मिसिल स.- 8(92)/2021/डी.पी/एनपीपीए-डीवी-II
F. No. 8(92)/2021/DP/NPPA-Div. II

कार्यवाही स. : 224/92/2021/F
Proceeding No: 224/92/2021/F

Minutes of the 224th (overall) and 92nd meeting of the Authority under DPCO, 2013 held on 08.09.2021 at 11:30 AM

The 224th meeting of the Authority (overall), which is the 92nd meeting under the DPCO, 2013, was held on 08th of September 2021 at 11:30 AM under the Chairmanship of Shri Kamlesh Kumar Pant, Chairman, NPPA. The following Authority members of NPPA were present during the meeting:

(i) Shri N. I. Chowdhury, Member Secretary (In-Charge), NPPA
(ii) Ms. A. Srija, Economic Advisor, Department of Economic Affairs
(iii) Shri Amardeep Singh Chowdhary, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure

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

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

(i) Ms. Rashmi Tahiliani, Jt Director (Pricing)
(ii) Shri Prasenjit Das, Deputy Director (Pricing)
(iii) Shri Mahaveer Saini, Deputy Director (Pricing)

The Authority members welcomed the new Chairman and after a brief introduction session, the proceeding of the Authority meeting started.
The Authority members expressed gratitude to ex-chairman Ms. Shubhra Singh and applauded her contribution towards price regulation and availability of essential drugs in the country. It was under her Chairmanship that the Trade Margin Rationalisation (TMR) of Anti-cancer drugs as a Pilot project had been rolled out. Subsequently, the TMR has been extended to six medical devices which have resulted in considerable savings to the consumers. Medical oxygen was one of the critical drugs under COVID management. She led from the front during the COVID pandemic, to ensure that pricing issues do not interrupt the continuous availability of medical oxygen.

II. Agenda items

1. Agenda item no. 1 - Confirmation of the Minutes of the 91st Meeting held on 29.07.2021.

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 91st Meeting held on 29.07.2021.

2.1 The Authority noted that due action has been taken.

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 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(xxiii) (total 23 Form I applications containing retail price fixation of 23 new drugs) falling under the purview of Para 2(u) of DPCO, 2013 and approved the retail prices of 23 (twenty three) 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

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(i)	Levetiracetam Infusion 500mg/100ml	Each 100ml contains: Levetiracetam IP 500mg, Sodium Chloride IP 820mg water for injection	1 ML	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Linux Laboratories Pvt. Ltd.	91.56 (Note 3)
4(ii)	Methotrexate Topical Gel	Composition: Methotrexate IP 1.0% w/w	1 GM	M/s Ajanta Healthcare Pvt. Ltd. / M/s IPCA Laboratories Ltd.	13.21
4(iii)	Erythropoietin Injection IP 2000IU (r-DNA origin)	Each 2.0ml Cartridge for pen contains: Erythropoietin concentrated solution IP 20000 IU with HSA stabilizer,	Each Pack	M/s Wockhardt Limited	2054.82
4(iv)	Paracetamol Infusion IP 1%w/v	Each 100ml contains: Paracetamol IP..... 1000mg	Each Pack	M/s. Aishwarya Healthcare / M/s FDC Limited	295.58
4(v)	Levetiracetam in 0.82% Sodium Chloride Injection	Each 100ml contains: Levetiracetam IP 500mg Sodium Chloride IP 820mg Water for Injections IP q. s.	Each Pack	M/s. Sun pharmaceutical Industries Limited / M/s Sun Pharma Laboratories Limited	91.56 (Note 4)
4(vi	Levetiracetam	Each 100ml contains:	Each	M/s. Sun	148.72

