मिसिल स.- 8(78)/2020/डी.पी/एनपीपीए-डीवी-II
F. No. 8(78)/2020/DP/NPPA-Div. II

कार्यवाहीस. : 210/78/2020/F
Proceeding No : 210/78/2020/F

Minutes of the 210th (overall) and 78th meeting of the Authority under DPCO, 2013 held on 14.09.2020 at 11:00 AM

The 210th meeting of the Authority (overall), which is the 78th meeting under the DPCO, 2013, was held on the 14th of September, 2020 at 11:00 AM under the Chairmanship of Ms. Shubhra Singh, Chairman, NPPA. The following Authority members of the NPPA were present:

(i) Dr. Vinod Kotwal, Member Secretary
(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, Ministry of Health & Family Welfare was also present.

Dr. S. Eswara Reddy, Jt. Drug Controller, CDSCO, was invited as special invitee in connection with the agenda relating to Oxygen.

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, Asstt. Director (Pricing)
(iv) Shri Prakash Hemani, Asstt. Director (Pricing)

II. Agenda items

1. Agenda item no. 1 - Confirmation of the Minutes of the 77th meeting held on 06.08.2020.

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 77th meeting dated 06.08.2020

2.1 The Authority noted that due actions have been taken.

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

3.1 The Authority noted that out of the 41 applications received for new drug pricing, 33 applications were listed as agenda in the meeting and remaining are under process. The Authority appreciated timely disposal of the new drug applications.

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(xxxii) (total 33 Form I applications containing retail price fixation of 33 new drugs) falling under the purview of Para 2(u) of DPCO, 2013 and approved the retail prices of 26 (twenty six) new drugs [except 7 formulations as per agenda no. 4(vii), 4(xiv), 4(xxviii), 4(xxx), 4(xxxi) and 4(xxxii)] under Para 5 and 15 of the DPCO 2013, as detailed below:

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

Agenda item No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(i)	Dapagliflozin + Metformin Hydrochloride Extended Release Tablet	Each film coated extended release tablet contains: Dapagliflozin 10 mg, Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Micro Labs Ltd.	40.44 (Note 2)
4(ii)	Dapagliflozin + Metformin Hydrochloride Extended Release Tablet	Each film coated extended release tablet contains: Dapagliflozin 10mg, Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Micro Labs Ltd.	42.00 (Note 2)
4(iii)	Glimepiride Tablet	Each uncoated tablet contains: Glimepiride IP 3mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd.	8.38
4(iv)	Glimepiride Tablet	Each uncoated tablet contains: Glimepiride IP 4mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd.	9.71
4(v)	Telmisartan + Metoprolol Succinate Extended Release Tablet (Telsartan Beta 25)	Each film coated tablet contains: Telmisartan IP 40mg, Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Dr. Reddy's Laboratories	10.75

Agenda item No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		25mg (As Extended Release Form)		Limited	
4(vi)	Telmisartan + Metoprolol Succinate Extended Release Tablet (Telsartan Beta 50)	Each film coated bilayered tablet contains: Telmisartan IP 40mg, Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate 50mg (As Extended Release Form)	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Dr. Reddy's Laboratories Limited	13.32
4(vii)	Atorvastatin + Clopidogrel + Aspirin Capsule (Atocor Gold 20)	Each hard gelatine capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 20mg (As film coated tablet form), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As film coated tablet form), Aspirin IP 75mg (As enteric coated Tablet form)	1 Capsule	M/s Pure & Cure Healthcare Pvt. Ltd / M/s Dr. Reddy's Laboratories Ltd.	Rejected (Note 3)
4(viii)	Atorvastatin + Clopidogrel + Aspirin Capsule (Atocor Gold 10)	Each hard gelatine capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 10mg (As film coated tablet form), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As film coated tablet form), Aspirin IP 75mg (As enteric coated Tablet form)	1 Capsule	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Dr. Reddy's Laboratories Ltd.	4.07
4(ix)	Rabeprazole + Ondansetron Tablet	Each Enteric Coated tablet contains: Rabeprazole Sodium IP 20mg, Ondansetron Hydrochloride IP eq. to Ondansetron 4mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s German Remedies Pharmaceuticals Pvt. Ltd.	8.04
4(x)	Nifedipine + Lidocaine Cream	Cream Contains: Nifedipine IP 0.30%w/w Lidocaine IP 1.50% w/w	1 gram	M/s Om Sai Pharma Pack / M/s Zydus Healthcare Limited	4.79
4(xi)	Cefixime + Ofloxacin Dispersible Tablet	Each uncoated dispersible tablet contains: Cefixime IP (as trihydrate) eq. to Anhydrous Cefixime	1 Tablet	M/s Windlas Biotech Pvt. Ltd. / M/s Intas Pharmaceuticals Limited	11.28

