

मिसिलस.- 8(120)/2024/डी.पी/एनपीपीए-डीवी-II  
F. No. 8(120)/2024/DP/NPPA-Div. II

कार्यवाहीस. : 252/120/2024/F  
Proceeding No: 252/120/2024/F

**Minutes of the 252<sup>nd</sup>(overall) and 120<sup>th</sup>meeting of the Authority under DPCO, 2013 held on 24.01.2024 at 11:30 AM.**

The 252<sup>nd</sup> meeting of the Authority (overall), which is the 120<sup>th</sup> meeting under the DPCO, 2013 was held on 24<sup>th</sup> January, 2024 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) 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

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

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

- (i) Shri Sanjay Kumar, Advisor (Cost-I)
- (ii) Ms. Rashmi Tahiliani, Jt. Director (Pricing)
- (iii) Shri. Mahaveer Saini, Deputy Director (Pricing)
- (iv) Ms. Yuvika Panwar, Assistant Director (Pricing)

**II. Agenda items**

**1. Agenda item no. 1 - Confirmation of Minutes of the 119<sup>th</sup> Meeting held on 15.12.2023.**

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 119<sup>th</sup> Meeting held on 15.12.2023.**

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**

4.1 The Authority discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 4 (i) to 4 (xvi) (total 39 Form I applications containing retail price fixation of 39 new drug) falling under the purview of Para 2(1)(u) of DPCO, 2013 and approved the retail prices of 39(thirty-nine) 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**

<b>Agenda No.</b>	<b>Name of the Formulation / Brand Name</b>	<b>Strength</b>	<b>Unit</b>	<b>Manufacturer &amp; Marketing Company</b>	<b>Retail Price (in Rs.)</b>
<b>(1)</b>	<b>(2)</b>	<b>(3)</b>	<b>(4)</b>	<b>(5)</b>	<b>(6)</b>
4 (i)	Paracetamol and Dicyclomine Hydrochloride Tablets	<b>Each uncoated tablet contains:</b> Paracetamol IP 325mg Dicyclomine Hydrochloride IP 20mg	1 Tablet	M/s Prosperity Drugs Pvt. Ltd. / M/s Torrent Pharmaceuticals Limited	2.12
4 (ii)	Albendazole & Ivermectin Suspension	Each 5ml contains: Albendazole IP 200mg Ivermectin IP 3mg	1 ml	M/s. Prochem Pharmaceuticals Pvt. Ltd. / M/s Indoco Remedies Limited	1.36
4 (iii)	Amoxicillin and Potassium Clavulanate Oral Suspension	<b>Each 5ml of reconstituted suspension contains:</b> Amoxicillin Trihydrate IP eq. to Amoxicillin 600mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 42.9mg	1 ml	M/s Alps Communication Pvt. Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	3.17
4 (iv)	Cefuroxime Axetil & Potassium Clavulanate IP Tablets	<b>Each film coated tablet contains:</b> Cefuroxime Axetil IP eq. to Anhydrous Cefuroxime 500mg Potassium Clavulanate Diluted IP Eq. to Clavulanic Acid 125mg	1 Tablet	M/s Theon Pharmaceuticals Ltd. / M/s Torrent Pharmaceuticals Ltd.	56.98
4 (v)	Amoxicillin and Potassium Clavulanate Tablets IP	<b>Each film coated tablet contains:</b> Amoxicillin Trihydrate IP eq. to Amoxicillin 875mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 125mg	1 Tablet	M/s Brooks Laboratories Ltd. / M/s German Remedies Pharmaceuticals Private Limited	40.03
4 (vi)	Zolpidem Tartrate	<b>Each film coated</b>	1 Tablet	M/s Abbott	14.12



Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Prolonged release tablets	<b>bilayered Prolonged release tablets contains:</b> Zolpidem Tartrate IP 12.50mg		India Limited	(Note 1)
4 (vii)	Zolpidem Tartrate Prolonged release tablets	<b>Each film coated bilayered Prolonged release tablets contains:</b> Zolpidem Tartrate IP 6.25mg	1 Tablet	M/s Abbott India Limited	11.41
4 (viii)	Meropenem and Sulbactam for Injection	<b>Each vial contains:</b> Meropenem IP (Sterile) eq. to Anhydrous Meropenem 1000mg Sodium Carbonate IP (As buffer) eq. to Sodium 90.2mg Sulbactam Sodium IP (Sterile) eq. to Sulbactum 500mg	1 vial	M/s Aqua Vitoe Laboratories / M/s FDC Limited	1584.24
4 (ix)	Rosuvastatin + Clopidogrel Capsules	<b>Each Hard gelatin capsule contains:</b> Rosuvastatin Calcium IP Eq. to Rosuvastatin 20mg (As film coated Tablet form) Clopidogrel Bisulphate IP Eq. to Clopidogrel 75mg (As Film coated Tablet form)	1 Capsule	M/s Pure and cure Healthcare Pvt. Ltd. / Dr. Reddy's Laboratories Limited	19.21
4 (x)	Diclofenac Diethylamine, Virgin Linseed Oil, Methyl Salicylate, Menthol & Capsacin Gel	<b>Contains:</b> Diclofenac Diethylamine IP 1.16% w/w, Virgin Linseed Oil BP 3% w/w, Methyl Salicylate 10% w/w, Menthol IP 5% w/w Capsacin USP 0.025% w/w	1 gram	M/s Curetech Skincare / M/s J.B. Chemicals & Pharmaceuticals Ltd.	3.41
4 (xi)	Omeprazole & Domperidone Capsules IP	<b>Each hard gelatin capsule contains:</b> Omeprazole IP 20mg (as enteric coated pallets) Domperidone IP 10mg	1 Capsule	M/s Innova Captab Limited / M/s Eris Healthcare Pvt. Ltd.	6.18
4 (xii)	Linagliptin,	<b>Each film coated</b>	1 Tablet	M/s Synokem	9.18



Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Metformin Hydrochloride (Extended Release) Tablets	<b>bilayered tablet contains:</b> Linagliptin 2.5mg Metformin Hydrochloride IP 1000mg (As Extended Release)		Pharmaceuticals Limited / M/s Mankind Pharma Limited	
4 (xiii) a	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 1 mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Micro Labs Limited	11.61
4 (xiii) b	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 1 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Lupin Limited	13.35
4 (xiii) c	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 1 mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Abbott Healthcare Pvt. Ltd.	13.35
4 (xiii) d	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 1 mg	1 Tablet	M/s Synkem Pharmaceuticals Ltd. / M/s Mankind Pharma Limited	13.35
4 (xiii) e	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin	1 Tablet	M/s Exemed Pharmaceuticals / M/s Glenmark Pharmaceuticals Limited	13.35



Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Hydrochloride IP 1000mg Glimepiride IP 1 mg			
4 (xiii) f	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 1 mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Emcure Pharmaceuticals Limited	13.35
4 (xiii) g	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 1 mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Torrent Pharmaceuticals Limited	13.35
4 (xiii) h	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 1 mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Eris Lifesciences Limited	13.35
4 (xiii) i	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 1 mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Torrent Pharmaceuticals Limited	13.35
4 (xiii) j	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 1 mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Dr. Reddy's Laboratories Limited	13.35
4 (xiv) a	Sitagliptin	<b>Each film coated</b>	1 Tablet	M/s Exemed	13.39

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Phosphate, Metformin Hydrochloride and Glimepiride Tablets	<b>tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 2 mg		Pharmaceuticals / M/s Micro Labs Limited	
4 (xiv) b	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 2 mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Abbott Healthcare Pvt. Ltd.	15.03
4 (xiv) c	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 2 mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Glenmark Pharmaceuticals Limited	15.03
4 (xiv) d	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 2 mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Mankind Pharma Limited	15.03
4 (xiv) e	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 2 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Lupin Limited	15.03
4 (xiv) f	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Emcure Pharmaceuticals Limited	15.03





Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Tablets	Metformin Hydrochloride IP 1000mg Glimepiride IP 2 mg			
4 (xiv) g	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 2 mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Torrent Pharmaceuticals Limited	14.30
4 (xiv) h	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 2 mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Torrent Pharmaceuticals Limited	14.30
4 (xiv) i	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 2 mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Dr. Reddy's Laboratories Limited	15.03
4 (xiv) j	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	<b>Each film coated tablet contains:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 2 mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Eris Lifesciences Limited	15.03
4 (xv) a	Dapagliflozin, Metformin Hydrochloride Extended Release and Glimepiride Tablets	<b>Each film coated tablet contains:</b> Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 500mg (As extended	1 Tablet	M/s Sun Pharma Laboratories Limited	15.15



Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		release) Glimepiride IP 2 mg			
4 (xv) b	Dapagliflozin, Metformin Hydrochloride Extended Releaseand Glimepiride Tablets	<b>Each film coated tablet contains:</b> Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 500mg (As extended release) Glimepiride IP 1 mg	1 Tablet	M/s Sun Pharma Laboratories Limited	13.47
4 (xv) c	Dapagliflozin, Metformin Hydrochloride Extended Releaseand Glimepiride Tablets	<b>Each film coated tablet contains:</b> Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 1000mg (As extended release) Glimepiride IP 2 mg	1 Tablet	M/s Sun Pharma Laboratories Limited	16.00
4 (xv) d	Dapagliflozin, Metformin Hydrochloride Extended Releaseand Glimepiride Tablets	<b>Each film coated tablet contains:</b> Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 1000mg (As extended release) Glimepiride IP 1 mg	1 Tablet	M/s Sun Pharma Laboratories Limited	14.50
4 (xvi) a	Linagliptin + Metformin Hydrochloride (ER) Tablet	<b>Each film coated bilayered tablet contains:</b> Linagliptin 5mg Metformin Hydrochloride IP 1000mg (as Extended release)	1 Tablet	M/s Exemed Pharmaceuticals Ltd. / M/s USV Private Limited	14.37 (Note 2)
4 (xvi) b	Linagliptin + Metformin Hydrochloride (ER) Tablet	<b>Each film coated bilayered bilayered tablet contains:</b> Linagliptin 5mg Metformin Hydrochloride (as	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Emcure Pharmaceuticals Limited	14.72





Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Extended release) IP 1000mg			
4 (xvi) c	Linagliptin + Metformin Hydrochloride (ER) Tablet	<b>Each film coated tablet contains:</b> Linagliptin 5mg Metformin Hydrochloride (as Extended release) IP 1000mg	1 Tablet	M/s Exemed Pharmaceuticals Ltd. / M/s Abbott Healthcare Pvt. Ltd.	11.61

*Note 1: The Authority noted the representation received from M/s Abbott India Limited for correction in the PTR of one of the line items considered in the uploaded draft worksheet. However, the same was not considered as the revision in the PTR in the Pharmatrac data as contended by M/s Abbott India Limited was done in June 2023 whereas the PTR for the retail price fixation of the subject formulation at S No. 4(vi) has been considered for the month of May 2023 i.e. 6 months prior to the date of application. Hence, the Authority decided that no change is required in the draft worksheet uploaded.*

*Note 2: The Authority noted the representation received from M/s USV Pvt. Ltd. stating that higher retail price has been recommended by MDC for the same formulation for other two manufacturers/ marketers, by considering the different ceiling price for Metformin modified release 1000 mg tablet. However, the same was not considered as the ceiling price of Metformin modified release 1000 mg tablet considered by MDC is the ceiling price as applicable for the month ending immediately before six months of receipt of application for fixing the price of the new drug as per para 9 (4) of DPCO 2013. The price fixation was done considering the prices as applicable for the month of March 2023 in case of USV Pvt. Ltd. since the date of receipt of complete application is 5.10.2023*

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

5.1 Noted

## **6. Agenda item no. 6 –Minutes of 56th meeting of Multidisciplinary Committee of Experts held on 20.12.2023.**

6.1 Noted

## **7. Agenda item no. 7 –Approval for ceiling price of different dosage forms and strength of I.V Fluids with packaging in non-glass container with special features notified vide S.O No. 1569 (E), 1570 (E), 1571 (E), 1574 (E), 1576 (E), 1577 (E) dt. 31.03.2023 by M/s Promea Therapeutics Pvt. Ltd.**

