मिसिलस.- 8(115)/2023/डी.पी/एनपीपीए-डीवी-II
F. No. 8(115)/2023/DP/NPPA-Div. II

कार्यवाहीस. : 247/115/2023/F
Proceeding No: 247/115/2023/F

Revised Minutes of the 247th(overall) and 115thmeeting of the Authority under DPCO, 2013 held on 31.07.2023 at 03:00 PM.

The 247th meeting of the Authority (overall), which is the 115th meeting under the DPCO, 2013 was held on 31st July, 2023 at 03:00 PM under the Chairmanship of Shri Kamlesh Kumar Pant, Chairman, NPPA. The following Authority members of NPPA were present during the meeting:

(i) Dr. Vinod Kotwal, Member Secretary, NPPA
(ii) Shri G. Venkatesh, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure
(iii) Shri Antony Cyriac, Economic Advisor, Department of Economic Affairs through Video Conference

Shri A. K. Pradhan, Jt. Drug Controller, CDSCO, Ministry of Health & Family Welfare was also present.

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

(i) Shri Sanjay Kumar, Advisor
(ii) Shri G.L. Gupta, Director (M&E)
(iii) Shri Saurabh Bansal, Deputy Director (M&E)
(iv) Shri Mahaveer Saini, Deputy Director (Pricing)
(v) Ms. Yuvika Panwar, Assistant Director (Pricing)

II. Agenda items

1. Agenda item no. 1 - Confirmation of Minutes of the 114thMeeting held on 19.06.2023.

1.1 The Authority confirmed the minutes without any change.

2. Agenda item no. 2 – (a) Action Taken Report (ATR) on decisions taken by NPPA in its 114th Meeting held on 19.06.2023.

2.1 Noted.

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

3.1 Noted.

4. Agenda item no. 4 – New Drug applications for Price fixation under Para 5 and Para 15 of DPCO, 2013

4.1The Authority discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 4(i) to 4 (xxxviii) (total 44 Form I applications containing retail

price fixation of 44 new drug) falling under the purview of Para 2(1) (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 in **Table 1:**

Table No. 1: Retail price fixation of new drugs

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (i)	Paroxetine Controlled release & Clonazepam Capsules	**Each hard gelatine capsule contains:** Paroxetine Hydrochloride Hemihydrate IP eq. to Paroxetine 12.5mg (As enteric coated Paroxetine controlled release tablets IP) Clonazepam IP 0.5mg (as immediate release tablet)	1 Capsule	M/s Akums Drugs & Pharmaceuticals Limited / M/s Eris Lifesciences Limited	14.53
4 (ii)	Itraconazole Capsule (Supra-Bioavailable formulation)	**Each Capsule contains:** Itraconazole IP 65mg	1 Capsule	M/s Mascot Health Series Pvt. Ltd. / M/s Indchemie Health Specialities Pvt. Ltd.	12.06
4 (iii)	Levetiracetam, Sodium Chloride Infusion	**Each 100ml contains:** Levetiracetam IP 500mg Sodium Chloride IP 820mg	1 ml	M/s Akum Drugs & Pharmaceuticals Ltd. / M/s Mankind Pharma Ltd.	0.89
4 (iv)	Sitagliptin Phosphate and Metformin Hydrochloride Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s MSN Laboratories Pvt. Ltd. / M/s Sanofi India Limited	10.82
4 (v)	Sitagliptin Phosphate and Metformin Hydrochloride Tablets	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s MSN Laboratories Pvt. Ltd. / M/s Sanofi India Limited	9.21
4 (vi)	Telmisartan and	**Each film coated tablet contains:**	1 Tablet	M/s Mascot Health Series	10.12