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
)	in 0.75% Sodium Chloride Injection	Levetiracetam IP 1000mg Sodium Chloride IP 750mg Water for Injections IP q. s.	Pack	pharmaceutical Industries Limited / M/s Sun Pharma Laboratories Limited	
4(vii)	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 Dr. Reddy's Laboratories Ltd.	8.036
4(viii)	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 Dr. Reddy's Laboratories Ltd.	12.946
4(ix)	Chlorthalidone, Amlodipine & Telmisartan Tablets	Each film coated tablet contains: Chlorthalidone IP 12.50mg Amlodipine Besylate IP eq. to Amlodipine 5mg Telmisartan IP 40mg	1 Tablet	M/s. Akums Drugs & Pharmaceuticals Ltd. / M/s Dr. Reddy's Laboratories Ltd.	8.928
4(x)	Chlorthalidone, Amlodipine & Telmisartan Tablets	Each film coated tablet contains: Chlorthalidone IP 12.50mg Amlodipine Besylate IP eq. to Amlodipine 5mg Telmisartan IP 80mg	1 Tablet	M/s. Akums Drugs & Pharmaceuticals Ltd. / M/s Dr. Reddy's Laboratories Ltd.	13.39
4(xi)	Metoprolol Succinate (ER), Cilnidipine & Telmisartan Tablets	Each film coated tablet contains: Metoprolol Succinate IP 23.75mg eq. to Metoprolol tartrate 25mg (As Extended Release) Cilnidipine IP 10mg Telmisartan IP 40mg	1 Tablet	M/s. Pure & Cure Healthcare Pvt. Ltd. / M/s Lupin Limited	10.68
4(xii)	Metoprolol Succinate (ER), Cilnidipine & Telmisartan Tablets	Each film coated tablet contains: Metoprolol Succinate IP 47.5mg eq. to Metoprolol tartrate 50mg (As Extended Release) Cilnidipine IP 10mg Telmisartan IP 40mg	1 Tablet	M/s. Pure & Cure Healthcare Pvt. Ltd. / M/s Lupin Limited	12.95
4(xiii)	Rosuvastatin + Clopidogrel Capsule	Each hard Gelatin Capsule contains : Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (as pellets) & Clopidogrel Bisulphate IP eq.	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Micro Lab Ltd.	19.64

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		to Clopidogrel 75mg (as pellets)			
4(xiv)	Efavirenz + Tenofovir Disoproxil + Lamivudine Tablet	Each film coated tablet contains: Efavirenz IP 400mg Tenofovir Disoproxil fumarate IP 300mg equivalent to Tenofovir Disoproxil 245mg Lamivudine IP 300mg	1 Tablet	M/s Cipla Limited	59.80
4(xv)	Nebivolol + Telmisartan Tablet	Each uncoated bilayered tablet contains: Nebivolol Hydrochloride IP eq. to Nebivolol 5mg, Telmisartan IP 40mg	Tablet	M/s Windlas Biotech Pvt. Ltd. M/s Cadila Pharmaceuticals Ltd.	12.96
4(xvi)	Atorvastatin + Clopidogrel Capsule	Each Hard Gelatin Capsule Contains: Atorvastatin Calcium IP eq to Atorvastatin 20mg (As pellets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	16.55
4(xvii)	Amlodipine + Atenalol Tablet	Each uncoated tablet contains: Amlodipine Besylate IP eq. to Amlodipine 5mg Atenalol IP 50mg	1 Tablet	M/s Wings Biotech LLP / M/s Zuventus Healthcare Ltd.	5.00
4(xviii)	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	Each film-coated bilayered tablet contains: Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin 5mg, Metformin Hydrochloride IP 1000mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	7.54 (Note 5)
4(xix)	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	Each film-coated bilayered tablet contains: Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin 5mg, Metformin Hydrochloride IP 500mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	6.25 (Note 5)
4(xx)	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	Each film-coated bilayered tablet contains: Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 1000mg (As Extended	1 1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	11.17 (Note 5)

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		release form)			
4(xxi)	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	Each film-coated bilayered tablet contains: Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 500mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	9.65 (Note 5)
4(xxii)	Vildagliptin + Metformin Hydrochloride (SR) Tablet	Each uncoated bilayered tablet contains: Vildagliptin 50 mg, Metformin Hydrochloride 500 mg (as sustained release form)	1 Tablet	M/s Mascot Health Series Pvt. Ltd./M/s Aristo Pharmaceuticals Pvt. Ltd.	6.86 (Note 6)
4(xxiii)	Vildagliptin + Metformin Hydrochloride (SR) Tablet	Each uncoated bilayered tablet contains: Vildagliptin 50 mg, Metformin Hydrochloride 1000 mg (as sustained release form)	1 Tablet	M/s Mascot Health Series Pvt. Ltd./M/s Aristo Pharmaceuticals Pvt. Ltd.	7.51 (Note 6)