**7.1** The Authority noted the application filed by M/s Promea Therapeutics Pvt. Ltd vide letter dated 20.04.2023 for extension of separate ceiling price of I.V. Fluids with packaging in Non-Glass container with special features in respect of IV fluids mentioned in Table 2 below-

*Mk.*

**Table 2: Applications for extension of separate ceiling price**

S.No.	Medicines	Dosage form and strength	Unit
1.	Sodium Chloride (A) + Dextrose (B)	Injection 0.9% (A) + 5% (B)	500ml / LDPE Bottle/ Non-Glass container with special features- Eurohead Cap
2.	Sodium Chloride	Injection 0.9%	500ml / LDPE Bottle/ Non-Glass container with special features- Eurohead Cap
3.	Compound Sodium Lactate Injection IP (Ringer lactate of Injection)	Injection 500 ml	500ml / LDPE Bottle/ Non-Glass container with special features- Eurohead Cap
4.	Dextrose	Injection 5%	500ml / LDPE Bottle/ Non-Glass container with special features- Eurohead Cap
5.	Dextrose	Injection (25% w/v)	100 ml / LDPE Bottle/ Non-Glass container with special features- Eurohead Cap
6.	Sodium Chloride	Injection 0.9%	100ml / LDPE Bottle/ Non-Glass container with special features- Eurohead Cap
7.	Metronidazole	Injection (0.5%w/v)	100ml / LDPE Bottle/ Non-Glass container with special features- Eurohead Cap

7.2 The Authority noted that the matter was deliberated in 52<sup>nd</sup>, 53<sup>rd</sup>, 55<sup>th</sup> and 56<sup>th</sup> meeting of Multi-Disciplinary Committee (MDC) held on 11.07.2023, 08.08.2023, 17.10.2023. and 20.12.2023 respectively in which the product was demonstrated by the applicant and the Committee examined the documents submitted by the applicant. The Authority also noted the recommendation of the MDC to extend the current applicable separate ceiling price for seven applications for formulations (as mentioned in Table 2 above) in special packaging to M/s Promea Therapeutics Pvt. Ltd.

7.3 The Authority deliberated the matter in detail and accepted the recommendation of MDC and decided to extend the special ceiling prices of 7 formulations to M/s Promea Therapeutics Pvt. Ltd as mentioned below in Table 3-

**Table 3: Extension of special ceiling prices**

S.No.	Medicines	Dosage form and strength	Unit	Current applicable Ceiling price (in Rs.)
1.	Sodium Chloride (A) + Dextrose (B)	Injection 0.9% (A) + 5% (B)	500ml Non Glass with special features	85.52 per pack (SO No. 1571 dated 31.03.2023 & 4663 dated 25.10.2023)
2.	Sodium Chloride	Injection 0.9%	500ml Non Glass with special features	87.94 per pack (SO No. 1571 dated 31.03.2023 & 4663 dated 25.10.2023)



3.	Compound Sodium Lactate Injection IP (Ringer lactate of Injection)	Injection 500 ml	Each 500 ml pack having special features	64.96 per pack (SO No. 1570 dated 31.03.2023)
4.	Dextrose	Injection 5%	500ml Non Glass with special features	82.27 per pack (SO No. 1571 dated 31.03.2023)
5	Dextrose	Injection (25% w/v)	100 ml pack for packages in non-glass container in plastic bottle with euro head having special features	0.24 per ml(SO No. 1569 dated 31.03.2023)
6	Sodium Chloride	Injection 0.9%	100ml Non Glass with special features	42.06 per pack (SO No. 1571 dated 31.03.2023 & 4663 dated 25.10.2023)
7	Metronidazole	Injection (0.5%w/v)	100ml pack for packages in non glass container in plastic bottle with euro head having special features	0.25 per ml (SO No. 1576 dated 31.03.2023 & 4663 dated 25.10.2023)

**8. Agenda item no. 8 – Fixation of ceiling price of scheduled formulations under Revised Schedule-I (NLEM, 2022) based on October 2023 database.**

**8.1.** The Authority noted that as decided in its 104<sup>th</sup> meeting held on 23.11.2022; till 24.01.2024 NPPA has fixed ceiling prices of 700 formulation under NLEM,2022 using July,2022 database in line with Para 9(7) of DPCO 2013. Further, ceiling prices of approximately 225 formulations are yet to be fixed.

