

मिसिलस.- 8(86)/2021/डी.पी/एनपीपीए-डीवी-II

F. No. 8(86)/2021/DP/NPPA-Div. II

कार्यवाहीस. : 218/86/2021/F

Proceeding No: 218/86/2021/F

Minutes of the 218th (overall) and 86th meeting of the Authority under DPCO, 2013 held on 28.04.2021 at 11:30 AM through Video Conferencing

The 218th meeting of the Authority (overall), which is the 86th meeting under the DPCO, 2013, was held on 28th of April 2021 at 11:30 AM under the Chairmanship of Ms. Shubhra Singh, Chairman, NPPA through Video Conferencing (VC). The following Authority members of the NPPA were present during the meeting through VC:

- (i) Dr. Vinod Kotwal, Member Secretary, NPPA
- (ii) Shri A. K. Saha, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure
- (iii) 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-through VC
- (ii) Shri S. S. Ojha, Jt. Director (Pricing)-through VC
- (iii) Shri Prasenjit Das, Deputy Director (Pricing)

II. Agenda items

1. Agenda item no. 1 - Confirmation of the Minutes of the 85th meeting held on 23.03.2021.

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 84th meeting dated 10.03.2021 and 85th meeting dated 23.03.2021

2.1 The Authority noted that due action has been taken.

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.

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(xliv) (total 44 Form I applications containing retail price fixation of 44 new drugs) falling under the purview of Para 2(u) of DPCO, 2013 and approved the retail prices of 44 (forty four) 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 + 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 Sun Pharma Laboratories Limited	12.41
4(ii)	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 Sun Pharma Laboratories Limited	10.16
4(iii)	Paracetamol + Phenylephrine + Chlorpheniramine tablet	Each uncoated tablet contains: Paracetamol IP 500mg Phenylephrine Hydrochloride IP 10mg Chlorpheniramine maleate IP 2mg	1 Tablet	M/s Alembic Pharmaceuticals Limited	3.82
4(iv)	Telmisartan + Cilnidipine + Metoprolol (ER) tablet	Each film coated bilayered tablet contains: Telmisartan IP 40mg, Cilnidipine IP 10mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Cadila Pharmaceuticals Ltd.	10.16

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate (as extended release) 25mg			
4(v)	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 Cadila Pharmaceuticals Ltd.	12.41
4(vi)	Telmisartan + Chlorthalidone + Metoprolol (Extended Release) tablet	Each film coated tablet contains: Telmisartan IP 40mg, Chlorthalidone IP 12.50mg Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate (Extended Release form) 25mg	1 Tablet	M/s Ajanta Pharma Limited / M/s Glenmark Pharmaceuticals Ltd.	11.76
4(vii)	Telmisartan + Chlorthalidone + Metoprolol (Extended Release) tablet	Each film coated tablet contains: Telmisartan IP 40mg, Chlorthalidone IP 12.50mg Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate (Extended Release form) 50mg	1 Tablet	M/s Ajanta Pharma Limited / M/s Glenmark Pharmaceuticals Ltd.	13.97
4(viii)	Telmisartan + Chlorthalidone + Metoprolol (Extended Release) tablet	Each film coated tablet contains: Telmisartan IP 40mg, Chlorthalidone IP 6.25mg Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate (Extended Release form) 50mg	1 Tablet	M/s Ajanta Pharma Limited / M/s Glenmark Pharmaceuticals Ltd.	10.81

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(ix)	Telmisartan + Chlorthalidone + Metoprolol (Extended Release) tablet	Each film coated tablet contains: Telmisartan IP 40mg, Chlorthalidone IP 6.25mg Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate (Extended Release form) 25mg	1 Tablet	M/s Ajanta Pharma Limited / M/s Glenmark Pharmaceuticals Ltd.	9.86
4(x)	Amoxicillin Oral Suspension	Each 5ml of the reconstituted suspension contains: AmoxicillinTrihydrate eq. to Amoxicillin IP 125mg	1 ML	M/s Theon Pharmaceuticals Limited / M/s Torrent Pharmaceuticals Limited	0.80
4(xi)	Amoxicillin Dispersible Tablet IP	Each uncoated dispersible tablet contains: AmoxicillinTrihydrate IP eq. to Amoxicillin 125mg	1 Tablet	M/s Malik Lifesciences Pvt. Ltd. / M/s Torrent Pharmaceuticals Limited	4.64
4(xii)	Etamsylate & Tranexamic Acid Tablets	Each film coated tablet contains: Etamsylate BP 250mg, Tranexamic Acid IP 250mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Limited / M/s German Remedies Pharmaceuticals Private Limited	17.26
4(xiii)	Atorvastatin Tablet IP	Each film coated tablet contains: Atorvastatin Calcium IP eq. to Atorvastatin 80mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Limited / M/s Mankind pharma Ltd.	27.54
4(xiv)	Amoxicillin + Potassium Clavulanate Oral Suspension	Each 5ml after reconstituted suspension contains: AmoxicillinTrihydrate eq. to Amoxicillin IP 400mg Potassium Clavulanate Diluted eq. to Clavulanic	1 ML	M/s Torrent Pharmaceuticals Limited	3.54

