

**Minutes of the 242<sup>th</sup>(overall) and 110<sup>th</sup>meeting of the Authority under DPCO, 2013 held on 23.03.2023 at 03:00 PM.**

The 242<sup>nd</sup> meeting of the Authority (overall), which is the 110<sup>th</sup> meeting under the DPCO, 2013, was held on 23<sup>rd</sup> March, 2023 at 03:00 PM under the Chairmanship of Shri Kamlesh Kumar Pant, Chairman, NPPA. The following Authority members of NPPA were present during the meeting:

- (i) Dr. Vinod Kotwal, Member Secretary, NPPA
- (ii) Shri G. Venkatesh, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure
- (iii) Shri Saikat Sarkar, Economic Advisor, Department of Economic Affairs

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

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

- (i) Shri Manmohan Sachdeva, Advisor (Cost-I)
- (ii) Shri Sanjay Kumar, Advisor (Cost-II)
- (iii) Shri R. Jegan, Jt. Director (Overcharging / Medical Devices)
- (iv) Ms. Rashmi Tahiliani, Jt. Director (Pricing)
- (v) Shri Mahaveer Saini, Deputy Director (Pricing)

**II. Agenda items**

**1. Agenda item no. 1 - Confirmation of Minutes of the 109<sup>th</sup> Meeting held on 21.02.2023.**

1.1 The Authority confirmed the minutes without any change. However, Shri G. Venkatesh, the Authority Member made an observation on Para 4.2 of the minutes of 109<sup>th</sup> Authority Meeting mentioning that the methodology adopted by the MDC while recommending retail prices of the formulations, whereby a reduction of 20% of one of the components having lower price is done, needs refinement as recommended by Pronab Sen Committee. The Authority after deliberations decided that a committee may be constituted under the chairmanship of Advisor (Cost-I) with representatives from Department of Expenditure and CDSCO to examine the matter and submit its report. However, the current methodology may be followed till the recommendations of the committee are received and accepted by the Competent Authority.

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2. **Agenda item no. 2 – (a) Action Taken Report (ATR) on decisions taken by NPPA in its 109<sup>th</sup> Meeting held on 21.02.2023.**

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 (xxiv) (total 41 Form I applications containing retail price fixation of 41 new drug) falling under the purview of Para 2(1)(u) of DPCO, 2013 and approved the retail prices of 25 (Twenty Five) 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**

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (i)	Itraconazole Capsules 130mg (Supra- Bioavailable Formulation)	Each Hard Gelatin Capsule contains: Itraconazole BP 130mg	1 Capsule	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Abbott Healthcare Pvt. Ltd.	20.72
4 (ii)	Telmisartan & Chlorthalidone Tablets	Each uncoated bilayered tablet contains: Telmisartan IP 40mg Chlorthalidone IP 6.25mg	1 Tablet	M/s Innova Captablimied / M/s Indoco Remedies Limited	8.04
4 (iii)	Camylofin Dihydrochloride and Paracetamol Tablets	Each film coated tablet contains: Camylofin Dihydrochloride 50mg Paracetamol IP 325mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Abbott Healthcare Pvt. Ltd.	5.53
4 (iv)	Glimepiride tablets IP	Each uncoated tablet contains: Glimepiride IP 4mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s German Remedies Pharmaceuticals Pvt. Ltd.	11.57

