मिसिल स.- 8(75)/2020/डी.पी/एनपीपीए-डीवी-II
F. No. 8(75)/2020/DP/NPPA-Div. II

कार्यवाहीस. : 205/75/2020/F
Proceeding No : 205/75/2020/F

Minutes of the 207th (overall) and 75th meeting of the Authority under DPCO, 2013 held on 20.05.2020 at 11:00 AM

The 207th meeting of the Authority (overall), which is the 75th meeting under the DPCO, 2013, was held on the 20th of May, 2020 at 11:00 AM under the Chairmanship of Ms. Shubhra Singh, Chairman, NPPA. The following Authority members of the NPPA were present:

(i) Shri A. K. Saha, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure
(ii) Ms. A. Srija, Economic Advisor, Deptt of Economic Affairs

Shri A.K.Pradhan, Deputy Drug Controller, Deptt. 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 N. I. Chowdhury, Advisor
(ii) Shri S. S. Ojha, Jt. Director (Pricing)
(iii) Shi Manjesh Porwal, Dy. Director (M&E)
(iv) Shri Prasenjit Das, Asstt. Director (Pricing)
(v) Shri Prakash Hemani, Asstt. Director (Pricing)

II. Agenda items

1. Agenda item no. 1 - Confirmation of the Minutes of the 74th meeting held on 31.03.2020.

1.1 Noted.

2. Agenda item no. 2 – Action Taken Report on decisions taken by NPPA in its 74th meeting dated 31.03.2020

2.1 Noted.

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

3.1 Noted.

4. Agenda item no. 4 – New Drug application Price fixation under para 5 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(xl) (total 43 Form I applications) falling under the purview of para 2(u) of DPCO, 2013 and approved the retail prices in 43 (forty three) cases under para 5 and 15 of the DPCO 2013, as detailed below:

A. Retail price fixed under para 5 of DPCO, 2013

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(i)	Voglibose + Metformin Tablet (My Vobo 0.3 M)	Each uncoated bilayered tablet contains: Voglibose IP 0.3mg, Metformin Hydrochloride IP 500mg, (Sustained Release)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Mylan Pharmaceuticals Pvt. Ltd.	6.50
4(ii)	Voglibose + Metformin Tablet (My Vobo 0.2 M)	Each uncoated bilayered tablet contains: Voglibose IP 0.2mg, Metformin Hydrochloride IP 500mg, (Sustained Release)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Mylan Pharmaceuticals Pvt. Ltd.	5.50
4(iii)	Glimepiride + Metformin Tablet (My GainPro SR2 Forte)	Each uncoated bilayered tablet contains: Glimepiride IP 2mg, Metformin Hydrochloride IP 1000 mg, (Prolonged Release)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Mylan Pharmaceuticals Pvt. Ltd.	7.30
4(iv)	Glimepiride + Metformin Tablet (My GainPro SR2)	Each uncoated bilayered tablet contains: Glimepiride IP 1mg, Metformin Hydrochloride IP 500 mg, (Prolonged Release)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Mylan Pharmaceuticals Pvt. Ltd.	4.80
4(v)	Omeprazole + Domperidone Capsule (Oldolan)	Each hard Gelatin capsule contains: Omeprazole IP(As Gastro-Resistant Granules) 20mg, Domperidone IP 10mg	1 Capsule	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Mylan Pharmaceuticals Pvt. Ltd.	5.10
4(vi)	Pantoprazole tablet (MyPrazol)	Each enteric coated tablet contains: Pantoprazole Sodium IP eq. to Pantoprazole 40mg,	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Mylan Pharmaceuticals Pvt. Ltd.	6.18
4(vii)	Glimepiride + Metformin + Pioglitazone Tablet (MyGainPro P2)	Each uncoated bilayered tablet contains: Glimepiride IP 2 mg, Metformin Hydrochloride IP 500 mg, (Sustained	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Mylan Pharmaceuticals	7.80