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 noted that M/s Linux Laboratories have launched the product in July 2020 without prior price approval. Accordingly, the Authority decided that the retail price of the formulation for M/s Linux Laboratories to be calculated based on the data which is six month prior to its launch date i.e. December 2019. However, no data of the formulation was available for the month December 2019 and the data started appearing since January 2020. Accordingly, the calculation has been done based on January 2020 data. The Authority also decided further necessary action be initiated for violation of the provisions of DPCO 2013 for launching the formulation without prior price approval.*

Note 4. *The Authority decided that since M/s Linux Laboratories have launched the product in July 2020 without prior price approval, the data of M/s Linux laboratories was excluded while calculating the retail price for M/s Sun Pharma laboratories Ltd.*

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 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 6. *The Authority deliberated upon the matter in detail and decided to approve the retail price in line with the decision as recorded in Note 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 The Authority noted that in respect of retail price of new drugs which have become off-patent, the retail price has been fixed based on Form-V data. The Authority deliberated upon the matter in detail and is of the view that the off-patent price as given based on Form-V data may be appearing in AWACS database after its introduction in the market. Accordingly the Authority opined that fixation of retail price of off-patented drugs based on market based data as per AWACS database, in respect of drugs whose retail price has been fixed based on Form-V data for a considerable period, may be explored.

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

5.1 Noted.

6. Agenda item no. 6 – Application filed by M/s Cipla Ltd for grant of separate price / special price for 'Ciphaler Inhaler Device" under the provisions of para 11(3) of DPCO 2013

6.1 The Authority noted that the application of M/s Cipla Ltd for separate/ special price of 'Ciphaler Inhaler Device' under Para 11(3) of DPCO 2013 was placed before the Multidisciplinary Committee of Experts in its 35th meeting dated 18.08.2021.

6.2 The Authority further noted that the Committee deliberated upon the matter in detail and observed that the claim of M/s Cipla Ltd regarding the efficacy of the product is yet to be validated and the report as submitted by M/s Cipla Ltd is not based on the product of M/s Cipla Ltd. Accordingly, the Committee decided to reject the application of M/s Cipla Ltd for grant of separate price / special price for 'Ciphaler Inhaler Device" under the provisions of Para 11(3) of DPCO 2013.

6.3 The Authority deliberated upon the matter in detail and accepted the recommendation of the Multidisciplinary Committee of Experts and decided to reject the application of M/s Cipla Ltd for grant of separate price / special price for 'Ciphaler Inhaler Device" under the provisions of Para 11(3) of DPCO 2013.

7. Agenda item no. 7 - Application by M/s Otsuka Pharmaceuticals India Pvt. Ltd for separate price under Para 11(3) of DPCO 2013 with respect to Metronidazole Injection IP (0.5% w/v) 100ml in Non-glass pack having Special features

7.1 The Authority noted that M/s Otsuka Pharmaceuticals India Pvt. Ltd have applied for separate ceiling price of Metronidazole Injection IP (0.5% w/v) in 100ml pack for packages in non-glass container in plastic bottle with euro head having special features like (i) self-collapsibility and self-sealeability (ii) not having air-vent and (iii) there is no chance of contamination during manufacture/ infusion/ admixing levels.

7.2 The Authority further noted that the matter was deliberated in the 35th meeting of the Multidisciplinary Committee of Experts held on 18.08.2021 in which it was observed/deliberated/ recommended as follows:

".....Metronidazole Injection 500mg/100ml is a scheduled formulation and its ceiling price is fixed. The present applicable ceiling price is Rs. 0.20 per ml excluding GST. The Committee observed that the formulation Metronidazole Injection IP (0.5% w/v) 100ml is same as Metronidazole Injection 500mg/100 ml and is a scheduled formulation. The Committee also noted the demonstration given by M/s Otsuka Pharmaceuticals Pvt. Ltd and observed that the that the non-glass pack of Metronidazole Injection IP (0.5% w/v) 100ml of M/s Otsuka Pharmaceuticals Pvt. Ltd have 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.

