marketing of "(i) Insulin Human Injection, 200IU/ml (ii) Isophane Insulin Human Suspension 200IU/ml and (iii) 70% Isophane Insulin Human Suspension

and 30% Insulin Human Injection 200IU/ml”by M/s Wockhardt Ltd being an existing manufacturer.”

“ The Committee deliberated upon the matter in detail and is of the view that the retail price is to be fixed for “(i) Insulin Human Injection, 200IU/ml (ii) Isophane Insulin Human Suspension 200IU/ml and (iii) 70% Isophene Insulin Human Suspension and 30% Insulin Human Injection 200IU/ml” for M/s Wockhardt Ltd”

“.....the Committee deliberated upon the matter relating to fixation of the retail price of the formulations and decided to fix the retail price as per Para 5 of DPCO 2013 by taking the data for the month which is six month prior to the month of the meeting in which the price is recommended i.e. the data for the month of July 2020”

“The Committee also decided not to fix the retail price of ‘Isophane Insulin Human Suspension 200IU/ml’ for M/s Wockhardt Ltd since the company have not launched/ manufactured the formulation.”

Accordingly, the Committee recommended the retail price of (a) Insulin Human Injection, 200IU/ml at Rs. 106.65 per ml excluding GST and (b) 70% Isophene Insulin Human Suspension and 30% Insulin Human Injection 200IU/ml at Rs. 106.65 per ml excluding GST for M/s Wockhardt Ltd.

17.2.5 The Authority deliberated upon the matter in detail and accepted the recommendations of the Committee in its 27th meeting dated 10.02.2021 and decided to approve the retail price of ‘(a) Insulin Human Injection, 200IU/ml at Rs. 106.65 per ml excluding GST and (b) 70% Isophene Insulin Human Suspension and 30% Insulin Human Injection 200IU/ml at Rs. 106.65 per ml excluding GST for M/s Wockhardt Ltd. The Authority further decided that the price would be applicable prospectively.

17.3 It was also directed that future approvals under Para 32 of DPCO 2013 should state the requirement that company should seek Retail Price approval, if applicable, three month before the expiry of the exemption granted under Para 32 of DPCO 2013 and clear direction to be given in this regard.

18. Agenda item no. 18 - Review order no. 31015/05/2020-Pricing dated 14.12.2020 relating to application filed by M/s Bharat Serums and Vaccines Ltd for ceiling price fixation of Human normal Immunoglobulin 16.5% vide SO. 1241(E) dated 03.04.2020

18.1 The Authority observed the documents/ notification submitted by M/s Bharat Serums and vaccines Ltd showing that Human Normal Immunoglobulin attracting nil rate excise duty.

18.2 The Authority deliberated upon the matter in detail and decided to revise the ceiling price of Human normal Immunoglobulin 16.5% to Rs. 396.04 per ml excluding GST by taking the applicable GST factor i.e. 1 by considering nil rate of excise duty towards implementation of the review order no. 31015/05/2020-Pricing dated 14.12.2020.

The meeting ended with a vote of thanks to the Chair.

Sd/-
(Dr. Vinod Kotwal)
Member Secretary