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Cilnidipine Tablet	Telmisartan IP 40mg Cilnidipine IP 10mg		Pvt. Ltd. / M/s Indchemie Health Specialities Pvt. Ltd.	
4 (vii)	Aceclofenac + Paracetamol + Serratiopeptidase Tablet	**Each film coated tablet contains:** Aceclofenac IP 100mg, Paracetamol IP 325mg Serratiopeptidase IP 15mg (As enteric coated granules eq. to 30000 enzyme activity unit of serratiopeptidase)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. /M/s Abbott Healthcare Pvt. Ltd.	8.38
4 (viii)	Chlorthalidone, Amlodipine & Telmisartan Tablets	**Each film coated tablet contains:** Chlorthalidone IP 6.25mg Amlodipine Besylate IP eq. to Amlodipine 5mg Telmisartan IP 40mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Cipla Ltd.	10.34
4 (ix)	Chlorthalidone, Amlodipine & Telmisartan Tablets	**Each film coated tablet contains:** Chlorthalidone IP 12.5mg Amlodipine Besylate IP eq. to Amlodipine 5mg Telmisartan IP 40mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Cipla Ltd.	10.24
4 (x)	Chlorthalidone, Amlodipine & Telmisartan Tablets	**Each film coated tablet contains:** Chlorthalidone IP 6.25mg Amlodipine Besylate IP eq. to Amlodipine 5mg Telmisartan IP 80mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Cipla Ltd.	16.77
4 (xi)	Chlorthalidone, Amlodipine & Telmisartan Tablets	**Each film coated tablet contains:** Chlorthalidone IP 12.5mg Amlodipine Besylate IP eq. to Amlodipine 5mg Telmisartan IP 80mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Cipla Ltd.	15.20
4 (xii)	Levocetirizine, Montelukast &	**Each uncoated bilayered tablet**	1 Tablet	M/s Akums Drugs &	15.89

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	(SR) Ambroxol Hydrochloride Tablets	**contains:** Levocetirizine Hydrochloride IP 5mg Montelukast Sodium IP eq. to Montelukast 10mg Ambroxol Hydrochloride IP 75mg (as sustained release)		Pharmaceuticals Ltd. / M/s Cipla Ltd.	
4 (xiii)	Rabeprazole Sodium and Ondansetron Tablets	**Each Film coated tablet contains:** Rabeprazole Sodium IP 20mg (As Enteric Coated Form) Ondansetron Hydrochloride IP eq. to Ondansetron 4mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Cipla Ltd.	6.83
4 (xiv)	Vitamin D3 Oral Solution	**Each 5ml contains:** Cholecalciferol IP 60000IU (In nano Droplet form)	1 ML	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Eris Lifesciences Limited	11.94
4 (xv)	Glimepiride, Voglibose & Metformin Hydrochloride (as Extended-release form) tablet	**Each uncoated bilayered tablet contains:** Glimepiride IP 1mg Voglibose IP 0.2mg Metformin Hydrochloride IP 1000mg (As Extended Release)	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Alkem Laboratories Limited	11.83
4 (xvi)	Linagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Linagliptin 2.5mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Synokem Lifesciences Pvt. Ltd. / M/s Mankind Pharma Ltd.	8.97 (Note 1)
4 (xvii)	Linagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Linagliptin 2.5mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Synokem Lifesciences Pvt. Ltd. / M/s Mankind Pharma Ltd.	9.60 (Note 1)
4 (xviii)	Linagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Linagliptin 2.5mg Metformin	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Cipla Ltd.	9.60 (Note 1)