The Committee deliberated upon the matter in detail and recommended that an increase of 15% over and above the present applicable ceiling price be allowed to M/s Otsuka Pharmaceuticals Pvt. Ltd for the product Metronidazole Injection IP (0.5% w/v) 100ml in non-glass having special features. Accordingly, the Committee recommended the ceiling price of Rs. 0.23 per ml excluding GST for the formulation 'Metronidazole Injection IP (0.5% w/v) 100ml in non glass having special features' for 100 ml pack for M/s Otsuka Pharmaceuticals Pvt. Ltd. The Committee also recommended that Wholesale Price Index (WPI), as applicable for scheduled formulation, on the ceiling price of Rs. 0.23 per ml excluding GST for the formulation 'Metronidazole Injection IP (0.5% w/v) in non-glass having special features' for 100 ml pack for M/s Otsuka Pharmaceuticals Pvt. Ltd."

7.3 The Authority deliberated upon the matter in detail and accepted the recommendation of the Multidisciplinary Committee of Experts. Accordingly, the Authority decided to approve the ceiling price of Metronidazole Injection IP (0.5% w/v) for 100 ml pack for packages in non-glass container in plastic bottle with euro head having special features like (i) self-collapsibility and self-sealeability (ii) not having air-vent and (iii) there is no chance of contamination during manufacture/ infusion/ admixing levels for M/s Otsuka Pharmaceuticals Pvt. Ltd at Rs. 0.23 per ml excluding GST. The Authority also decided that the price revision based on Wholesale Price Index (WPI), as applicable for scheduled formulation, on the ceiling price of Rs. 0.23 per ml excluding GST for the formulation 'Metronidazole Injection IP (0.5% w/v) for 100 ml pack for packages in non-glass container in plastic bottle with euro head having special features like (i) self-collapsibility and self-sealeability (ii) not having air-vent and (iii)

there is no chance of contamination during manufacture/ infusion/ admixing levels for M/s Otsuka Pharmaceuticals Pvt. Ltd be allowed

8. Agenda item no. 8 – Application by M/s Otsuka Pharmaceuticals India Pvt. Ltd for separate price under Para 11(3) of DPCO 2013 with respect Mannitol Injection 20% in Non-glass pack having Special features.

8.1 The Authority noted that M/s Otsuka Pharmaceuticals India Pvt. Ltd have applied for separate ceiling price of Mannitol Injection 20% in 100 ml pack for packages in non-glass container in plastic bottle with euro head having special features like (i) self-collapsibility and self-sealeability (ii) not having air-vent and (iii) there is no chance of contamination during manufacture/ infusion/ admixing levels.

8.2 The Authority further noted that the matter was deliberated in the 35th meeting of the Multidisciplinary Committee of Experts held on 18.08.2021 in which it was observed/deliberated/ recommended as follows:

"....Mannitol Injection 20% is a scheduled formulation and its ceiling price is fixed. The present applicable ceiling price is Rs. 0.30 per ml excluding GST. The Committee also noted the demonstration given by M/s Otsuka Pharmaceuticals Pvt. Ltd and observed that the that the non-glass pack of Mannitol Injection 20% in 100ml pack of M/s Otsuka Pharmaceuticals Pvt. Ltd have 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.

The Committee deliberated upon the matter in detail and recommended that an increase of 15% over and above the present applicable ceiling price be allowed to M/s Otsuka Pharmaceuticals Pvt. Ltd for the product Mannitol Injection 20% in non-glass having special features for 100 ml pack. Accordingly, the Committee recommended the ceiling price of Rs. 0.345 per ml excluding GST for the formulation 'Mannitol Injection 20% in non-glass having special features' for 100 ml pack' for M/s Otsuka Pharmaceuticals Pvt. Ltd. The Committee also recommended that Wholesale Price Index (WPI), as applicable for scheduled formulation, on the ceiling price of Rs. 0.345 per ml excluding GST for the formulation 'Mannitol Injection 20% in non-glass having special features' for 100 ml pack for M/s Otsuka Pharmaceuticals Pvt. Ltd."