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (v)	Glimepiride tablets IP	Each uncoated tablet contains: Glimepiride IP 3mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s German Remedies Pharmaceuticals Pvt. Ltd.	9.77
4 (vi)	Gliclazide (MR) and Metformin Hydrochloride (ER) Tablets	Each uncoated bilayered tablet contains: Gliclazide IP 30mg (in MR form) Metformin Hydrochloride IP 500mg (as Extended Release)	1 Tablet	M/s Swiss GarniersGenexiaa Sciences Pvt. Ltd. / M/s Servier India Pvt. Ltd.	6.57
4 (vii)	Bilastine and Montelukast Ondispersible Tablets	Each uncoated Orodispersible tablet contains: Montelukast Sodium IP Eq. to Montelukast 10mg Bilastine 20mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Sun Pharmaceuticals Industries Limited	13.21
4 (viii)	Chlorpheniramine Maleate and Phenylephrine Hydrochloride Syrup	Each 5ml contains: Chlorpheniramine Maleate IP 2mg Phenylephrine Hydrochloride IP 5mg	1 ml	M/s Stedman Pharmaceuticals Pct. Ltd.	1.16
4 (ix) a.	Dapagliflozin & Metformin Hydrochloride (Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg Metformin Hydrochloride IP (Extended Release) 1000mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Alembic Pharmaceuticals Ltd.	7.31
4 (ix) b.	Dapagliflozin & Metformin Hydrochloride (Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Alembic Pharmaceuticals Ltd.	10.53

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Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Metformin Hydrochloride IP (Extended Release) 1000mg			
4 (ix) c.	Dapagliflozin & Metformin Hydrochloride (Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Metformin Hydrochloride IP (Extended Release) 500mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Alembic Pharmaceuticals Ltd.	9.10
4 (ix) d.	Dapagliflozin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 500mg (as Extended Release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Mankind Prime Labs Pvt.Ltd.	9.10
4 (ix) e.	Dapagliflozin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 1000mg (as Extended Release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Mankind Prime Labs Pvt.Ltd.	10.53
4 (x)	Levocetirizine, Montelukast & (SR) Ambroxol Hydrochloride Tablets	Each uncoated bilayered tablet contains: Levocetirizine Dihydrochloride IP 5mg Montelukast Sodium IP eq. to Anhydrous Montelukast 10mg Ambroxol Hydrochloride IP 75mg (As Sustained Release)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Emcure Pharmaceuticals Ltd.	15.39
4 (xi)	Omeprazole &	Each hard gelatin	1	M/s Innova Captab Limited	5.90

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Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Domperidone Capsules IP	capsule contains: Omeprazole IP 20mg (as gastro-resistant pellets) Domperidone IP 10mg (as pellets)	Capsule	/ M/s Torrent Pharmaceuticals Limited	
4 (xii)	Combi pack of Clarithromycin Tablets IP, Esomeprazole Tablets IP & Amoxicillin Tablets USP	Each Strip contains: A. Clarithromycin Tablets IP 2 Tablets Each film coated tablet contains: Clarithromycin IP 500mg B. Esomeprazole Tablets IP 2 Tablets Each Enteric coated tablet contains: Esomeprazole Magnesium Trihydrate IP eq. to Esomeprazole 40mg C. Amoxicillin Tablets USP 2 Tablets Each Film coated tablet contains: Amoxicillin Trihydrate IP eq. to Amoxicillin 750mg	Combi Pack of 6 Tablets	M/s Malik Lifesciences Pvt. Ltd. / M/ Zuventus Healthcare Limited	152.17
4 (xiii)	Bisoprolol Fumarate & Amlodipine Besylate tablets	Each film coated tablet contains: Bisoprolol Fumarate IP 5mg Amlodipine Besylate IP Eq. to Amlodipine 5mg	1 Tablet	M/s Tha Madras Pharmaceuticals / M/s Cipla Ltd.	8.34
4 (xiv)	Bisoprolol Fumarate & Amlodipine Besylate tablets	Each film coated tablet contains: Bisoprolol Fumarate IP 2.5mg Amlodipine Besylate IP Eq. to Amlodipine 5mg	1 Tablet	M/s Tha Madras Pharmaceuticals / M/s Cipla Ltd.	6.19
4 (xv)	Erythropoietin Injection BP 6000 IU/ml	Each pre-filled Syringe contains: Erythropoietin Concentrated Solution Ph. Eur. 6000IU Albumin Human	1 ml	M/s GennovaBlopharmaceuticals Ltd. / M/s Wockhardt Limited	1449.74