		Release form) Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg		Pvt. Ltd.	
4(viii)	Glimepiride + Metformin + Piaglitazone Tablet (MyGainPro P1)	Each uncoated bilayered tablet contains: Glimepiride IP 1 mg, Metformin Hydrochloride IP 500 mg, (Sustained Release form) Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Mylan Pharmaceuticals Pvt. Ltd.	5.90
4(ix)	Pantoprazole + Levosulpiride capsule (MyPrazol L)	Each hard gelatin capsule contains: Pantoprazole Sodium IP eq. to Pantoprazole 40mg (as gastro-resistant tablet), Levosulpiride 75mg (as uncoated sustained release tablet)	1 Capsule	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Mylan Pharmaceuticals Pvt. Ltd.	13.50
4(x)	Pantoprazole + Domperidone tablet (MyPrazol D)	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 Mylan Pharmaceuticals Pvt. Ltd.	5.65
4(xi)	Temisartan + Hydrochlorothiazide Tablet (MyTenslo H)	Each uncoated bilayered Tablet contains: Temisartan IP 40mg, Hydrochlorothiazide IP 12.5mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Mylan Pharmaceuticals Pvt. Ltd.	7.90
4(xii)	Glimepiride + Metformin Tablet (My GainPro SR1 Forte)	Each uncoated bilayered tablet contains: Glimepiride IP 1 mg, Metformin Hydrochloride IP 1000 mg (Prolonged Release)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Mylan Pharmaceuticals Pvt. Ltd.	6.50
4(xiii)	Glimepiride + Metformin Tablet (My GainPro SR1)	Each uncoated bilayered tablet contains: Glimepiride IP 1mg, Metformin Hydrochloride IP 500 mg, (Prolonged Release)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Mylan Pharmaceuticals Pvt. Ltd.	5.60
4(xiv)	Losartan + Hydrochlorothiazide tablet (MyLosdro H)	Each film coated tablet contains: Losartan potassium IP 50 mg Hydrochlorothiazide IP 12.5 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Mylan Pharmaceuticals Pvt. Ltd.	7.62
4(xv)	Temisartan + Amlodipine Tablet (MyTenslo A)	Each uncoated bilayered Tablet contains: Temisartan IP 40mg, Amlodipine Besilate IP eq. to Amlodipine 5 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Mylan Pharmaceuticals Pvt. Ltd.	7.90
4(xvi)	Atorvastatin + Ezetimibe tablet	Each film coated tablet contains:	1 Tablet	M/s East African (India) Overseas /	30.32

		Atorvastatin Calcium IP eq. to Atorvastatin 40mg Ezetimibe IP 10 mg		M/s Zydus Healthcare Ltd.	
4(xvii)	Atorvastatin + Ezetimibe tablet	Each film coated tablet contains: Atorvastatin Calcium IP eq. to Atorvastatin 20mg Ezetimibe IP 10 mg	1 Tablet	M/s East African (India) Overseas / M/s Zydus Healthcare Ltd.	21.01
4(xviii)	Rabeprazole + Domperidone tablet (Ridzogas D)	Each enteric coated tablet contains: Rabeprazole Sodium IP 20 mg, Domperidone Maleate IP eq. to Domperidone 10 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Mylan Pharmaceuticals Pvt. Ltd.	5.22
4(xix)	Rabeprazole + Domperidone Capsule (Ridzogas SR D)	Each hard gelatin capsule contains: Rabeprazole Sodium IP 20 mg (as gastro resistant pellets), Domperidone IP 30 mg (as sustained release pellets)	1 Capsule	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Mylan Pharmaceuticals Pvt. Ltd.	8.69
4(xx)	Norethisteone Acetate Tablet	Each film coated controlled release tablet contains: Norethisteone Acetate BP 10 mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Torrent Pharmaceuticals Ltd.	15.08
4(xxi)	Esomeprazole + Domperidone Capsule	Each hard gelatin capsule contains: Esomeprazole Magnesium IP eq. to Esomeprazole IP 40 mg (as enteric coated pellets) Domperidone IP 30 mg (as sustained release pellets)	1 Capsule	M/s Skymap Pharmaceuticals Pvt. Ltd.	9.02
4(xxii)	Glimepiride + Voglibose + Metformin Hydrochloride Tablet	Each uncoated bilayered tablet contains: Glimepiride IP 1 mg Voglibose IP 0.2 mg Metformin Hydrochloride IP 500 mg (as Extended Release)	1 Tablet	M/s Sun Pharma Laboratories Ltd.	8.65
4(xxiii)	Glimepiride + Voglibose + Metformin Hydrochloride Tablet	Each uncoated bilayered tablet contains: Glimepiride IP 2 mg Voglibose IP 0.2 mg Metformin Hydrochloride IP 500 mg (as Extended Release)	1 Tablet	M/s Sun Pharma Laboratories Ltd.	12.20
4(xxiv)	Atorvastatin + Clopidogrel + Aspirin Capsule	Each hard gelatin capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 10 mg (as film coated tablets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg Aspirin IP 75 mg (As Gastro resistant tablets)	1 Capsule	M/s Micro Labs. Limited	3.80
4(xxv)	Atorvastatin + Clopidogrel + Aspirin	Each hard gelatin capsule contains:	1 Capsule	M/s Micro Labs. Limited	5.27