8.3 The Authority deliberated upon the matter in detail and accepted the recommendation of the Multidisciplinary Committee of Experts. Accordingly, the Authority decided to approve the ceiling price of Mannitol Injection 20% in 100 ml pack for packages in non-glass container in plastic bottle with euro head having special features like (i) self-collapsibility and self-sealeability (ii) not having air-vent and (iii) there is no chance of contamination during manufacture/ infusion/ admixing levels for M/s Otsuka Pharmaceuticals Pvt. Ltd at Rs. 0.345 per ml excluding GST. The Authority also decided that the price revision based on Wholesale Price Index (WPI), as applicable for scheduled formulation, on the ceiling price of Rs. 0.345 per ml excluding GST for the formulation Mannitol Injection 20% in 100 ml pack for packages in non-glass container in plastic bottle with euro head having special features like (i) self-collapsibility and

self-sealeability (ii) not having air-vent and (iii) there is no chance of contamination during manufacture/ infusion/ admixing levels for M/s Otsuka Pharmaceuticals Pvt. Ltd be allowed.

9. Agenda item no. 9 - Application by M/s Otsuka Pharmaceuticals India Pvt. Ltd for separate price under Para 11(3) of DPCO 2013 with respect Dextrose Injection (25% w/v) 100 ml in Non-glass pack having Special features.

9.1 The Authority noted that M/s Otsuka Pharmaceuticals India Pvt. Ltd have applied for separate ceiling price of Dextrose Injection (25% w/v) in 100 ml pack for packages in non-glass container in plastic bottle with euro head having special features like (i) self-collapsibility and self-sealeability (ii) not having air-vent and (iii) there is no chance of contamination during manufacture/ infusion/ admixing levels.

9.2 The Authority further noted that the matter was deliberated in the 35th meeting of the Multidisciplinary Committee of Experts held on 18.08.2021 in which it was observed/deliberated/ recommended as follows:

> *"....Glucose Injection 25% is a scheduled formulation and its ceiling price is fixed. The Committee observed the clarification provided by Central Drugs Standard Control Organisation (CDSCO) vide letter dated 13.08.2021 that Dextrose Injection 25% w/v and Glucose Injection 25% w/v are the same. The present applicable ceiling price of Glucose Injection 25% is Rs. 0.17 per ml excluding GST Accordingly, the Committee concluded that Dextrose Injection 25% is a scheduled formulation. The Committee also noted the demonstration given by M/s Otsuka Pharmaceuticals Pvt. Ltd and observed that the that the non-glass pack of Dextrose Injection 25% in 100ml pack of M/s Otsuka Pharmaceuticals Pvt. Ltd have 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.*
>
> *The Committee deliberated upon the matter in detail and recommended that an increase of 15% over and above the present applicable ceiling price be allowed to M/s Otsuka Pharmaceuticals Pvt. Ltd for the product Dextrose Injection 25%% in non-glass having special features for 100 ml pack. Accordingly, the Committee recommended the ceiling price of Rs. 0.195 per ml excluding GST for the formulation 'Dextrose Injection 25% in non-glass having special features' for 100 ml pack' for M/s Otsuka Pharmaceuticals Pvt. Ltd. The Committee also recommended that Wholesale Price Index (WPI), as applicable for scheduled formulation, on the ceiling price of Rs. 0.195 per ml excluding GST for the formulation 'Dextrose Injection 25% in non-glass having special features' for 100 ml pack for M/s Otsuka Pharmaceuticals Pvt. Ltd."*

9.3 The Authority also noted the representation of M/s Otsuka Pharmaceutical Pvt. Ltd that 15% increase from the present applicable ceiling price comes to Rs. 0.1955 per ml excluding GST whereas the Multidisciplinary Committee of Experts has recommended Rs.0.195 per ml excluding GST.

9.4 The Authority deliberated upon the matter in detail and accepted the recommendation of the Multidisciplinary Committee of Experts and also the representation of M/s Otsuka Pharmaceuticals Pvt. Ltd as mentioned Para 9.3 above. Accordingly, the Authority decided to approve the ceiling price of Dextrose Injection (25% w/v) in 100 ml pack for packages in non-glass container in plastic bottle with euro head having special features like (i) self-collapsibility and self-sealeability (ii) not having air-vent and (iii) there is no chance of contamination during manufacture/ infusion/ admixing levels for M/s Otsuka Pharmaceuticals Pvt. Ltd at Rs. 0.1955 per ml excluding GST. The Authority also decided that the price revision based on Wholesale Price Index (WPI), as applicable for scheduled formulation, on the ceiling price of Rs. 0.1955 per ml excluding GST for the formulation Dextrose Injection (25% w/v) in 100 ml pack for packages in non-glass container in plastic bottle with euro head having special features like (i) self-collapsibility and self-sealeability (ii) not having air-vent and (iii) there is no chance of contamination during manufacture/ infusion/ admixing levels for M/s Otsuka Pharmaceuticals Pvt. Ltd be allowed.

