

Minutes of the 209th (overall) and 77th meeting of the Authority under DPCO, 2013 held on 06.08.2020 at 11:00 AM

The 209th meeting of the Authority (overall), which is the 77th meeting under the DPCO, 2013, was held on the 6th of August, 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.

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 Alok Ranjan, Asstt. Director (Medical Devices)

II. Agenda items

1. Agenda item no. 1 - Confirmation of the Minutes of the 76th meeting held on 22.06.2020.

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 76th meeting dated 22.06.2020

2.1 The Authority noted that due actions have been taken.

2.2 The Authority further noted that the ceiling price of TD vaccine in 0.5 ml and 5 ml pack could not be notified due to receipt of representation on the draft working sheet

uploaded on NPPA's website. Accordingly, the Authority directed to place the case before it after examination of the representation.

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

3.1 The Authority noted that of the 34 applications received for new drug pricing, 31 applications were listed as agenda in the meeting. 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 Economic Adviser (Department of Economic Affairs) furnished a Note examining the present procedure of calculating retail price by taking the data of the companies having 1% or more market share. The Note illustrated the changes in prices by altering the market share threshold. The Authority deliberated upon the matter in detail and appreciated the viewpoint presented by the Member. The Authority noted that the present practice of taking data of the companies having 1% and more market share is as per the provisions of DPCO 2013 and the same is based on National Pharmaceutical Pricing Policy, 2012 (NPPP 2012) which is approved by the Cabinet. Any alteration of market share threshold requires change in the policy. Hence, the retail price calculation has to be as per the applicable provisions of DPCO 2013.

4.2 The Authority discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 4 (i) to 4(xxxi) (total 31 Form I applications containing retail price fixation of 34 new drugs) falling under the purview of para 2(u) of DPCO, 2013 and approved the retail prices in 30 (thirty) new drugs [except four applications at sl no. 4(xvii, xviii, xxii and xxiii)] under para 5 and 15 of the DPCO 2013, as detailed below:

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

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(i)	Memantine Hydrochloride + Donepezil Hydrochloride Tablet	Each film coated tablet contains: Memantine Hydrochloride IP 10mg Donepezil	1 Tablet	M/s Intas Pharmaceuticals Limited	16.55

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Hydrochloride IP 10mg			
4(ii)	Rosuvastatin+ Clopidogrel Capsule (Cardipill CV 10mg)	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg (As pellets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As Pellets)	1 Capsule	M/s Synokem Pharmaceuticals Limited /M/s Aristo Pharmaceuticals Pvt. Limited	14.09
4(iii)	Rosuvastatin+ Clopidogrel Capsule (Cardipill CV 20mg)	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (As pellets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As Pellets)	1 Capsule	M/s Synokem Pharmaceuticals Limited /M/s Aristo Pharmaceuticals Pvt. Limited	18.70
4(iv)	Rosuvastatin+ Aspirin + Clopidogrel Capsule (Cardipill Gold 10mg)	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg (As pellets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As Pellets) Aspirin IP 75mg (As Enteric coated Pellets)	1 Capsule	M/s Synokem Pharmaceuticals Limited /M/s Aristo Pharmaceuticals Pvt. Limited	11.89
4(v)	Rosuvastatin+ Aspirin + Clopidogrel Capsule (Cardipill Gold 20mg)	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (As pellets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As Pellets) Aspirin IP 75mg (As Enteric coated Pellets)	1 Capsule	M/s Synokem Pharmaceuticals Limited /M/s Aristo Pharmaceuticals Pvt. Limited	18.34
4(vi)	Metronidazole ER Tablet	Each Extended Release Film Coated Tablet contains: Metronidazole IP 600mg	1 Tablet	M/s Abbott Healthcare Pvt. Ltd.	4.47
4(vii)	Desvenlafaxine ER + Clonazepam Tablet (MDD-XR Plus 50)	Each uncoated Bilayered tablet contains: Desvenlafaxine Succinate USP eq. to Desvenlafaxine 50mg (As Extended Release	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Abbott Healthcare Pvt. Ltd.	12.42