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Hydrochloride IP 1000mg			
4 (xix)	Linagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Linagliptin 2.5mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Cipla Ltd.	8.97 (Note 1)
4 (xx)	Paracetamol, Phenylepherine Hydrochloride and Chlorpheniramine Maleate Syrup	**Each 5ml contains:** Paracetamol IP 250mg Phenylepherine Hydrochloride 5mg Chlorpheniramine Maleate IP 2mg	1 ML	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Micro Labs Limited	1.21
4 (xxi)	Glimepiride, Voglibose & Metformin Hydrochloride (as Extended release form) tablet	**Each uncoated bilayered tablet contains:** Glimepiride IP 2mg Voglibose IP 0.2mg Metformin Hydrochloride IP 1000mg (As Extended Release)	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Alkem Laboratories Limited	13.37
4 (xxii)	Diclofenac Diethylamine, Methyl Salicylate & Menthol Topical Gel	**Composition:** Diclofenac Diethylamine IP 2.32% (eq. to Diclofenac Sodium 2% w/w) Methyl Salicylate IP 10.00% w/w Menthol IP 5.0% w/w	1 Gram	M/s Pontika Aerotech Limited / M/s Intas Pharmaceuticals Ltd.	4.08
4 (xxiii)	Faropenem Sodium &Potassium Clavulanate Tablet	**Each film coated tablet contains:** Faropenem Sodium eq. to Faropenem 200mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 125mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Cipla Ltd.	90.28
4 (xxiv)	Pantoprazole Dual-release Gastro-resistant Tablet	**Each Dual-release Gastro-resistant tablet contains:** Pantoprazole Sodium IP eq. to Pantoprazole 80mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Cadila Pharmaceuticals Ltd.	13.39

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (xxv)	Tacrolimus Capsule	**Each hard gelatin capsule contains:** Tacrolimus IP eq. to Anhydrous Tacrolimus 0.25mg	1 Capsule	M/s Rivpra Formulation Pvt. Ltd. / M/s RPG Life Sciences Ltd.	11.05
4 (xxvi)	Clobazam Oral Suspension	**Each ml of the suspension contains:** Clobazam IP 2.5mg	1 ml	M/s Windlas Biotech Limited / M/s Sanofi India Limited	2.42
4 (xxvii)	Cefuroxime Axetil Tablet	**Each film coated tablet contains:** Cefuroxime Axetil eq. to Cefuroxime 250mg	1 Tablet	M/s Hetero Labs Limited / M/s Sun Pharmaceuticals Industries Limited	25.69
4 (xxviii)	Linagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Linagliptin 2.5mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Corona Remedies Pvt. Ltd.	8.97 (Note 1)
4 (xxix)	Amoxycillin and Potassium Clavulanate Oral Suspension (Combi pack with Sterile Water for Reconstitution of Dry Syrup)	**Each combi pack contains:** A. Amoxycillin and Potassium Clavulanate Oral suspension IP Composition: Each 5ml of reconstituted suspension contains: Amoxycillin Trihydrate IP eq. to Amoxycillin 600mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 42.9mg B. 2 Ampoules of sterile water for reconstitution of dry syrup each ampoule contains: sterile water for injection IP 25ml	Each Combi Pack	M/s Malik Lifesciences Pvt. Ltd. / M/s Macleods Pharmaceuticals Ltd.	162.11 (Note 2)
4 (xxx)	Clarithromycin for Oral	**Each 5 ml of reconstituted suspension**	1 ml	M/s Vapi Care Pharma Pvt. Ltd. / M/s	6.09

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Suspension USP	**contains:** Clarithromycin IP 250mg		Mankind Pharma Ltd.	
4 (xxxi)	Linagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Linagliptin 2.5mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Sai Primus Life Biotech Private Limited / M/s Primus Remedies Pvt. Ltd.	8.97 (Note 1)
4 (xxxii)	Linagliptin + Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Linagliptin 2.5mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Sai Primus Life Biotech Private Limited / M/s Primus Remedies Pvt. Ltd.	9.60 (Note 1)
4 (xxxiii)	Oral Rehydration Salts with Zinc	**Each sachet contains:** **Zinc Sulphate** Monohydrate IP 0.011g Sodium Citrate IP 0.58g Potassium Chloride IP 0.30g Sodium Chloride IP 0.52g Dextrose Anhydrous IP 2.70g	1 Sachet of 4.4 gram	M/s Acme Diet Care Pvt. Ltd. / M/s Alkem Laboratories Limited	6.12
4 (xxxiv)	Cefixime Oral Suspension IP	**Each 5ml of reconstituted suspension contains:** Cefixime IP (As Trihydrate) eq. to Anhydrous Cefixime 200mg	1 ml	M/s Alkem Healthscience (A unit of Alkem Laboratories Ltd.) / M/s Alkem Laboratories Ltd.	4.06
4 (xxxv)	Telmisartan and Bisoprolol Fumarate Tablets	**Each film coated tablet contains:** Telmisartan IP 40mg Bisoprolol Fumarate IP 2.5mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Zuventus Healthcare Limited	11.01
4 (xxxvi)	Telmisartan and Bisoprolol Fumarate	**Each film coated tablet contains:** Telmisartan IP 40mg	1 Tablet	M/s Ravenbhel Healthcare	13.12