Agenda item No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		200mg Ofloxacin IP 200mg			
4(xii)	Desvenlafaxine (Extended Release) + Clonazepam Tablet	Each uncoated Bilayered tablet contains: Desvenlafaxine Succinate USP eq. to Desvenlafaxine 100mg (As Extended Release Form) Clonazepam IP 0.5mg	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Intas Pharmaceuticals Limited	20.38
4(xiii)	Diclofenac + Virgin Linseed oil + Methyl salicylate + Menthol Gel (Proxyfen Nano)	Gel contains: Diclofenac Diethylamine IP1.16% w/w (equivalent to Diclofenac sodium 1% w/w). Virgin Linseed oil BP 3.0% w/w (Containing Predominantly Alpha Linolenic acid), Methyl salicylate 10% w/w, Menthol IP 5% w/w,	1 Gram	M/s Akums Drugs & Pharmaceuticals Ltd. /M/s Wockhardt Limited	2.69
4(xiv)	Norethindrone Acetate Controlled Release Tablet	Each film coated controlled released table contains: Norethindrone Acetate USP 10mg Tablet	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Cadila Pharmaceuticals Limited	Deferred (Note 4)
4(xv)	Norethisterone Acetate Controlled Release Tablet	Each film coated controlled released table contains: Norethisterone Acetate BP 15mg Tablet	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Cadila Pharmaceuticals Limited	18.00
4(xvi)	Metformin Hydrochloride(Prolonged release) + Glimepiride Tablet (GEMINOR M 3)	Each uncoated bilayered tablet contains: Metformin Hydrochloride IP 500mg (As Prolonged Release form), Glimepiride IP 3mg	1 Tablet	M/s Macleods Pharmaceuticals Limited	8.00
4(xvii)	Metformin Hydrochloride (Prolonged release)+ Glimepiride Tablet (GEMINOR M4)	Each uncoated bilayered tablet contains: Metformin Hydrochloride IP 500mg (As Prolonged Release form), Glimepiride IP 4mg	1 Tablet	M/s Macleods Pharmaceuticals Limited	9.83
4(xviii)	Telmisartan + Cilnidipine Tablet (TELMIDUCE CL)	Each film coated Tablet contains: Telmisartan IP 40mg, Cilnidipine IP 10mg,	1 Tablet	M/s Macleods Pharmaceuticals Limited	8.94
4(xix)	Telmisartan + Cilnidipine +	Each Film Coated Tablet contains:	1 Tablet	M/s Macleods Pharmaceuticals	12.16