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Form) Clonazepam IP 0.5mg			
4(viii)	Desvenlafaxine ER + Clonazepam Tablet (MDD-XR Plus 100)	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 Abbott Healthcare Pvt. Ltd.	20.38
4(ix)	Glimepiride + Metformin Tablet (MyGainPro 2)	Each uncoated tablet contains: Glimepiride IP 2mg, Metformin Hydrochloride IP 500mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Mylan Pharmaceuticals Pvt. Ltd.	8.00
4(x)	Amlodipine +Atenolol Tablet (MyAdol)	Each uncoated tablet contains: Amlodipine Besilate IP eq. to Amlodipine 5mg, Atenolol IP 50mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Mylan Pharmaceuticals Pvt. Ltd.	5.03
4(xi)	Amlodipine + Losartan Potassium Tablet (MyLosdro A)	Each film coated tablet contains: Amlodipine Besylate IP eq. to Amlodipine 5mg, Losartan Potassium IP 50mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Mylan Pharmaceuticals Pvt. Ltd.	7.30
4(xii)	Calcium Carbonate +Vitamin D3 Tablet (MyVitacillin)	Each film coated tablet contains: Calcium Carbonate from an organic source (Oyster shell) eq. to Elemental Calcium 500mg, Vitamin D3 IP 250 IU	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Mylan Pharmaceuticals Pvt. Ltd.	4.81
4(xiii)	Metoprolol + Cilnidipine Tablet	Each film coated bilayered tablet contains: Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate 50mg (In prolonged release form), Cilnidipine IP 10mg	1 Tablet	M/s Safetab Life Science / M/s Lupin Limited	9.25
4(xiv)	Tolperisone SR + Diclofenac Tablet	Each uncoated bilayered sustained release tablet contains: Tolperisone	1 Tablet	M/s Inventia Healthcare Pvt. Ltd. / M/s Intas Pharmaceuticals	27.05

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Hydrochloride 450mg, Diclofenac Sodium IP 100mg		Limited	
4(xv)	Dexamethasone Tablet	Each uncoated tablet contains: Dexamethasone IP 4mg	1 Tablet	M/s Zydus Healthcare Limited	3.69
4(xvi)	Metoprolol PR + Cilnidipine Tablet	Each film coated bilayered tablet contains: Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate 25mg (In prolonged release form), Cilnidipine IP 10mg	1 Tablet	M/s Safetab Life Science / M/s Lupin Limited	7.22
4(xvii)	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	Deferred (Note 2)
4(xviii)	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 Pharma Laboratories Limited	Deferred (Note 2)
4(xix)	Paracetamol + Mefenamic Acid suspension (Sumo-L Plus DS)	Each 5ml contains: Paracetamol IP 250mg, Mefenamic Acid IP 100mg	1 ML	M/s Alkem Laboratories Ltd.	0.67
4(xx)	Bisoprolol + Amlodipine Tablet	Each film coated tablet contains: Bisoprolol Fumarate IP 2.5mg, Amlodipine Besilate IP 5mg	1 Tablet	M/s Swiss Garnier Genexiaa Sciences Pvt. Ltd.M/s Lupin Ltd.	5.89
4(xxi)	Bisoprolol + Amlodipine Tablet	Each film coated tablet contains: Bisoprolol Fumarate IP 5mg,	1 Tablet	M/s Swiss Garnier Genexiaa Sciences Pvt. Ltd.M/s Lupin Ltd.	7.69

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Amlodipine Besilate IP 5mg			
4(xxii)	Dapagliflozin + Metformin Hydrochloride ER Tablet	Each film coated extended release tablet contains: Dapagliflozin 10 mg, Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Micro Labs Ltd.	Deferred (Note 3)
4(xxiii)	Dapagliflozin + Metformin Hydrochloride Tablet	Each film coated extended release tablet contains: Dapagliflozin 10mg, Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Micro Labs Ltd.	Deferred (Note 3)
4(xxiv)	Mesalazine Suppository	Each Suppository contains: Mesalazine IP 1gm	1 Suppository	M/s Bliss GVS Pharma Ltd. / M/s Sun Pharma Laboratories Limited	97.88
4(xxv)	Glimepiride + Voglibose + Metformin Hydrochloride Tablet (Gemer V2)	Each uncoated Bilayer tablet contains: Glimepiride IP 2mg, Voglibose IP 0.2mg Metformin Hydrochloride IP 500mg (As Extended Release form)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Sun Pharma Laboratories Limited	12.35
4(xxxi)	Vildagliptin + Metformin HCL Tablet	Each film coated tablet contains: Vildagliptin 50mg, Metformin Hydrochloride IP 500mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Glenmark Pharmaceuticals Limited	6.17