	Capsule	Atorvastatin Calcium IP eq. to Atorvastatin 20 mg (as film coated tablets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg Aspirin IP 75 mg (As Gastro resistant tablets)			
4(xxvi)	Vildagliptin + Metformin Tablet	Each film coated tablet contains: Vildagliptin 50 mg Metformin Hydrochloride IP 1000 mg	1 Tablet	M/s Morepen Laboratories Ltd	6.66
4(xxvii)	Vildagliptin + Metformin Tablet	Each film coated tablet contains: Vildagliptin 50 mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Morepen Laboratories Ltd	6.15
4(xxviii)	Levocarnitine + Methylcobalamin + Folic acid tablet (Carnitor Plus)	Each film coated tablet contains: L-Carnitine L-Tartrate Eq. to Levocarnitine 500mg Methylcobalamin IP 1500 mcg Folic acid IP 1.5 mg	1 Tablet	M/s Modi-Mundipharma Pvt. Ltd. / M/s Win-Medicare Pvt. Ltd.	13.64
4(xxix)	Ramipril + Metoprolol Tablet	Each film coated bilayered tablet contains: Ramipril IP 2.5 mg Metoprolol Succinate IP 23.75 mg equivalent to Metoprolol Tartrate 25 mg (as extended release form)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Cipla Ltd.	11.08
4(xxx)	Ramipril + Metoprolol Tablet	Each film coated bilayered tablet contains: Ramipril IP 5 mg Metoprolol Succinate IP 47.50 mg equivalent to Metoprolol Tartrate 50 mg (as extended release form)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Cipla Ltd.	16.91
4(xxxi)	Metformin Hydrochloride + Gliclazide Tablet (Glikey-M)	Each uncoated bilayered tablet contains: Metformin Hydrochloride IP 500mg (in sustained release form) Gliclazide IP 60 mg (in sustained release form)	1 Tablet	M/s USV Pvt. Ltd.	9.47
4(xxxii)	Metoprolol + Telmisartan + Chlorthalidone Tablet	Each film coated bilayered tablet contains: Metoprolol Succinate IP 47.50 mg eq. to Metoprolol Tartrate IP (as extended release) 50 mg Telmisartan IP 40 mg Chlorthalidone IP 12.5 mg	1 Tablet	M/s Sun Pharma Laboratories Ltd.	12.76
4(xxxiii)	Metoprolol + Telmisartan + Chlorthalidone Tablet	Each film coated bilayered tablet contains: Metoprolol Succinate IP 23.75 mg eq. to Metoprolol Tartrate IP (as extended release) 25 mg	1 Tablet	M/s Sun Pharma Laboratories Ltd.	10.78

		Telmisartan IP 40 mg Chlorthalidone IP12.5 mg			
4(xl)	Escitalopram + Clonazepam Tablet	Each film coated tablet contains: Escitalopram Oxalate IP eq. to Escitalopram 5mg Clonazepam IP 0.5mg	1 Tablet	M/s Ravian Life Sciences (P) Ltd. / M/s Zydus Healthcare Ltd.	6.41