Agenda item No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Chlorthalidone Tablet (NEXOV AS TC)	Cilnidipine IP 10mg, Telmisartan IP 40mg, Chlorthalidone IP 12.5mg		Limited	
4(xx)	Levetiracetam + Sodium Chloride Infusion (Levenue RTU 500)	Each 100ml contains: Levetiracetam IP 500mg Sodium Chloride IP 820mg	per 100 ml pack	M/s Akums Drugs & Pharmaceuticals Limited / M/s Alkem Laboratories Ltd.	91.56
4(xxi)	Levetiracetam + Sodium Chloride Infusion (Levenue RTU 1000)	Each 100ml contains: Levetiracetam IP 1000mg Sodium Chloride IP 750mg	per 100 ml pack	M/s Akums Drugs & Pharmaceuticals Limited / M/s Alkem Laboratories Ltd.	148.72
4(xxii)	Paracetamol + Mefenamic Acid Suspension	Each 5ml contains: Paracetamol IP 250mg, Mefenamic Acid IP 100mg	1 ml	M/s Tirupati Medicare Ltd. / M/s Cipla Limited	0.67
4(xxiii)	Camylofin Dihydrochloride + Paracetamol tablet	Each film coated tablet contains: Camylofin Dihydochloride 50 mg + Paracetamol IP 325 mg	1 Tablet	M/s Khandelwal Laboratories Pvt. Ltd./ M/s Abbott Healthcare Pvt. Ltd.	4.93 (Note 5)
4(xxiv)	Glimepiride +Voglibose and Metformin HCL (extended Release) Tablet (GEMER V 1)	Each uncoated bilayer tablet contains: Glimepiride IP 1 mg , Voglibose IP 0.2 mg , Metformin Hydrochloride IP 500 mg (as extended release form)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Sun Pharma Laboratories Ltd.	9.54 (Note 6)
4(xxv)	Pantoprazole Gastro Resistant tablet	Each Gastro resistant tablet contains: Pantoprazole Sodium IP eq. to Pantoprazole 40 mg	1 Tablet	M/s Panacea Biotech Pharma Ltd.	5.80
4(xxvi)	Telmisartan, Chlorthalidone & Cilnidipine Tablet	Each film coated tablet contains: Telmisartan IP 40 mg, Cilnidipine IP 10 mg , Chlorthalidone IP 12.5 mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd./ M/s Mankind Pharma Ltd.	12.28
4(xxx)	Metformin SR + Glimepiride + Voglibose Tablet	Each uncoated bilayer tablet contains: Metformin Hydrochloride IP 1000mg (As Sustained Release form), Glimepiride IP 2mg Voglibose IP 0.2mg Tablet	1 Tablet	M/s Swiss Garnier Genexiaa Sciences / M/s Sun Pharmaceutical Industries Limited	Rejected (Note 7)
4(xxxi)	Metformin SR + Glimepiride + Voglibose Tablet	Each uncoated bilayer tablet contains: Metformin	1 Tablet	M/s Swiss Garnier Genexiaa Sciences / M/s Sun Pharma	Rejected (Note 7)

Agenda item No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Hydrochloride IP 1000mg (As Sustained Release form), Glimepiride IP 2mg Voglibose IP 0.2mg Tablet		Laboratories Limited	

B. 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(xxvii)	Human Prothrombin Complex IP 250IU	Each vial contains: Human Coagulation Factor II 175-412 IU Human Coagulation Factor VII 40-260 IU Human Coagulation Factor IX 250 IU Human Coagulation Factor X 150-530 IU Protein C 230 – 450IU Protein S 220 – 440IU Heparin 15 – 30 IU Total Protein Not More than 52 g/l	Per vial	M/s Intas Pharmaceuticals Limited	19819.49
4(xxviii)	Betadine Alcoholic Hand Rub	Each 100 ml contains:- Povidone Iodine IP 1.0g(Available Iodine 0.1 g), 2-Propanol IP 50 mg	Per 200 ml pack	M/s G.S. Pharmbutor Pvt. Ltd. M/s Win-Medicare Pvt. Ltd.	Deferred (Note 8)
4(xxix)	Evogliptin + Metformin hydrochloride Sustained release Tablet (Valera M 500)	Each film-coated bilayer tablet contains: Evogliptin Tartrate eq. to Evogliptin 5mg, Metformin hydrochloride IP 500mg (As sustained release form)	1 Tablet	M/s Alkem Healthscience/ M/s Alkem Laboratories Ltd.	17.11

Note1. *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. *(i) The Authority noted that M/s AstraZeneca has represented that it holds the Patent in India in respect of formulations for which M/s Micro Labs Ltd applied for retail price.*

(ii) The Authority also noted the Office Memorandum dated 8th August 2019 issued by Department of Promotion of Industry and Internal Trade, Ministry of Commerce & Industry which states as follows:

a) There is no provision under the TRIPS agreement providing an obligation on the member countries to provide for Patent Linkage.

b) The Indian Patents Act, 1970 does not contain any provision to link the patent rights to marketing approval for a product.

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

Accordingly, the Authority reiterated that looking into the aspects of Patent is not requisite for fixation of retail price of drug formulation as per the provisions of DPCO 2013.

(iii) The Authority recalled its 72nd meeting dated 20.01.2020 in which it was decided "that benefit of price reduction in case of formulations becoming off-patent ought to be passed on to the consumers in public interest and decided to fix the retail price as per the Price To Retailer (PTR) based on Form-V data submitted by the companies for whom retail prices were earlier approved for these subject FDCs.