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Acid 57mg			
4(xv)	Mefenamic Acid & Tranexamic Acid Tablets	Each film coated tablet contains: Mefenamic Acid IP 250mg Tranexamic Acid IP 500mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s German Remedies Pharmaceuticals Private Limited	25.07
4(xvi)	Povidone Iodine Gargle	Contains: Povidone-Iodine IP 2% w/v (Available Iodine 0.2w/v)	1 ML	M/s NanzMedscience Pharma Pvt. Ltd. / M/s Glenmark Pharmaceuticals Ltd.	1.72 (Note 2)
4(xvii)	Azelnidipine + Telmisartan Tablet	Each film coated bi-layered tablet contains: Azelnidipine IP 8mg Telmisartan IP 80mg	1 Tablet	M/s Synokem Pharmaceuticals Limited / M/s Mankind pharma Ltd.	13.22
4(xviii)	Azelnidipine + Telmisartan Tablet	Each film coated bi-layered tablet contains: Azelnidipine IP 8mg Telmisartan IP 40mg	1 Tablet	M/s Synokem Pharmaceuticals Limited / M/s Mankind pharma Ltd.	11.02
4(xix)	Nebivolol Hydrochloride + Telmisartan Tablet	Each uncoated bilayered tablet contains: Nebivolol Hydrochloride IP eq. to Nebivolol 5mg Telmisartan IP 40mg	1 Tablet	M/s Windlas Biotech Private Limited / M/s Mankind pharma Ltd.	12.59
4(xx)	Vitamin D3 (Cholecalciferol) orally disintegrating strips	Each orally disintegrating strips contains: Vitamin D3 (Cholecalciferol) IP 60000 IU	Per Strip	M/s Zim Laboratories Ltd. / M/s Cadila Pharmaceuticals Ltd.	20.16
4(xxi)	Torseamide + Spironolactone Tablet	Each Uncoated tablet contains: Torseamide IP 5mg Spironolactone IP 50mg	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd. / M/s RPG Life Sciences Ltd.	3.61 (Note 2)
4(xxii)	Torseamide +	Each Uncoated tablet	1	M/s Pure & Cure	5.07

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Spironolactone Tablet	contains: Torsemide IP 10mg Spironolactone IP 50mg	Tablet	Healthcare Pvt. Ltd. / M/s RPG Life Sciences Ltd.	(Note 2)
4(xxiii)	Pantoprazole & Domperidone Tablet	Each enteric coated tablet contains: Pantoprazole Sodium IP eq. to Pantoprazole 40mg Domperidone IP 10mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Torrent Pharmaceuticals Ltd.	6.67
4(xxiv)	Pantoprazole & Domperidone Tablet	Each enteric coated tablet contains: Pantoprazole Sodium IP eq. to Pantoprazole 20mg Domperidone IP 10mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Torrent Pharmaceuticals Ltd.	5.72
4(xxv)	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 Eris Lifesciences Limited	10.16
4(xxvi)	Telmisartan, Cilnidipine & Metoprolol (ER) Tablet	Each film coated bilayered tablet contains: Telmisartan IP 40mg, Cilnidipine IP 10mg Metoprolol Succinate IP 47.5mg eq. to Metoprolol Tartrate (as extended release) 50mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Eris Lifesciences Limited	12.41
4(xxvii)	Budesonide Tablet	Each film coated extended release tablet contains: Budesonide IP 9mg	1 Tablet	M/s Sun Pharmaceutical Industries Limited / M/s Sun Pharma Laboratories Limited	40.17