B. Retail price fixed under para 15 of DPCO, 2013

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(xxxiv)	Ferric Ammonium Citrate + Vitamin B12 + Folic Acid + Zinc Sulphate Monohydrate Syrup	Each 15 ml syrup contains: Ferric Ammonium Citrate IP 160mg Vitamin B12 IP 5mcg Folic Acid IP 1 mg Zinc Sulphate Monohydrate IP 30mg	1 ML	M/s Zydus Healthcare Ltd.	0.50
4(xxxv)	Docaravimab + Miromavimab Injection 3000IU /5 ml	Each1ml injection contains: Docaravimab (r-DNA Origin) (INH) 300 IU Miromavimab (r-DNA Origin) (INH) 300 IU	Each Pack	M/s Cadila Healthcare Ltd	26064.00
	Docaravimab and Miromavimab Injection 3000 IU /10 ml	Each1ml injection contains: Docaravimab (r-DNA Origin) (INH) 150 IU Miromavimab (r-DNA Origin) (INH) 150 IU	Each Pack	M/s Cadila Healthcare Ltd	26064.00
	Docaravimab and Miromavimab Injection 1500 IU /2.5 ml	Each1ml injection contains: Docaravimab (r-DNA Origin) (INH) 300 IU Miromavimab (r-DNA Origin) (INH) 300 IU	Each Pack	M/s Cadila Healthcare Ltd	13032.00
	Docaravimab and Miromavimab Injection 600 IU / ml	Each1ml injection contains: Docaravimab (r-DNA Origin) (INH) 300 IU Miromavimab (r-DNA Origin) (INH) 300 IU	Each Pack	M/s Cadila Healthcare Ltd	5212.80
4(xxxvi)	Alpha Lipoic Acid + Folic Acid + Methylcobalamin + Vitamin D3 + Pyridoxine Tablets	Each film coated tablet contains: Alpha Lipoic Acid USP 100mg Folic Acid IP 1.5mg Methylcobalamin IP 1500mcg Vitamin D3 IP 1000IU Pyridoxine Hydrochloride (Vitamin B6) IP 3mg	1 Tablet	M/s East African (India) Overseas / M/s Cadila Pharmaceuticals Limited	13.33
4(xxxvii)	Calcium Carbonate + Vitamin D3 + Mecobalamin + L-Methylfolate + Pyridoxal -5 Phosphate Tablet	Each film coated tablet contains: Calcium Carbonate IP 1250 mg eq. to elemental calcium 500 mg Vitamin D3 IP 2000 IU	1 Tablet	M/s Akums Drugs & pharmaceuticals Pvt. Ltd. / M/s Cadila Pharmaceuticals	17.59

		Mecobalamin IP (Methylcobalamin) 1500 mcg L-Methylfolate Calcium 1 mg Pyridoxal -5 Phosphate 20 mg		Ltd.	
4(xxxviii)	Atorvastatin Tablet	Each film coated tablet contains: Atorvastatin Calcium IP eq to Atorvastatin 60mg	1 Tablet	M/s Intas Pharmaceuticals Limited	25.00
4(xxxix)	Atorvastatin Tablet	Each film coated tablet contains: Atorvastatin Calcium IP eq to Atorvastatin 30mg	1 Tablet	M/s Intas Pharmaceuticals Limited	13.96

Note 1. The retail prices are to be notified after 10 days from uploading of draft working sheet/ minutes of the 18th meeting of the Multidisciplinary Committee of Experts.

Note 2. The representative of DCGI confirmed that the formulation as per agenda no. xxiv, xxv, xxviii and xxxiv is approved.

Note 3. The Authority reiterated the decision taken in its 72nd meeting dated 20.01.2020 in which it decided that the retail price of Fixed Dose Combinations (FDCs) of Metformin and Vildigliptin tablets for various companies is to be fixed by adding 16% retailer margin to the average Price To Retailer (PTR) based on the Form-V data submitted by the companies for whom retail prices were earlier approved for these subject FDCs since Fixed Dose Combinations (FDCs) of Metformin and Vildagliptin tablets are off-patent items and any retail price fixation on the basis of para 5 of DPCO 2013 by taking six month prior data (when the patent was in force) would result in extending the price of patented products to off-patent products.