(iv) The Authority further noted that M/s Sun Pharma Laboratories Ltd and M/s Abbott Healthcare Pvt. Ltd have launched these formulations with taking prior price approval and accordingly, the Authority fixed retail price for these companies vide SO. 957(E) dated 03.03.2020 based on the decision taken in its 73rd meeting dated 25.02.2020. However, M/s Sun Pharma Laboratories Ltd and M/s Abbott Healthcare Pvt. Ltd hve not submitted the Form-V showing the revised price as required under the provisions of DPCO 2013. Accordingly, the Authority decided to examine the matter for non-submission and sought clarification for such non-compliance, as applicable.

(v) The Authority deliberated upon the matter in detail and observed that since M/s Sun Pharma Laboratories Ltd and M/s Abbott Healthcare Pvt has not submitted Form-V, the retail price may be fixed based on the retail price given to these companies vide SO. 957(E) dated 03.03.2020. Further, the Authority observed that the patent of these formulations are held by M/s Astrazenecea and accordingly decided not to consider the data of the product of M/s Astrazenecea while fixing the retail price so as to pass on the benefit of lower price of off-patent items to consumers in public interest.

(vi) Accordingly, the Authority decided to consider the retail price.

Note 3. *The Authority noted that as per the Form-I application submitted by the company, it is shown M/s Pure and Cure Healthcare Pvt. Ltd as the manufacturer whereas in the copy of*

drug license submitted by the company, it is showing M/s Akums Drugs & Pharmaceuticals Ltd. Accordingly, the Authority decided to reject the new drug application due to variance in documentation.

Note 4. *The Authority noted that the manufacturer has got approval for the formulation from DCG (I) at a date later than the approval from State Drug Licensing Authority. The Authority directed to obtain comments from DCG(I) to understand the latest directions in this regard and the approval status of the formulation.*

Note 5. *The Authority noted that CDSCO has provided permission to M/s Khandelwal Laboratories Pvt. Ltd for conducting phase IV clinical trials for FDC of Camylofin Dihydrochloride 50 mg + Paracetamol IP 325 mg film coated tablet. Accordingly, clarification was sought from CDSCO as to whether M/s Khandelwal Laboratories Pvt. Ltd is allowed to manufacture/ market the formulation. DCG(I) confirmed that this office has issued Phase-IV clinical trials and therefore the company can continue to manufacture and market the formulation.*

Note 6. *The Authority noted that CDSCO has provided permission to M/s Akums Drugs & Pharmaceuticals Ltd for conducting phase IV clinical trials for FDC of Glimepiride IP 1 mg + Voglibose 0.2 mg + Metformin Hydrochloride IP 500 mg (as extended release) uncoated bilayered tablet. Accordingly, clarification was sought from CDSCO as to whether M/s Akums Drugs & Pharmaceuticals Ltd is allowed to manufacture/ market the formulation. DCG(I) confirmed that this office has issued Phase-IV clinical trials and therefore the company can continue to manufacture and market the formulation.*

Note 7. *The Authority noted that DCG (I) has not approved the formulation. Accordingly, the Authority decided to reject the application.*

Note 8. *The Authority noted the representation has been received on the minutes of the 21st meeting of the Multidisciplinary Committee of Experts uploaded on NPPA's website and directed to place before the Authority after examination of the same.*

4.2 Agenda item no. 4(xxxii) - The Authority noted that the two retail price application of M/s Beta Drugs Ltd (manufacturer)/M/s Metta Life Sciences Pvt. Ltd (marketers) were pending due to want of clarification from the Office of CDSCO. Accordingly, the Authority directed to obtain clarification from CDSCO. Under the Ecosystem adopted by the Authority, disposal of application under Para 15(2) of DPCO 2013 is envisaged within 60 days. Accordingly, CDSCO may ensure that comments, wherever sought are provided within 5 days.