10. Agenda item no. 10 - Intimation of Minutes of 35th meeting of Multidisciplinary Committee of Experts held on 18.08.2021

10.1 Noted.

11. Agenda item no. 11 – Extension of revised Ceiling price of Heparin Injection 1000IU/ml and 5000IU/ml.

11.1 The Authority noted that the revised ceiling price of Heparin Injection 5000IU/ml and 1000 IU/ml fixed vide SO. 2151(E) dated 30.06.2020 are applicable up to 31.12.2020 and the same was extended up to 31.03.2021 vide SO. 4333(E) dated 03.12.2020 and again it was further extended upto 30.09.2021 or until further order, whichever is earlier, vide SO. 1236(E) dated 17.03.2021. The Authority further noted the opinion of the Committee constituted to monitor Export/Import trends of APIs, Formulations and Medical Devices needed for COVID-19 dated 01.09.2021. The Committee that "*...NPPA may continue with the increased ceiling for Heparin Injection 5000 IU/ml , to ensure continuous availability of this essential drug. This extension of ceiling of Heparin may be considered for duration of six months or maybe reviewed earlier as deemed fit.*"

11.2 The Authority deliberated upon the matter in detail and considered the aspect of availability of Heparin Injection 1000IU/ ml and Heparin Injection 5000IU/ ml, a scheduled formulation, especially during the pandemic situation of COVID-19. Therefore, due to extra-ordinary situation, the Authority decided that the revised ceiling price of Heparin Injection 5000IU/ml and 1000 IU/ml fixed vide SO. 2151(E) dated 30.06.2020 and extended upto 31.03.2021 vide SO. 4333(E) dated 03.12.2020 and again extended upto 30.09.2021 or until further order, whichever is earlier, vide SO. 1236(E)

dated 17.03.2021 to be further extended upto 31.03.2022 or until further order, whichever is earlier, in public interest.

11.3 The Authority further directed that the provisions of para 13(2) of DPCO 2013 would not be applicable on the revised ceiling price of Heparin 1000IU/ml Injection and Heparin 5000IU/ml Injection up to 31.03.2022 or until further order, whichever is earlier.

12. Agenda item no. 12 - Extension of revised price of Medical Oxygen

12.1 The Authority noted that the price fixed for Liquid Medical Oxygen (LMO) and Oxygen Inhalation (Medicinal gas) vide SO. 3322(E) dated 25.09.2020 are applicable up to 31.03.2021 and was further extended upto 30.09.2021 or until further order, whichever is earlier, vide SO. 1335(E) dated 25.03.2021.

12.2 The Authority further noted that Department for Promotion of Industry & Internal Trade (DPIIT), Ministry of Commerce and Industry, Government of India vide its Office Memorandum dated 31.08.2021 stated as follows:

> *"...the matter has been examined in this Department and it is recommended that the prices of above may further be extended till 31.12.2021 after which the issue may be reviewed again"*

12.3 The Authority considered the matter and in view of continuing extraordinary circumstances due to the COVID pandemic decided that the revised price of Liquid Medical Oxygen (LMO) and Oxygen Inhalation (Medicinal gas) fixed vide SO. 3322(E) dated 25.09.2020 and extended vide SO. 1335(E) dated 25.03.2021be further extended up to 31.12.2021 or until further order, whichever is earlier, in public interest.

13. Agenda item no. 13 - Ceiling Prices of Orthopaedic Knee Implants for Knee Replacement System.

13.1 The Authority noted the representation of industry associations as follows:
a. Onetime increase by 20% from the ceiling price due various reasons like exchange rate, increase in wholesale price, increase in logistics cost and increase in manpower cost due to low volume.
b. Separation of bone cement from knee price order and allow bone cement to be charged as per free market trend.
c. Removal of complex implants like revision surgery implants and implants for cancer patients from the purview of price control
d. Imposition of various levies and cess by Ministry of Finance etc together with sharp decline in volume due to COVID

13.2 The Authority deliberated upon the matter in detail and observed that exchange rate was more or less at the same level during the period under consideration. Further, the quantity of Orthopaedic Knee Implants for Knee Replacement System for the year 2018-19 and 2019-20 has increased in comparison to 2017-18 [the year in which it came into price regulation] indicates that the price regulation has contributed to

increased access to affordable healthcare to general public. The decrease in quantity during 2020-21 may be due to COVID pandemic which appears to have resulted in reduction in the number of elective procedures. However, looking at the present situation it is expected that the demand may improve which would take care of the margin. The Authority also observed that the existing price contributes to increase the accessibility of Orthopaedic Knee Implants for Knee Replacement System to general public.