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(xxviii)	Dapagliflozin + Metformin Hydrochloride extended release Tablet	Each film coated tablet contains: Metformin Hydrochloride IP 1000mg (as extended release form) Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Wockhardt Limited	8.04 (Note 3)
4(xxix)	Dapagliflozin + Metformin Hydrochloride extended release Tablet	Each film coated tablet contains: Metformin Hydrochloride IP 500mg (as extended release form) Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Wockhardt Limited	9.98 (Note 4)
4(xxx)	Dapagliflozin + Metformin Hydrochloride extended release Tablet	Each film coated tablet contains: Metformin Hydrochloride IP 1000mg (as extended release form) Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Wockhardt Limited	11.53 (Note 4)
4(xxxi)	Dapagliflozin + Metformin Hydrochloride extended release Tablet	Each film coated tablet contains: Metformin Hydrochloride IP/USP 500mg (As extended release) Dapagliflozin 5mg	1 Tablet	M/s MSN Laboratories Pvt. Ltd. / M/s Alembic Pharmaceuticals Limited	6.65 (Note 3)
4(xxxii)	Dapagliflozin + Metformin Hydrochloride extended release Tablet	Each film coated tablet contains: Metformin Hydrochloride IP/USP 1000mg (As extended release) Dapagliflozin 5mg	1 Tablet	M/s MSN Laboratories Pvt. Ltd. / M/s Alembic Pharmaceuticals Limited	8.04 (Note 3)
4(xxxiii)	Dapagliflozin	Each film coated tablet	1	M/s MSN	9.98

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: Metformin Hydrochloride IP/USP 500mg (As extended release) Dapagliflozin 10mg	Tablet	Laboratories Pvt. Ltd. / M/s Alembic Pharmaceuticals Limited	(Note 4)
4(xxxiv)	Dapagliflozin + Metformin Hydrochloride extended release Tablet	Each film coated tablet contains: Metformin Hydrochloride IP/USP 1000mg (As extended release) Dapagliflozin 10mg	1 Tablet	M/s MSN Laboratories Pvt. Ltd. / M/s Alembic Pharmaceuticals Limited	11.53 (Note 4)
4(xxxv)	Dapagliflozin + Metformin Hydrochloride extended release Tablet	Each film coated tablet contains: Metformin Hydrochloride IP/USP 500mg (as extended release form) Dapagliflozin 5mg	1 Tablet	M/s MSN Laboratories Pvt. Ltd.	6.65 (Note 3)
4(xxxvi)	Dapagliflozin + Metformin Hydrochloride extended release Tablet	Each film coated tablet contains: Metformin Hydrochloride IP/USP 1000mg (as extended release form) Dapagliflozin 5mg	1 Tablet	M/s MSN Laboratories Pvt. Ltd.	8.04 (Note 3)
4(xxxvii)	Dapagliflozin + Metformin Hydrochloride extended release Tablet	Each film coated tablet contains: Metformin Hydrochloride IP/USP 500mg (as extended release form) Dapagliflozin 10mg	1 Tablet	M/s MSN Laboratories Pvt. Ltd.	9.98 (Note 4)
4(xxxviii)	Dapagliflozin + Metformin Hydrochloride extended release Tablet	Each film coated tablet contains: Metformin Hydrochloride IP/USP 1000mg (as extended release form) Dapagliflozin 10mg	1 Tablet	M/s MSN Laboratories Pvt. Ltd.	11.53 (Note 4)
4(xxxix)	Vildagliptin +	Each uncoated	1	M/s Mascot	6.86