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Tablets	Bisoprolol Fumarate IP 5mg		Pvt. Ltd. / M/s Zuventus Healthcare Limited	
4 (xxxvii) a.	Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Sustained Release) Tablets	**Each uncoated bilayered tablet contains:** Vildagliptin (As Sustained release) IP 100mg Metformin Hydrochloride (as Sustained Release) IP 1000mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Macleods Pharmaceuticals Ltd.	13.81
4 (xxxvii) b.	Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Sustained Release) Tablets	**Each uncoated bilayered tablet contains:** Vildagliptin (As Sustained release) IP 100mg Metformin Hydrochloride (as Sustained Release) IP 500mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Macleods Pharmaceuticals Ltd.	12.27
4 (xxxvii) c.	Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	**Each film coated bilayered tablet contains:** Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 1000mg (as Sustained Release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Alkem Laboratories Ltd.	13.81
4 (xxxvii) d.	Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	**Each film coated bilayered tablet contains:** Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 500mg (as Sustained Release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Micro Labs Ltd.	12.27
4 (xxxvii) e.	Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	**Each film coated bilayered tablet contains:** Vildagliptin IP 100mg (As Sustained Release) Metformin	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Alkem Laboratories Pvt. Ltd.	12.27

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Hydrochloride IP 500mg (as Sustained Release)			
4 (xxxvii) f.	Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	**Each film coated bilayered tablet contains:** Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 1000mg (as Sustained Release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Micro Labs Ltd.	13.81
4 (xxxvii) g.	Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Sustained Release) Tablets	**Each uncoated bilayered tablet contains:** Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin (As Sustained release) IP 100mg Metformin Hydrochloride (as Sustained Release) IP 1000mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Macleods Pharmaceuticals Ltd.	20.14
4 (xxxviii)	Azelnidipine and Telmisartan Tablet	**Each film coated tablet contains:** Azelnidipine IP 16mg Telmisartan IP 40mg.	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Ipca Laboratories Limited	17.96 (Note 3)

Note 1: *The Authority noted the representations received on the methodology adopted in retail price calculation in view of DPCO amendment dated 11.05.2023. It was observed by the Authority that data considered for present working of retail price fixation by applying 50% reduction are as provided under Para 5(3)(i) of DPCO,2013. Therefore, the Authority was of the view that the methodology followed is in compliance with the provisions of DPCO, 2013 and the representations were rejected.*

Note 2: *The Authority observed from the agenda that the pack size is mentioned as 1 vial without mentioning the quantity of the vial and directed that same may be checked and the correct pack size may be mentioned in the minutes and the notification.*

Note 3: *The Authority noted that MDC recommended Rs. 1.89 per tablet as claimed by the applicant in Form-I application against the worked out price of Rs. 17.96 per tablet in 52nd*

meeting held on 11.07.2023. The Authority also noted the representation of the applicant dated 17.07.2023 stating that 'There is a typographical mistake in their Form-I application. Retail price claimed was Rs. 1.89 per tablet. The correct retail price claimed is Rs. 18.90 per tablet against Rs. 1.89 per tablet." It was also observed by the Authority that ceiling price of Telmisartan 40mg tablet alone is Rs. 7.32 per tablet and retail Price of Azelnidipine 16mg tablet is Rs. 12.10 per tablet. After deliberations, Authority approved the workout price i.e., Rs. 17.96 per tablet as lower than the claim of Rs. 18.90 per tablet.

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

5.1 Noted.

6. Agenda item no. 6 –Minutes of 52nd meeting of Multidisciplinary Committee of Experts (MDC) held on 11.07.2023.

Noted. It was also brought to notice of the Committee that MDC had discussed the Report of the Committee to examine the issue relating to 20% reduction and noted that the issue needs more deliberations. Hence, it may be taken up for further discussions in the next MDC meetings.