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

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

6. Agenda item no. 6 – Meeting of the Multidisciplinary Committee of Experts

6.1 Noted.

7. Agenda item no. 7 - Representation of M/s Boehringer Ingelheim regarding retail price fixation of Empaglifozin+ Metformin combinations tablet for various companies which have launch the formulations without prior price approval

7.1 The Authority deliberated upon the matter in detail and noted that the existing manufacturer is required to apply for prior price approval for launching of new drugs. The Authority further noted that M/s Boefringer Ingelheim India Pvt. Ltd is not the existing manufacturer in so far the Fixed Dose Combinations (FDCs) tablets of Metformin and Empagliflozin is concerned.

7.2 Accordingly, the Authority decided that the retail price notified as per sl. No. 9, 10 and 11 of the notification SO. 957(E) dated 03.03.2020 would not be applicable to products which are imported/manufactured and marketed by M/s Boehringer Ingelheim India Pvt. Ltd. However, it would be applicable to the products which are manufactured/imported by M/s Boehringer Ingelheim India Pvt. Ltd and marketed by M/s Lupin Ltd.

8. Agenda item no. 8 - Action taken by NPPA in the wake of outbreak of COVID-19 pandemic .

8.1. The Authority noted and appreciated the action taken by NPPA in response to the outbreak of COVID-19 pandemic.

9. Agenda item no. 9 - Upward revision of Ceiling Price of select Scheduled formulations under para 19 of DPCO, 2013.

Record note for members being circulated separately.

10. Agenda item no. 10 – Matter relating to discontinuation cases under DPCO 2013

10.1 The Authority deliberated upon the matter in detail with respect to the applications for discontinuation being filed by the companies and decided as follows:

S.No.	Company Brand Name / Composition /	Present Position	Decision

1	M/s Neon Laboratories Tropine 1ml Injection (Atropine Sulphate Injection 0.6mg/ml)	Company is the largest player with 83% market share for the formulation. NPPA vide its letter dated 06.01.2020 has directed to the company to continue production / import and sale upto 20.06.2021. Simultaneously, the case was also referred to Committee constituted for examination of cases under Para 21 of DPCO, 2013 to inform urgency or emergency for invocation of Para 3 of DPCO, 2013. In the 4th meeting of the above referred Committee held on 13.05.2020, the Committee recommended that this is an essential medicine and hence discontinuation may not be allowed.	Authority considered the case and decided that NPPA may continue to monitor the production and availability of above referred scheduled formulation till above referred period i.e. 20.06.2021.
2	M/s Menarini India Pvt Ltd (i) Cetrilak Solution 100ml (Cetrimide IP 20%) (ii) Phenzee Syrup 60 ml (Promethazine HCl IP 5mg) (iii) Scabper Lotion 30ml (Permethrin 5%)	Company is the largest player for all the 3 scheduled formulations with 100%, 74% & 47% market share respectively. NPPA vide its letter dated 01.05.2020 has directed to the company to continue production / import and sale upto 15.05.2021. Simultaneously, the case was also referred to Committee constituted for examination of cases under Para 21 of DPCO, 2013 to inform urgency or emergency for invocation of Para 3 of DPCO, 2013. In the 4th meeting of the above referred Committee held on 13.05.2020, the Committee recommended that these are essential medicines and hence discontinuation may not be allowed.	Authority considered the case and decided that NPPA may continue to monitor the production and availability of above referred scheduled formulation till above referred period i.e. 15.05.2021.
3	M/s 3M India Limited Glutarex 2%, Glutaral Disinfectant Solution (Glutraldehyde 2%)	As per market database referred by NPPA, no information is available whether any other company is producing /marketing this formulation. In view of which, it was decided to assume 100% market share. In this regard, NPPA vide its letter dated 01.05.2020 has directed the company to continue production / import and sale upto 13.05.2021. Simultaneously, the case was also referred to Committee constituted for examination of cases under Para 21 of DPCO, 2013 to inform urgency or emergency for invocation of Para 3 of DPCO, 2013. In the 4th meeting of the above referred Committee held on 13.05.2020, the Committee recommended that this is an essential medicine and hence discontinuation may not be allowed.	Authority considered the case and decided that NPPA may request CDSCO to provide the list of manufacturers producing /marketing above referred scheduled formulation and NPPA may take necessary action accordingly.
4	M/s Allergan Celluvisc 0.4 ml	For this scheduled formulation, there are only two products of 1% strength are available in the market. Out of which, Celluvisc 0.4ml is unique in the sense that it does not use	Authority considered the case and decided that NPPA may continue to monitor the production