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Metformin Hydrochloride (SR) Tablet	bilayered tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 500mg (As sustained release form)	Tablet	Health Series Pvt. Ltd. / M/s Alembic Pharmaceuticals Ltd.	(Note 5)
4(xl)	Vildagliptin + Metformin Hydrochloride (SR) Tablet	Each uncoated bilayered tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 1000mg (As sustained release form)	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Alembic Pharmaceuticals Ltd.	7.51 (Note 5)
4(xli)	Alpha Lipoic Acid, Methylcobalamin, Selenium, Chromium Picolinate, Zinc Sulphate, Myo-Inositol & Folic Acid Capsule	Each soft gelatin capsule contains: Alpha Lipoic Acid USP 200mg Methylcobalamin IP 1500mcg, Selenium Dioxide Monohydrated USP eq. to Elemental Selenium 55mcg Chromium Picolinate USP 200mcg Zinc Sulphate IP 27.5mg Myo-Inositol BP 100mg Folic Acid IP 1.5mg	1 Capsule	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Intas Pharmaceuticals Ltd.	13.76
4(xlii)	Iron with Folic Acid & Cyanocobalamin Syrup	Each 5ml contains: Ferric Ammonium Citrate IP 110mg eq. to Elemental Iron 22.55mg Folic Acid IP 1.5mg Cyanocobalamin IP 15mcg	1 ml	M/s Biogenetic Drugs Pvt. Ltd./ M/s Intas pharmaceuticals Ltd.	0.16 (Note 2)
4(xliii)	Iron Vitamin B12 and Folic Acid Syrup	Each 5ml contains: Ferric Ammonium Citrate IP 110mg eq. to Elemental Iron 22.55mg Folic Acid IP 1.5mg	1 ml	M/s East African (India) Overseas / M/s Intas pharmaceuticals Ltd.	0.16 (Note 2)

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Cyanocobalamin IP 15mcg			
4(xliv)	Dexamethasone tablet	Each uncoated tablet contains: Dexamethasone 6 mg	1 tablet	M/s Cadila Healthcare Ltd/ M/s Zydus Healthcare Ltd	3.36

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 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 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 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.

4.2 With the outbreak of COVID 19 pandemic, the medicine Dexamethasone has been included in the COVID Management protocol. Accordingly, the availability of this drug is of paramount importance in these challenging times. With this view in mind, the price approval of Dexamethasone 6 mg tablet was fast tracked so as to enable the manufacturer/ marketer to launch the drug at the earliest and make it available in the country at the earliest.

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

5.1 It was noted that no review case is pending with NPPA for implementation.

6. Agenda item no. 6 - Application for extension of ceiling price for I.V. Fluids with packaging in Non-glass with special feature.

6.1 The Authority deliberated upon the matter in detail and noted that two companies namely, M/s Abaris Healthcare Pvt. Ltd and M/s Higgs Healthcare have applied for separate ceiling price of I.V. Fluids for packages in non-glass having special features. The Authority noted that the matter was deliberated in the 30th meeting of the Multidisciplinary Committee of Experts held on 19.04.2021 and the two companies namely, M/s Abaris Healthcare Pvt. Ltd and M/s Higgs Healthcare made demonstration before the Multidisciplinary Committee of Experts. The Authority further noted that the Committee recommended to extend the ceiling prices and the formulations mentioned in SO.1332(E) dated 25.03.2021 to the two companies namely, M/s Abaris Healthcare Pvt. Ltd and M/s Higgs Healthcare [for Higgs Healthcare, the product mentioned in Sl. No. 1,2,3,4,5,7 and 8 of S.O. 1332(E) dated 25.03.2021] for I.V. fluids in packages in non-glass with special features as (i) Self Collapsibility and self seal ability, (ii) not having air-vent and (iii) having no chance of contamination during manufacture / infusion / admixing levels.

6.2 Accordingly, the Authority decided to extend the ceiling prices and the formulations mentioned in S.O.1332(E) dated 25.03.2021 to the two companies namely, M/s Abaris Healthcare Pvt. Ltd and M/s Higgs Healthcare [for Higgs Healthcare, the product mentioned in Sl. No. 1,2,3,4,5,7 and 8 of S.O. 1332(E) dated 25.03.2021] for the products “Duo Port” and “Aquadrip” respectively in respect of I.V. fluids in packages in non-glass with special features as (i) Self Collapsibility and self-seal ability, (ii) not having air-vent and (iii) having no chance of contamination during manufacture / infusion / admixing levels.

6.3 The Authority also noted the recommendations of the Committee that an Office Memorandum be issued directing the manufacturers/ marketers of IV fluids having special features to make suitable modification in the labels by mentioning the details of special features. The Authority deliberated upon the matter in detail and decided to accept the recommendations of the Committee.

7. Agenda item no. 7 – Application for extension of ceiling price for Ringer Lactate Injection in packaging with special feature.