7. Agenda item no. 7 –Form-IV intimation received from M/s Neon Laboratories Limited for discontinuation of scheduled formulation viz., Lox5% Ointment (Lidocaine 5%) under para 21(2) of DPCO, 2013.

7.1 The Authority deliberated upon the matter in detail and decided to invoke Para 3 of DPCO, 2013 to direct M/s Neon Laboratories Limited to continue the production and sales of Lidocaine 5% Ointment up to 31.07.2024 and to ensure that the production is not reduced by more than 25% of the normal production level i.e. production level before filing of Form IV intimation.

8. Agenda item no. 8 –Application by M/s Troikaa Pharmaceuticals Limited for exemption from the provisions of Drug Price Control Order 2013 under Para 32 (i) to (iii) for the formulations "Paracetamol Injection (Intramuscular) 250mg/ml"-reg.

8.1The matter relates to exemption under Para 32 (i) to (iii) for the formulation "Paracetamol Injection (Intramuscular) 250mg/ml" applied by M/s Troikaa Pharmaceuticals Limited vide e-mail dated 01.10.2022. The applicant vide letter dated 10.11.2022 submitted the copy of Patent issued by the Patent Office under Indian Patent Act, 1970 dated 09.11.2022 for "Novel Composition comprising Paracetamol and process for preparing the same" bearing registration no. 411067 along with the claim filed with Patent Office (Application No. 630/MUM/2010) dated 09.10.2010.

8.2 The Authority noted that the matter was deliberated in 47th & 50th meetings of the MDC held on 02.12.2022 & 21.04.2023 respectively. The Authority also noted that the matter was deliberated in 113th meeting of Authority held on 26.05.2023, wherein further information on following points was required:

(a) The company may clearly clarify under which specific para of DPCO, 2013 i.e. 32(i)/32(ii)/32(iii) the exemption is sought with reasons.
(b) Detailed inputs of the Office of DCGI regarding the approval of the said drug.

8.3 The matter was again deliberated in 52nd Meeting of MDC held on 11.07.2023, wherein it was noted that:

(a) The applicant vide letter dated 16.06.2023 submitted that their "product Paracetamol Injection (Intramuscular) 250mg/ml is eligible for exemption under Para 32(i) of DPCO 2013". The applicant also submitted the advantages of their novel Paracetamol Injection (Intramuscular) 250mg/ml over conventional Paracetamol injection 300 mg/2ml or 450 mg/3ml available in market.
(b) The representative of the DCGI stated that although Paracetamol Injections are available in the market but the applicant's formulation can administer higher strength in low volume and deliver the right dose. It has advantage over other available intramuscular injections of Paracetamol. Further, applicant was issued 'new drug' permission after examination of rationality and clinical trial data including Pharmacokinetics in consultation with Subject Expert Committee. The same has also been confirmed by DCGI vide letter no. 12-69/2023-DC(Pt-Misc/SND) dated 24.07.2023.

8.4 The Authority also noted that:

a. Paracetamol is covered under Schedule-I of DPCO, 2013 and Paracetamol injection 150mg/ml is scheduled formulation. Applicant has submitted the patent issued by the Patent Office under Indian Patent Act, 1970 dated 09.11.2022 for "Novel Composition comprising Paracetamol and process for preparing the same" bearing registration no. 411067 along with the claim filed with Patent Office (Application No. 630/MUM/2010) dated 09.10.2010.Applicant has also submitted the Patent Status of this drugs in other 76 Countries.
b. Applicant has submitted DCGI approval No. MF/FF/SND/36/2022 dated 16.09.2022 for 'Paracetamol Injection Intramuscular, 2ml and each ml contains Paracetamol 250mg, Absolute Alcohol IP 30% v/v, Water for injection IP q.s.'
c. State Licensing permission also granted on 26.09.2022 for the formulation as stated in DCGI approval.