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(xxvi)	Capecitabine + Cyclophosphamide Tablet	Each film coated tablet contains: Capecitabine IP 700mg, Cyclophosphamide IP 32.1mg, Eq. to	1 Tablet	M/s Intas Pharmaceuticals Limited	168.53

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Anhydrous Cyclophosphamide 30mg			
4(xxvii)	Capecitabine + Cyclophosphamide Tablet	Each film coated tablet contains: Capecitabine IP 400mg, Cyclophosphamide IP 21.4mg Eq. to Anhydrous Cyclophosphamide 20mg	1 Tablet	M/s Intas Pharmaceuticals Limited	107.53
4(xxviii)	Methylcobalamin + Alpha Lipoic Acid + Pyridoxine + Folic Acid Capsule (MyFocoly)	Each Soft Gelatin Capsule contains: Methylcobalamin IP 1500 mcg, Alpha Lipoic Acid USP 100 mg, Pyridoxine Hydrochloride IP 3 mg, Folic Acid IP 1.5 mg	1 Capsule	M/s Akums Drugs & Pharmaceuticals Limited/M/s Mylan Pharmaceuticals Pvt. Limited	12.37
4(xxix)	Folic Acid+ Methylcobalamin + Pyridoxine Hydrochloride Tablet	Each film coated tablet contains: Folic Acid IP 5mg, Methylcobalamin IP 1500mcg Pyridoxine Hydrochloride IP 20mg	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	3.87
4(xxx)	Chlorhexidine Gluconate + Isopropyl Alcohol Topical Solution	Contains: Chlorhexidine Gluconate Solution IP 2.5% v/v eq. to Chlorhexidine Gluconate 0.5% w/v, Isopropyl Alcohol IP 70% v/v	100ml pack	M/s Stedman Pharmaceuticals Pvt. Limited	42.37
	Chlorhexidine Gluconate + Isopropyl Alcohol Topical Solution	Contains: Chlorhexidine Gluconate Solution IP 2.5% v/v eq. to Chlorhexidine Gluconate 0.5% w/v, Isopropyl Alcohol IP 70% v/v	200ml pack	M/s Stedman Pharmaceuticals Pvt. Limited	84.75
	Chlorhexidine Gluconate + Isopropyl Alcohol Topical Solution	Contains: Chlorhexidine Gluconate Solution IP 2.5% v/v eq. to Chlorhexidine	500ml pack	M/s Stedman Pharmaceuticals Pvt. Limited	211.87

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Gluconate 0.5% w/v, Isopropyl Alcohol IP 70% v/v			
	Chlorhexidine Gluconate + Isopropyl Alcohol Topical Solution	Contains: Chlorhexidine Gluconate Solution IP 2.5% v/v eq. to Chlorhexidine Gluconate 0.5% w/v, Isopropyl Alcohol IP 70% v/v	5000ml pack	M/s Stedman Pharmaceuticals Pvt. Limited	2118.64

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: DCGI in the meeting confirmed that they have already given permission for Phase IV trials of the subject formulations which mean that they have permission for manufacturing and marketing. However, the Authority directed to get the written confirmation from DCGI.

Note 3: The Authority noted the representation made by M/s AstraZeneca on the draft working sheet uploaded on NPPA's website and directed to place before the Authority after examination of the same.

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

5.1 The Authority noted that no review orders were pending for implementation as on 20.07.2020.

6. Agenda item no. 6 - Intimation of Minutes of 19th meeting of Multidisciplinary Committee of Experts held on 17.06.2020.

6.1 Noted.

7. Agenda item no. 7 - Application for extension of ceiling price for I.V. Fluids with packaging in Non-glass with special feature.