7.1 The Authority deliberated upon the matter in detail and noted that two companies namely, M/s Abaris Healthcare Pvt. Ltd and M/s Higgs Healthcare have applied for separate

ceiling price of ringer lactate injection in packages having special features. The Authority further noted that the matter was deliberated in the 30th meeting of the Multidisciplinary Committee of Experts held on 19.04.2021 and the two companies namely, M/s Abaris Healthcare Pvt. Ltd and M/s Higgs Healthcare had made demonstration before the Multidisciplinary Committee of Experts. The Authority further noted that the Committee recommended to extend the ceiling prices and the formulations mentioned in SO.1333(E) dated 25.03.2021 to the two companies namely, M/s Abaris Healthcare Pvt. Ltd [for M/s Abaris Healthcare Pvt. Ltd product mentioned in Sl. No. 2,3 and 4 of S.O. 1333(E) dated 25.03.2021] and M/s Higgs Healthcare [for M/s Higgs Healthcare product mentioned in Sl. No. 3 and 4 of S.O. 1333(E) dated 25.03.2021] for ringer lactate injection in packages with special features as (i) Self Collapsibility and self-seal ability, (ii) not having air-vent and (iii) having no chance of contamination during manufacture / infusion / admixing levels.

7.2 Accordingly, the Authority decided to extend the ceiling prices and the formulations mentioned in S.O.1333(E) dated 25.03.2021 to the two companies namely, M/s Abaris Healthcare Pvt. Ltd [for M/s Abaris Healthcare Pvt. Ltd product mentioned in Sl. No. 2,3 and 4 of S.O. 1333(E) dated 25.03.2021] and M/s Higgs Healthcare [for M/s Higgs Healthcare product mentioned in Sl. No. 3 and 4 of S.O. 1333(E) dated 25.03.2021] for ringer lactate injection in packages with special features as (i) Self Collapsibility and self seal ability, (ii) not having air-vent and (iii) having no chance of contamination during manufacture / infusion / admixing levels.

7.3 The Authority also noted the recommendations of the Committee that an Office Memorandum be issued directing the manufacturers/ marketers of ringer lactate injection having special features to make suitable modification in the labels by mentioning the details of special features. The Authority deliberated upon the matter in detail and decided to accept the recommendations of the Committee.

8. Agenda item no. 8 - Intimation of Minutes of 29th & 30th meeting of Multidisciplinary Committee of Experts held on 12.04.2021 & 19.04.2021.

8.1 Noted.

9. Agenda item no. 9 - Ceiling price fixation of Levothyroxine 37.5 mcg tablet

9.1 The Authority deliberated upon the matter in detail and approved the ceiling price of Levothyroxine 37.5 mcg tablet at Rs. 1.18 per tablet excluding GST.

10. Agenda item no. 10 - Submission of Form-IV Intimation by M/s GlaxoSmithKline Pharmaceuticals Ltd in respect of scheduled formulation viz., Grisovin FP 250mg Tablet under para 21(2) of DPCO, 2013-reg

10.1 Noted.

11. Agenda item no. 11 –Issues relating to the price of Remdesivir drugs

11.1 The Authority was informed that with the sudden outbreak of COVID 19 in the country in the 2nd wave, the demand for Remdesivir injection has increased manifold and has outstripped the production. The State-wise allocation is also being done jointly by DoP & MoHFW. For existing lyophilized injections, MRPs of various brands varied up to Rs 5400/ per vial. However, on the intervention of the government, the major manufacturers/marketers of the Remdesivir Injection (a non-scheduled Drug) have voluntarily reduced its retail prices and the reduced prices uploaded on NPPA website vide OM 17.04.2021.

11.2 The Authority noted that to meet the ever increasing demand for Remdesivir, on the request of the Government, the manufacturers of Remdesivir injection are ramping up the production capacity and have introduced liquid Remdesivir injection in various dosage forms which has a shorter manufacturing cycle. Drug Controller General (India), an Authority member clarified that Remdesivir Injection (liquid) and Remdesivir Powder for Injection (lyophilized) are two different dosage forms of Remdesivir. CDSCO has approved both Remdesivir Injection (liquid) and Remdesivir Powder for Injection (lyophilized) separately under the New Drugs and Clinical Trials Rules, 2019.