13.4 Accordingly, the Authority decided that the ceiling prices of knee implants for knee replacement system as applicable on 15th September 2021 may be further extended for one year up to 15th September 2022.

14.1 Agenda item no. 14(i) - Form-IV Intimation received from M/s Cipla Limited for discontinuation of 5 scheduled formulations viz., (i) Abamune L Tablets (ii) Abamune Tablets (iii) Efavir 200 Capsules (iv) Hepcvir 28 Tablets and (v) Tenvir L Tablets under para 21(2) of DPCO, 2013

14.1.1 The Authority noted the application of M/s Cipla Ltd for discontinuation of the following five formulations as detailed below:

Table

S. No.	Brand Name of M/s. Cipla Limited	Composition
1	Abamune L Tablets	Abacavir 600mg + Lamivudine 300mg
2	Abamune Tablets	Abacavir 300mg
3	Efavir 200 Capsules	Efavirenz 200mg
4	Tenvir L Tablets	Lamivudine 300mg + Tenofovir Disoproxil Fumarate 300mg
5	Hepcvir 28 Tablets	Sofosbuvir 400mg

14.1.2 The Authority further noted that the matter was referred to the Standing Committee which in its 4th meeting dated 16.06.2021 recommended to obtain view of National Aids Control Organisation (NACO) with respect to the formulation as per Sl. 1 to 4 of the Table above and to allow discontinuation of the formulation mentioned in Sl. No. 5 of the Table above subject to other conditions of DPCO 2013.

14.1.3 The Authority also noted that based on the reply of NACO, Standing Committee in its 5th meeting dated 02.09.2021 recommended that the discontinuation of four formulation as per Sl. 1 to 4 of the Table above is not acceptable since it may effect the availability of the drugs since these drugs are required under National Aids Control Programme.

14.1.4 The Authority deliberated upon the matter in detail and accepted the recommendation of the Committee and decided to allow discontinuation of the formulation mentioned in Sl. No. 5 of the Table above subject to the other conditions of DPCO 2013 to M/s Cipla Ltd. The Authority further decided not to allow M/s Cipla Ltd to discontinue the formulations mentioned in Sl. No. 1 to 4 of the Table above.

14.2 Agenda item no. 14(ii) - Form-IV Intimation received from M/s Novartis India Limited for discontinuation of scheduled formulation viz., Voltafalm 50mg (Diclofenac Potassium BP 50mg) under Para 21(2) of DPCO, 2013

14.2.1 The Authority noted the application made by M/s Novartis India Limited for discontinuation of scheduled formulation viz., Voltafalm 50mg (Diclofenac Potassium BP 50mg) tablet.

14.2.2 The Authority further noted that the matter was referred to the Standing Committee which in its 5th meeting dated 02.09.2021 recommended as follows:

> *'The Drug 'Voveran GE 50 MG Gelatin Coated Tablet (Dicofenac Sodium) having market share 56% and Voltaflam 50mg' (Diclofenac Potassium BP 50mg) having market share 7.15%. Both the drugs are of the same composition "diclofenac".*
> *The company has priced Voveran GE, substantially higher than the ceiling price of diclofenac. The matter as to whether Voveran GE would be considered as a scheduled formulation is pending before Hon'ble High Court.*
> *Accordingly, till the matter is finally decided by the Hon'ble Court, the company may be directed to maintain normal production, distribution and availability of Voltaflam 50mg in the market.'*

14.2.3 The Authority deliberated upon the matter in detail and accepted the recommendation of the Committee and decided that till the matter is finally decided by the Hon'ble Court, the company may be directed to maintain normal production, distribution and availability of Voltaflam 50mg in the market.

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

10-9-2021

(N. I. Chowdhury)
Member Secretary (In-Charge)