7.1 The Authority deliberated upon the matter in detail and noted that five companies namely, M/s Realcade Lifescience Pvt Ltd , M/s Rusoma Laboratories Private Ltd, M/s Shree Krishna Keshav Laboratories Ltd, M/s Axa Parenterals Limited and M/s Eurolife Healthcare Private Limited have applied for separate ceiling price of I.V. Fluids for packages

in non-glass having special features. The Authority noted that the matter was deliberated in the 20th meeting of the Multidisciplinary Committee of Experts held on 17.07.2020 and out of five companies, three companies namely, M/s Shree Krishna Keshav Laboratories Ltd, M/s Axa Parenterals Ltd and M/s Eurolife Healthcare 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 the two companies namely, M/s Shree Krishna Keshav Laboratories Ltd and M/s Axa Parenterals 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 and decided that further examination is required of the applications of M/s Eurolife Healthcare Pvt. Ltd.

7.2 Accordingly, the Authority decided to extend the ceiling prices and the formulations mentioned in SO.1215(E) dated 25.03.2020 to the two companies namely, M/s Shree Krishna Keshav Laboratories Ltd for its products “Easyport bottle with Eurohead” and M/s Axa Parenterals Ltd for its products “Steri Drip bottle with Eurohead” 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.

7.3 The Authority further decided to reject the applications of M/s Realcade Lifescience Pvt Ltd and M/s Rusoma Laboratories Private Ltd as they did not demonstrate their products before the Multidisciplinary Committee of Experts.

8. Agenda item no. 8 - Application for extension of ceiling price for Ringer lactate injection in packaging with special feature.

8.1 The Authority deliberated upon the matter in detail and noted that three companies namely, M/s Denis Chem Lab Ltd, M/s Amanta Healthcare Ltd and M/s Shree Krishna Keshav Laboratories 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 20th meeting of the Multidisciplinary Committee of Experts held on 17.07.2020 and three companies namely; M/s Denis Chem lab Ltd, M/s Amanta Healthcare

Ltd and M/s Shree Krishna Keshav Laboratories 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 three companies namely, M/s Denis Chem lab Ltd, M/s Amanta Healthcare Ltd and M/s Shree Krishna Keshav Laboratories 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.

8.2 Accordingly, the Authority decided to extend the ceiling prices and the formulations mentioned in SO.1216(E) dated 25.03.2020 to the three companies namely, M/s Denis Chem lab Ltd, M/s Amanta Healthcare Ltd and M/s Shree Krishna Keshav Laboratories 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.

9. Agenda item no. 9 - Application for separate price under para 11(3) of DPCO 2013 filed by M/s Abbott India Ltd in respect of Digene Stickpack.

9.1 The Authority deliberated upon the matter in detail and noted that application filed by M/s Abbott India Ltd for separate price of Digene Stickpack under para 11(3) of DPCO 2013 was examined by the Multidisciplinary Committee of Experts in its 20th meeting dated 17.07.2020 and decided to reject the application since the application for separate price is only for change in packaging and there is no incremental innovation and significant therapeutic efficacy. The Authority also noted that the M/s Abbott India Ltd has not provided separate license from DCGI/ State Licensing Authority showing approval of manufacturing/ marketing of Digene Stickpack.

9.2 Accordingly, the Authority decided to reject the application of M/s Abbott India Ltd for separate price of Digene Stickpack under Para 11(3) of DPCO 2013.

10. Agenda item no. 10 – Development and Implementation of Eco System for timely disposal and monitoring of various applications filed to NPPA

10.1 The Authority noted with appreciation the proposal for implementation of ecosystem for timely attending, disposing and monitoring of various applications filed under various provisions of DPCO, 2013 is a welcome step. It would lead to more transparency and ease of doing business.

10.2 The Authority noted the procedure and time frame proposed under the Eco-system and observed that in case of application for exemption under Para 32 of DPCO,2013, at present it is not possible to adhere given procedure and time limit as there is no clarity in the operational application of provisions of this Para. Further, on this issue a consultation process is going on within the govt.