11.3 The Authority deliberated upon the matter in detail. It was noted that Remdesivir is a non scheduled drug and hence does not carry a ceiling price. Being a non scheduled drug, manufacturers can launch different dosages under different brand name and MRP. The Authority further noted that the liquid form of Remdesivir injection introduced by M/s Cadila Healthcare Ltd at MRP of Rs. 1299 per vial is different from its lyophilized brand currently being sold at Rs 899/- per vial. The Company has recently undertaken voluntary reduction in the MRP of its lyophilized brand from Rs 2800/- per vial to Rs 899/- per vial. The Authority further noted that the brand of liquid Remdesivir injection introduced by M/s Cadila Healthcare Ltd at MRP of Rs. 1299 per vial will continue to be the lowest priced

brand in the market different from lyophilized form. The Form V submitted by the company is noted.

It was also decided that information be obtained from other manufacturers as to the various dosage forms of Remdesivir injection being manufactured/ marketed by them.

12. Agenda item no. 12 - Initiatives taken by NPPA in view of COVID 2.0 pandemic

12.1 The Authority was informed that NPPA has set-up a Control Room with Helpline No. 1800111255 on 20th March 2020 to respond to queries/ complaints and message dealing with COVID-19. An e-mail ID has also been created for Control Room (monitoring-nppa@gov.in). Most of the complaints received are pertaining to Remdesivir. The allocation of Remdesivir is made to the respective State/UT governments. The complaints are compiled and sent to respective State/UT government for their resolution. Matter has been taken up with DoP to explore the possibility of looking at any other modalities so as to enable NPPA to provide expeditious resolution to requests received in the control room.

12.2 A Monitoring Cell is operational under NPPA and CDSCO for implementation of the Allocation for Remdesivir injections to States/UTS undertaken by MoHFW and DoP. Daily report is collated regarding supplies made by seven licensed manufacturers against this allocation and submitted to DoP. The Authority was also informed about the extensive coordination being undertaken with the manufacturers of Remdesivir to ensure that supplies are made to the respective State/UT governments as per allocation. Institutional requests are also being addressed. NPPA is also resolving issues related to supply disruption at State level, with support from MHA.

12.3 Production and supply issues related to Other Drugs under Covid Protocol and Covid Plus Drugs including Favipiravir, Tocilizumab, Enoxaparin, Methyl Prednisolone, Dexamethasone, Paracetamol and Itolizumab are being assessed, monitored and addressed. DCGI has been requested to take strict measures for prevention of black-marketing and hoarding of essential drugs. State level team formation has been urged for field level action monitoring.

12.4 The Authority noted the initiatives taken by NPPA in view of outbreak of COVID19 pandemic.

13. Agenda item no. 13 - Application of M/s Torrent Pharmaceutical Limited for exemption from DPCO under Para 32(i) of DPCO, 2013 for New Drug Formulation "TAPENTADOL Nasal Spray" each spray (0.1ml) containing Tapentadol Hydrochloride 22.5mg + Benzalkonium Chloride (50%) 0.02%w/v (As preservative).

13.1 The Authority noted the application filed by M/s Torrent Pharmaceuticals Ltd for exemption under para 32(i) of DPCO 2013 for the formulation TAPENTADOL Nasal Spray" each spray (0.1ml) containing Tapentadol Hydrochloride 22.5mg + Benzalkonium Chloride (50%) 0.02%w/v (As preservative).

13.2 The Authority further noted the document submitted by the applicant company as follows:

a. Patent No. 355890 granted to M/s Torrent Pharmaceuticals Ltd for invention titled "PHARMACEUTICAL INVENTION OF TAPENTADOL" issued on 15th January, 2021, having validity for 20 years from 19th July, 2012, issued by the Indian Patent Office.

b. Approval from Central Drugs Standard Control Organisation (CDSCO) dated 02nd September, 2020, in form CT-23, granted to M/s Torrent Pharmaceuticals Ltd to manufacture the new drug Nasal Spray in which "Each spray (0.1ml) containing Tapentadol Hydrochloride 22.5mg + Benzalkonium Chloride (50%) 0.02%w/v (As preservative).

13.3 The Authority deliberated upon the matter in detail and decided to obtain (CDSCO) as to whether the new drug approval provided is within the scope of the Patent granted by India Patent Office vide Patent No. 355890 and put up after obtaining the clarification.

14. Agenda item no. 14 - Intimation of Minutes of 31st meeting of Multidisciplinary Committee of Experts held on 27.04.2021.

14.1 Noted.

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

Sd/-
(Dr. Vinod Kotwal)
Member Secretary