8.2 The Authority noted that for ceiling price fixation under NLEM, 2015, NLEM was notified as Schedule-I in March, 2016 and the database of August 2015 i.e. 6 months prior to date of notification of Schedule-I, was considered. However, after promulgation of Para 9(7) w.e.f. 3.01.2019, ceiling prices were fixed under NLEM, 2015 considering the database of the month of August 2015 as well as other months.

8.3 The Authority observed that October 2023 database used for price fixation would capture the PTR duly revised based on WPI for 2023 as availed by the companies. Accordingly, it was decided to use October 2023 database and the month of October, 2023 for fixation of the ceiling prices of remaining formulations under NLEM, 2022 under para 9 (7) of DPCO, 2013.



**9. Agenda Item no. 9 - Retail Price fixation under Para 5 of DPCO 2013 of a new drug or the new drugs that contain molecules or components of ingredients, that have become off-patent or about to become off-patent under the Patents Act, 1970 (39 of 1970).**

9.1 The Authority noted the DPCO, 2013 amendment dated 11.05.2023 and specific provisions w.r.t. fixation of retail price of a new drug or the new drug that contains molecules or components or ingredients that have become off-patent or about to become off-patent.

9.2 As per the provisions of Para 5(3) of the DPCO,2013, in case retail price fixation of a new drug or the new drug that contain molecules or components or ingredients that have become off-patent or about to become off-patent, if the market-based data is available; the prices are to be fixed as per provisions of para 5(3)(i) by calculating 50% of prices fixed under para 4(1).However, after one year from the date on which the retail price was fixed as per Para 5(3)(i) or the date on which "price to retailer" of at least one company fixed as per Para 5(3)(i) is captured in the pharmaceutical market database, whichever is later, then their retail prices are to fixed as per para 4(1) excluding Patent/License holder prices under Para 5(3)(ii).

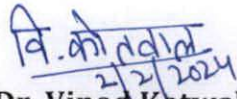
9.3 The Authority noted that NPPA has received retail price fixation application for FDC of Dapagliflozin 10mg + Vildagliptin 100 + Metformin SR 500mg and Sitagliptin 100mg + Pioglitazone 15mg+ Metformin SR 500mg/1000mg for which market data is available and the retail prices of these FDCs were first fixed by NPPA in 109<sup>th</sup> meeting held on 24.02.2023 and 114<sup>th</sup> meeting held on 19.06.2023 respectively.

9.4 The Authority noted that although one year has not elapsed since the price notification of above FDCs, the prices of these FDCs have started appearing in the market database. However, the prices appearing are only of those manufacturers for whom the retail prices were fixed by NPPA by applying 50% reduction and the prices of the Patent holder/License holder are not appearing in the market database.

9.5 The Authority deliberated upon the matter that if prices are fixed under Para 5(3)(i), then prices shall be further reduced by 50% from the prices that have been fixed by NPPA after applying 50% reduction earlier. After detailed deliberations, it was decided that the retail price of above formulations may be fixed based on the market database (excluding Patent/License holder, if any) under provisions of Para 5(3)(ii) of DPCO, 2013.

The Authority members and the officers present in the meeting placed on record the appreciation of the excellent contribution made by Shri A.K Pradhan, Jt. Drug Controller, CDSCO, Ministry of Health & Family Welfare as a representative of DCGI, CDSCO, Ministry of Health & Family Welfare to the Authority meetings and as a member of Multi Disciplinary committee of Experts and who is due for superannuation on 31.01.2024.

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

  
(Dr. Vinod Kotwal)  
Member Secretary