8.5 The Authority deliberated on the matter in detail & observed that M/s Troikaa Pharmaceuticals Limited fulfills the conditions as per Para 32(i) of DPCO, 2013 w.r.t. the formulation "Paracetamol Injection (Intramuscular) 250mg/ml". Accordingly, the Authority decided that exemption be granted to M/s Troikaa Pharmaceuticals Limited under Para 32(i) of DPCO, 2013 w.r.t. the formulation "Paracetamol Injection (Intramuscular) 250mg/ml" for a period of five years from the date of commencement of its commercial marketing by the manufacturer in the country or expiry of the Indian Patent, whichever may be earlier.

8.6 The Authority further directed that M/s Troikaa Pharmaceuticals Limited be directed to intimate the date of commercial marketing of formulation "Paracetamol Injection (Intramuscular) 250mg/ml" in the country and the launch price of the

product. Further, M/s Troikka Pharmaceuticals Limited may also be directed to seek the retail price approval, three months before the expiry of the exemption granted under Para 32(i) of DPCO, 2013.

9. Agenda item no. 9 – Guidelines for application received from the marketers for change in manufacturer for the formulations for which retail price already notified and product launched in the market.

9.1 The issue relating to change of manufacturer by the marketing companies was deliberated in the 113th meeting of the Authority held on 26.05.2023 wherein it was decided that all future cases of change of manufacturer shall be examined on following parameters on a case to case basis. Cases falling within the ambit of these parameters may be permitted change in manufacturer:

i. Cancellation/ seizure of license of the manufacturing company
ii. Natural calamity/civil riots leading to destruction of plant of manufacturing company
iii. Dissolution/ winding up of the manufacturing company
iv. Closure of the concerned business segment by the manufacturing company, etc.
v. Any other circumstance(s) proved to be beyond the control of manufacturer/ marketer

The onus to prove the above conditions requesting for change of manufacturer will be on the applicant company with documentary evidence. The requests will be examined on case to case basis and the earlier cases may not be treated as a precedent for future cases.

9.2 The minutes of the 113th authority meeting were uploaded on NPPA's website on 08.06.2023. Subsequently, suggestions have been received from the Industry/ Industry Associations that change of manufacturer may be notified by way of filing Form V only instead of seeking approval and change in manufacturer to produce in marketer's own plant may be allowed.

9.3 The Authority noted that the retail price as fixed by NPPA is applicable to the specific individual manufacturer and marketer who have applied for the same by submitting Form-I for price fixation as stipulated under DPCO, 2013 and subject to fulfillment of all the applicable statutory requirements as laid down by the Government under relevant statutes/ rules, including manufacturing license permission from the competent authority i.e. the Central/State Licensing Authority, as may be applicable, by the concerned manufacturer/marketing company. The notifications are also issued in the name of specific manufacturer/marketer. Further, the compliances to various provisions of DPCO, 2013 such as Para 20 are also seen in the context of retail price notifications issued. Hence, simply filing Form-V intimating the change in manufacturer may not be sufficient. Further, ensuring availability of the drug is primarily the responsibility of the marketer, hence shifting of the manufacturing from manufacturer to its own plant by the marketer may be allowed.

9.4 The Authority deliberated on the suggestions made by the industry and decided to modify the parameters for allowing change of manufacturer as decided in its 113th meeting as follows by adding point (v) as given below:

i. Cancellation/ seizure of license of the manufacturing company
ii. Natural calamity/civil riots leading to destruction of plant of manufacturing company
iii. Dissolution/ winding up of the manufacturing company
iv. Closure of the concerned business segment by the manufacturing company, etc.
v. Shifting of manufacturing to its own plant by the existing marketing entity
vi. Any other circumstance(s) proved to be beyond the control of manufacturer/ marketer

The onus to prove the above conditions requesting for change of manufacturer will be on the applicant company with documentary evidence. The requests will be examined on case to case basis and the earlier cases may not be treated as a precedent for future cases.

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

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8/8/2023

(Dr. Vinod Kotwal)
Member Secretary