	(Carboxymethylcellulose)	stabilizing agent "oxychloro" which causes side effects in some patients as brought out in grievance received in PMO through CPGRAMS (PMOPG/E/2017/0628989 dated 14.12.2017) of Shri Birender Singh. The other product available in market (On-Tears Gel 1% of M/s Sentiss Pharma Pvt. Ltd) contains stabilizing agent "oxychloro" due to which market share of unique product of M/s. Allergan India Private Limited was considered as 100%'. In this regard, Company vide letter dated 16.12.2019 has been directed to continue production / import and sale upto 15.05.2021. Simultaneously, the case was also referred to Committee constituted for examination of cases under Para 21 of DPCO, 2013 to inform urgency or emergency for invocation of Para 3 of DPCO, 2013. In the 4th meeting of the above referred Committee held on 13.05.2020, the Committee recommended that this is an essential medicine and hence discontinuation may not be allowed.	and availability of above referred scheduled formulation till above referred period i.e. 15.05.2021.
5	M/s Procter & Gamble Livogen Injection (Elemental Iron)	Company is the largest player with 50.11% market share of Livogen Injection. NPPA vide its letter dated 19.12.2019 has directed the company to continue production / import and sale upto 23.03.2021. Simultaneously, the case was also referred to Committee constituted for examination of cases under Para 21 of DPCO, 2013 to inform urgency or emergency for invocation of Para 3 of DPCO, 2013. In the 4th meeting of the above referred Committee held on 13.05.2020, the Committee recommended that this is an essential medicine and hence discontinuation may not be allowed.	Authority considered the case and decided that NPPA may continue to monitor the production and availability of above referred scheduled formulation till above referred period i.e. 23.03.2021.

10.2 The Authority also deliberated upon the matter relating to the cases in which para 3 of DPCO 2013 is invoked/ propose to be invoked and decided as follows:

S.No.	Company Brand Name / Composition /	Present Position	Decision
1	M/s Abbott Healthcare Pvt Ltd (i) Ambistryn 1.0 gm Inj (Streptomycin Injection 1000 mg) (ii) Ambistryn 0.75 gm Inj	Company is the largest player for both the scheduled formulations with 100% market share. Company has informed that it is used in tuberculosis management and this molecule has adverse impact on other organs. WHO has recommended not to use this molecule for TB and has laid down specific protocols to be followed by GOI for TB Patients.	Authority considered the case and decided that in view of WHO recommendation, the case may be referred to Standing National Committee on Medicines (SNCM) for examination and recommendation for