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

5.1 Noted.

6.1 Agenda item no. 6(i) – Matter relating to M/s Wockhardt Ltd for Methyldopa 500 mg tablet

6.1.1 The Authority deliberated upon the matter in detail and noted that M/s Medibios Laboratories Pvt. Ltd is an existing manufacturer and it manufactured Alphadopa 500mg tablet (Methyldopa 500 mg tablet) without prior price approval. Further, M/s Wockhardt Ltd marketed the product Methyldopa 500 mg tablet which was manufactured by M/s Medibios Laboratories Pvt. Ltd, without price approval. Therefore, M/s Medibios Laboratories Pvt. Ltd and M/s Wockhardt Ltd are jointly liable for the violation of the provisions of DPCO 2013.

6.1.2 The Authority observed that demand notice had been issued to M/s Wockhardt Ltd and M/s Medibios Laboratories Pvt. Ltd on the matter. Accordingly, the Authority directed that further necessary action be taken on both the companies for the violation as per the provisions of DPCO 2013.

6.2 Agenda item no. 6(ii) – Review order no. 31015/12/2019-Pricing dated 24.07.2020 relating to application filed by M/s Sun Pharma Laboratories Ltd for ceiling price fixation of Diltiazem 90 mg capsule vide SO. 1687(E) dated 09.05.2016

6.2.1 The Authority deliberated upon the matter in detail and noted that the ceiling price fixed for Diltiazem 90 mg capsule vide S.O. 1687(E) dated 09.05.2016 was based on the data of SR variants only. Thus, the ceiling price fixed vides SO. 1687(E) dated 09.05.2016 is also applicable for Diltiazem SR 90 mg capsule. Accordingly, the Authority decided that the review order no. 31015/12/2019-Pricing dated 24.07.2020 be treated as closed.

6.2.2 The Authority further noted that demand notice has been issued to M/s Sun Pharma Laboratories Ltd for violation of ceiling price fixed for Diltiazem 90 mg capsule and directed that further necessary action be taken for the violation as per the provisions of DPCO 2013.

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

7.1 The Authority deliberated upon the matter in detail and noted that two companies namely, M/s Axa Parenterals Ltd and M/s Rusoma Laboratories Pvt. Ltd 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 21st meeting of the Multidisciplinary Committee of Experts held on 28.08.2020 and two companies namely, M/s Axa Parenterals Ltd and M/s Rusoma Laboratories Pvt. Ltd 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.1216(E) dated 25.03.2020 to the two companies namely, M/s Axa Parenterals Ltd and M/s Rusoma Laboratories Pvt. Ltd 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.1216(E) dated 25.03.2020 to the two companies namely, M/s Axa Parenterals Ltd and M/s Rusoma Laboratories Pvt. Ltd 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.

8. Agenda item no. 8 - Application for extension of ceiling price for I.V. Fluids with packaging in Non-glass with special feature

8.1 The Authority deliberated upon the matter in detail and noted that one company namely, M/s Rusoma Laboratories Pvt. Ltd has 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 21st meeting of the Multidisciplinary Committee of Experts held on 28.08.2020 and M/s Rusoma Laboratories Pvt. Ltd 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.1215(E) dated 25.03.2020 to M/s Rusoma Laboratories Pvt. Ltd 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.

8.2 Accordingly, the Authority decided to extend the ceiling prices and the formulations mentioned in S.O.1215(E) dated 25.03.2020 to M/s Rusoma Laboratories Pvt. Ltd for its product "Puradrip" 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.

9. Agenda item no. 9 - Intimation of Minutes of 21st meeting of Multidisciplinary Committee of Experts held on 28.08.2020.

9.1 Noted.

10. Agenda item no. 10 – Ceiling price fixation of Tetanus + Diphtheria (TD) vaccine

10.1 The Authority deliberated upon the matter in detail and noted that the representation on the draft working sheet uploaded on NPPA's website regarding ceiling price fixation of Tetanus + Diphtheria (TD) vaccine was placed before the Multidisciplinary Committee of Experts in its 21st meeting held on 28.08.2020. The Multidisciplinary Committee of Experts recommended that separate ceiling price of TD vaccine be fixed for different strength as per explanation 3 of Schedule-I of DPCO 2013.