10.3 Accordingly, the Authority approved the procedure excluding proposal regarding para 32 of DPCO, 2013 for development and implementation of Ecosystem for timely disposal and monitoring of various applications filed with NPPA.

11. Agenda item no. 11 – Representation from Indian Pharmaceutical Alliance (IPA) due to COVID-19 Pandemic

11.1 The Authority noted the representation made by Indian Pharmaceutical Alliance (IPA) for grant of 5% upward price revision for all the drugs in scheduled and non-scheduled category on account of increase in cost of APIs and other COVID-19 related disruptions. Further, IPA has also sought to revise the ceiling price on the basis of Consumer Price Index (CPI) rather than Whole Price Index (WPI). The Authority further noted that NPPA has constituted a Committee to monitor export/import trends of APIs, formulations and medical devices needed for COVID-19. The Committee examined the price movement of 15 APIs due to COVID scenario and recommended that in respect of 13 APIs, there is no compelling situation for increase in the ceiling price of its formulations. The Committee however, recommended for price increase of Heparin Injection and Ascorbic Acid 500 mg tablet. NPPA has already taken action in respect of these two.

11.2 The Economic Adviser, Department of Economic Affairs (DEA) furnished a Note examining the representation of IPA. In the Note price change analysis has been done based on customs data on the APIs mentioned by IPA. The claim of IPA doesn't seem to be substantiated. In case of Paracetamol, IPA has claimed 51% increase in the price of API, while the data analysis by DEA indicates a negative change of 1% in the price. Accordingly, based on the analysis, DEA has observed that some spike in import prices have been witnessed in the post-COVID period in certain APIs, however, whether it warrants a rise in the ceiling price is not clear. Data does not seem to indicate a clear upward trend that is likely to sustain elevated prices of APIs in the future. The Note also mentions that Wholesale Price Index (WPI) would be a more appropriate than Consumer Price Index (CPI) for revising ceiling prices. The Authority appreciated the detailed analysis made by DEA based on the representation of IPA.

11.3 The Authority deliberated upon the matter in detail and observed that the recommendation of the Committee to monitor export/import trends of APIs, formulations and medical devices needed for COVID-19 and the analysis of DEA does not validate the claim of IPA for price increase. Accordingly, the Authority disposed off the representation of Indian Pharmaceutical Alliance (IPA).

12. Agenda item no. 12 – Draft guidelines for dealing cases of discontinuation of Scheduled formulations under para 21(2) of DPCO, 2013

12.1 The Authority deliberated upon the matter in detail and approved the simplified draft guidelines for dealing with cases of discontinuation of scheduled formulations under Para 21(2) of DPCO 2013.

13. Agenda item no. 13 – Price fixation as per Pharmaceuticals Purchase Policy (PPP) for products of Pharma Central Public Sector Enterprises (CPSEs) and their subsidiaries.

Record note of Discussion to be circulated separately to the members.

14. Agenda item no. 14 – Ceiling Prices of Orthopaedic Knee Implants for Knee Replacement System

14.1 The Authority noted that with a view to rationalize the huge trade margin, NPPA notified the ceiling price of orthopaedics knee implants for knee replacement system vide notification SO. No. 2668(E) dated 16.08.2017 by invoking Para 19 of DPCO 2013. This has resulted in price rationalization in the orthopaedics knee implants for knee replacement system which were mainly dominated by importers. The notified price was extended up to 15.08.2019. NPPA vide SO. 2934(E) dated 13.08.2019 notified that the existing ceiling prices shall be continued and be further monitored as per the provisions of Para 20(1) of DPCO, 2013 for a period of one year. The price intervention in orthopaedics knee implants for knee replacement system has resulted in approx. savings to the Rs. 1500 crore to the consumer. Further, the market share of indigenous companies/manufacturers has increased considerably.

14.2 The Authority further noted that Medical Technology Association of India (MTAI) had made a representation for one-time increase in ceiling price of 20% to orthopaedics knee implants for knee replacement system due to extraordinary financial situation which has created an unviable business environment.

14.3 The Authority observed that the data submitted by the manufacturers/ importers requires further deliberation on the matter. Accordingly, the Authority 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.

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

Sd/-
(Vinod Kotwal)
Member Secretary