	(Streptomycin Injection 750 mg)	The matter was also taken up with MoHFW which was inter alia informed that requirement of Injection Streptomycin has reduced significantly but the use of Streptomycin is still indicated in certain situations. In view of which, Company vide letter dated 23.12.2019 has been directed to continue production / import and sale upto 21.02.2021. Simultaneously, the case was also referred to Department of Pharmaceuticals (DoP) for invoking of Para 3 of DPCO, 2013, but DoP has not yet invoked Para 3 of DPCO, 2013.	invocation of Para 3.
2	M/s Abbott Healthcare Pvt Ltd (i) Hansepran 50 mg (Clofazimine Capsule 50mg) (ii) Hansepran 100 mg (Clofazimine Capsule 100mg)	Company is the largest player for both the scheduled formulations with 100% & 98% market share. NPPA vide its letter dated 27.11.2019 directed the company to continue production / import and sale for 12 months beyond the intended date of discontinuation i.e. upto 01.01.2021. It was also noted that Authority has allowed 50% upward price revision under Para 19 of DPCO, 2013 vide S.O. dated 13.12.2020. Simultaneously, the case was also referred to Department of Pharmaceuticals (DoP) for invoking of Para 3 of DPCO, 2013 for above referred 2 scheduled formulations beyond the above referred period of 12 months i.e.01.01.2021.	Authority considered the case and noted that 50% upward price revision has been allowed by Authority in its 71st meeting. In view of that the discontinuation intimation for the referred formulations may be treated as closed.
3	M/s GSK now manf. /mrkt by BBIL through Chiron Behring Vaccines Pvt. Ltd. Rabipur Inj. (Anti Rabies Vaccine)	In case of this scheduled formulation, DoP has invoked Para 3 directing the manufacturers to continue production and sale of Anti Rabies Vaccine till 27.06.2020 as the market share of the company was significant i.e. 38% in March, 2019. As per market database (March, 2020) referred by NPPA, Rabipur Injection is having 10% market share only and there are other major manufacturers for Anti Rabies Injection namely M/s Indian Immunologicals Ltd (33% market share), M/s Serum Institute of India Ltd (24% market share), Ranbaxy Laboratories Ltd (14% market share), M/s Zydus Cadila (4% market share), M/s Bharat Serum & Vaccine (3%) and M/s Zuventus Helathcare (8% market share). Vide letter dated 15.02.2019, M/s Chiron Behring Vaccines Pvt. Ltd. informed that GlaxoSmithKline Asia Pvt. Ltd. has sold its subsidiary company M/s Chiron Behring Vaccines Pvt. Ltd. (CBVPL) to M/s Bharat Biotech India Limited and M/s CBVPL will continue making available anti-rabies vaccines from its plant at Ankleshwar, Gujarat and will continue marketing the	Authority considered the case and decided that since there are other major manufacturers of the Anti Rabies Vaccine in the market and M/s CBVPL is making the product under new owner, there is no requirement to re-invoke Para 3 of DPCO, 2013 beyond 27.06.2020.

		vaccine in Indian market under new owner BBIL.	
4	M/s Serum Institute of India Diptheria and Tetanus Vaccine T.D. 0.5 ml (Combination with Tetanus Components)	In case of 3 scheduled formulations, DoP has invoked Para 3 directing the manufacturers to continue production and sale till 22.06.2020 as the market share of the company was 100%, 21.51% & 26.33% respectively. It is pertinent to mention that company is having 100% market share for Diptheria and Tetanus Vaccine (T.D.) 0.5ml and there is only one other company M/s Biological E Ltd in the market for Tetanus Toxoid 0.5ml and Tetanus Toxoid 5ml having 79% and 72% market share.	Authority considered the case and decided to re-invoke Para 3 of DPCO, 2013 i.r.o all the 3 scheduled formulations for a further period of six months beyond 22.06.2020 i.e. upto 22.12.2020
5	M/s Serum Institute of India Tetanus Toxoid 0.5 ml		
6	M/s Serum Institute of India Tetanus Toxoid Injection 5 ml		

11. Agenda item no. 11 – Development of ecosystems in NPPA

11.1 The Authority was appraised that with a view to bring transparency, regularity and timeliness of various processes in NPPA, an ecosystem has been envisaged to be developed in NPPA. In this regard, the timeline within which the various activities may be completed has been communicated to Department of Pharmaceuticals. The Authority was appraised that with a view to standardized the operations, it was decided that henceforth the meetings of the sub-committee, the meetings of the Multidisciplinary Committee of Experts and the Authority meeting is to be held in the second, third and fourth Wednesday respectively every month. It was also brought to the notice of the Authority that NPPA is in the process of development of online system and standardization of various forms and its processing. To achieve the above goal, a proposal with CDAC is under consideration. However, to execute it promptly, a system is being devised with the cooperation of NIC.

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

Sd/-

(N.I. Chowdhury)
Advisor (Cost)