10.2 Accordingly, the Authority approved the ceiling price of Tetanus + Diphtheria (TD) vaccine as detailed below:

S. No.	Formulation and strength	Pack size	Approved ceiling price (ex. GST)
1	TD Vaccine Containing Diphtheria Toxoid <5Lf (> 2IU) + Tetanus Toxoid >5Lf (> 40IU)	Per 0.5 ml pack	Rs. 12.77
2	TD Vaccine Containing Diphtheria Toxoid <5Lf (> 2IU) + Tetanus Toxoid >5Lf (> 40IU)	Per 5 ml pack	Rs. 118.11
3	TD Vaccine Containing Diphtheria Toxoid <25Lf (> 30IU) + Tetanus	Per 0.5 ml pack	Rs. 14.08

S. No.	Formulation and strength	Pack size	Approved ceiling price (ex. GST)
	Toxoid >5Lf (> 40IU)		

10.3 The Authority further directed to upload the draft calculation sheet in NPPA's website for 10 workings days before issue of notification.

11. Agenda item no. 11 – Ceiling price fixation of Orthopaedic Knee Implants for Knee Replacement System

11.1 The Authority deliberated upon the matter in detail and noted that the matter regarding ceiling price fixation of Orthopaedic Knee Implants for Knee Replacement System was discussed in its 77th meeting held on 06.08.2020 in which it was observed that the data submitted by the manufacturers/ importers requires further examination and accordingly decided that the ceiling prices of knee implants for knee replacement system as applicable on 15th August 2020 may be further extended for one month up to 15th September 2020.

11.2 The Authority further noted that analysis of data submitted by the manufacturers/ importers showed that the existing ceiling price of Orthopaedic Knee Implants for Knee Replacement System is sufficient to cover the margins.

11.3 The Authority also noted that fixing Ceiling Prices for Orthopaedic Knee Implants in the year 2017 had resulted in price reduction up to 69%, thereby increasing access to same at affordable prices. Further, domestic manufacturers have gained from this price cap and their market share has risen by 11% over the period of two years which is in line with the Government's motto of 'Atmanirbhar Bharat'.

11.4 The Authority noted the demand of the Industry Association for 20% price increase and decided that the impact of taxes imposed on imported medical devices cannot be passed on to the consumers.

11.5 Accordingly, the Authority decided that the ceiling prices of knee implants for knee replacement system as applicable on 15th September 2020 may be further extended for one year up to 15th September 2021.

12. Agenda item no. 12 – Application for price fixation of Liquid Medical Oxygen and price revision of ceiling price of Oxygen Inhalation (Medicinal Gas)

12.1 The Authority deliberated upon the matter in detail and observed that due to COVID-19 scenario, the uninterrupted availability of medical oxygen gas is of utmost importance particularly when its consumption has increased manifold. The Authority also noted the representation of various stakeholders. The Authority also noted that the matter was referred to the Committee constituted to monitor the Export/ Import trends of APIs, formulations Medical Devices needed for COVID-19 to examine the matter and give its recommendations. The Authority invited the Chairman of the Committee and obtained its understanding of the matter. Accordingly, the Authority decided that further deliberation needs to be taken in this regard.

13. Agenda item no. 13 - Submission of Form-IV by M/s Intas Pharmaceuticals Limited in respect of scheduled formulation Atro Eye Drops 5ml (Atropine Sulphate Ophthalmic Solution USP 1% w/v) under para 21(2) of DPCO, 2013

13.1 The Authority noted that the application in Form-IV by M/s Intas Pharmaceuticals Ltd for discontinuation of scheduled formulation Atro Eye Drops 5ml (Atropine Sulphate Ophthalmic Solution USP 1% w/v) under para 21(2) of DPCO, 2013 was placed in 1st meeting of the Standing Committee for examination the case related to discontinuation of scheduled formulation under Para 21(2) of DPCO, 2013 held on 31.08.2020 which recommended the following:

(i) M/s Intas Pharmaceutical Limited may be asked to explain the reason why the product is non-remunerative along with documentary evidences; and

(ii) M/s Intas Pharmaceutical Limited may be directed to continue manufacture / import and sale of the Atro Eye Drop 5ml (Atropine Sulphate Opthalmic Solution USP 1%w/v) for a period of upto twelve months from the assumed intended date of discontinuation i.e. 30.12.2021.

13.2 The Authority deliberated upon the matter in detail and approved the recommendation of the Standing Committee for examination the case related to discontinuation of scheduled formulation under Para 21(2) of DPCO, 2013.

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

Sd/-
(Dr. Vinod Kotwal)
Member Secretary