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Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		USP 2.5mg Sodium Chloride BP/Ph Eur 5.8mg Sodium Citrate BP/Ph. Eur 5.8mg Citric Acid monohydrate IP 5.8mg Water for Injections. BP/Ph Eur q.s. to 1ml			
4 (xvi)	Glycopyrronium Ph. Eur, Formoterol Fumarate IP and Budesonide Inhalation powder	Each Capsule contains: Glycopyrronium Bromide Ph. Eur eq. to Glycopyrronium 25mcg, Formoterol Fumarate (As Formoterol Fumarate Dihydrate IP) 12mcg Budesonide IP 400mg	1 Capsule	M/s Lupin Limited	12.19
4 (xvii)	Bisoprolol Fumarate & Amlodipine Tablets	Each film coated tablet contains: Bisoprolol Fumarate IP 5mg Amlodipine Besylate IP Eq. to Amlodipine 5mg	1 Tablet	M/s J. K. Printpack / M/s Zydus Healthcare Limited	8.34
4 (xviii)	Cilnidipine & Telmisartan Tablets	Each film coated tablet contains: Cilnidipine IP 20mg Telmisartan IP 40mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Glenmark Pharmaceuticals Limited	12.83
4 (xix)	Ceftazidime and Avibactam powder for concentrate for solution for infusion	Each vial contains: Ceftazidime (as ceftazidime Pentahydrate) IP 2gram Avibactam Sodium eq. to Avibactam 0.5gm	1 Vial	M/s BDR Pharmaceuticals International Pvt. Ltd. / M/s Wockhardt Limited	3773.31
4 (xx)	Cilnidipine, Telmisartan & Chlorthalidone Tablets	Each film coated tablet contains: Cilnidipine IP 10mg Telmisartan IP 40mg Chlorthalidone IP 6.25mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	13.17
4 (xxi) a	Dapagliflozin, Sitagliptin and	Each film coated bilayered tablet	1 Tablet	M/s Exemed Pharmaceuticals / M/s	Deferred (Note 1)



Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Metformin Hydrochloride (as Extended Release) Tablets	contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (as Extended Release)		Wockhardt Limited	
4 (xxi) b	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (as Extended Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Wockhardt Limited	Deferred (Note 1)
4 (xxii) a	Dapagliflozin, Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 500mg (as Sustained Release)	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Alkem Laboratories Ltd.	Deferred (Note 1)
4 (xxii) b	Dapagliflozin, Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Alkem Laboratories Ltd.	Deferred (Note 1)

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 1000mg (as Sustained Release)			
4 (xxiii) a	Vildagliptin (SR) & Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP (As Sustained Release) 100mg Metformin Hydrochloride IP (As Sustained Release) 500mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Intas Pharmaceuticals Ltd.	Deferred (Note 1)
4 (xxiii) b	Vildagliptin (SR) & Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP (As Sustained Release) 100mg Metformin Hydrochloride IP (As Sustained Release) 500mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Torrent Pharmaceuticals Ltd.	Deferred (Note 1)
4 (xxiii) c	Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 500mg (as Sustained Release)	1 Tablet	M/s Synokem Pharmaceuticals Pvt. Ltd. / M/s Zydus Healthcare Limited	Deferred (Note 1)
4 (xxiii) d	Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 500mg (as Sustained Release)	1 Tablet	M/s Synokem Pharmaceuticals Pvt. Ltd. / M/s Lupin Limited	Deferred (Note 1)
4 (xxiii) e	Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP	1 Tablet	M/s Synokem Pharmaceuticals Pvt. Ltd. / M/s Eris Lifesciences Limited	Deferred (Note 1)



Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		100mg (As Sustained Release) Metformin Hydrochloride IP 500mg (as Sustained Release)			
4 (xxiii) f	Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 500mg (as Sustained Release)	1 Tablet	M/s Synokem Pharmaceuticals Pvt. Ltd. / M/s Cipla Limited	Deferred (Note 1)
4 (xxiii) g	Vildagliptin (SR) & Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP (As Sustained Release) 100mg Metformin Hydrochloride IP (As Sustained Release) 1000mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Intas Pharmaceuticals Ltd.	Deferred (Note 1)
4 (xxiii) h	Vildagliptin (SR) & Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP (As Sustained Release) 100mg Metformin Hydrochloride IP (As Sustained Release) 1000mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Torrent Pharmaceuticals Ltd.	Deferred (Note 1)
4 (xxiii) i	Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 1000mg (as Sustained Release)	1 Tablet	M/s Synokem Pharmaceuticals Pvt. Ltd. / M/s Lupin Limited	Deferred (Note 1)
4 (xxiii) j	Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As	1 Tablet	M/s Synokem Pharmaceuticals Pvt. Ltd. / M/s Zydus Healthcare Limited	Deferred (Note 1)

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Sustained Release) Metformin Hydrochloride IP 1000mg (as Sustained Release)			
4 (xxiii) k	Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 1000mg (as Sustained Release)	1 Tablet	M/s Synokem Pharmaceuticals Pvt. Ltd. / M/s Eris Lifesciences Limited	Deferred (Note 1)
4 (xxiii) l	Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 1000mg (as Sustained Release)	1 Tablet	M/s Synokem Pharmaceuticals Pvt. Ltd. / M/s Cipla Limited	Deferred (Note 1)
4 (xxiv)	Zinc Sulfate Monohydrate, Sodium Citrate, Potassium Chloride, Sodium Chloride, Dextrose Anhydrous Sachet	Each sachet of 4.38g contains: Zinc Sulfate Monohydrate IP 0.011g Sodium Citrate IP 0.58g Potassium Chloride IP 0.30g Sodium Chloride IP 0.52g Dextrose Anhydrous IP 2.70g	1 Sachet	M/s FDC Limited	6.12

*Note 1: The Authority noted the representation of M/s Torrent Pharmaceuticals Limited (dated 13.03.2023) and Indian Pharmaceuticals Alliance (IPA) (dated 21.03.2023). The main contentions raised in the representation is regarding the price fixation of FDCs vide the captioned meeting (49<sup>th</sup> MDC) by reducing 50% price on the patent component. It is stated in the representations that certain drugs have become off-patent 2 to 3 years back. The prices of the drugs that have become off-patent have since been reasonably reduced as compared to the patent price due to market forces. Accordingly, they requested that 50% reduction on the prices of patented component should not have been carried out and*

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*pricing should have been carried out as per DPCO provisions i.e. the average price of the manufacturer having market share of more than 1%.*

The Authority deliberated upon the matter in detail and decided to refer the matter back to MDC for examination in the light of the representation made by M/s Torrent Pharmaceuticals and IPA.

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

5.1 Noted.

**6. Agenda item no. 6 –Minutes of 49th meeting of Multidisciplinary Committee of Experts held on 23.02.2023.**

Noted

**7. Agenda item no. 7 –Extension of Validity of TMR notification pertaining to Oxygen Concentrators.**

7.1 The Authority deliberated upon the matter and decided that the prices of Oxygen Concentrators as notified vide S.O. 2161 (E) dated 3<sup>rd</sup> June 2021, S.O 4909 (E) dated 30<sup>th</sup> November 2021, S.O. 2465(E) dated 30<sup>th</sup> May 2022, S.O.2983 (E) dated 30<sup>th</sup> June 2022 and S.O. 6177(E) dated 30<sup>th</sup> December 2022 may be extended till 30<sup>th</sup> June 2023 or till further order, whichever is earlier.

**8. Agenda item no. 8 –Extension of Validity of TMR notification pertaining to five medical devices, namely (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer & (v) Glucometer.**

8.1 The Authority deliberated upon the matter and decided that the price of five medical devices, namely, (1) Pulse Oximeter (2) Blood Pressure Monitoring Machine, (3) Nebulizer, (4) Digital Thermometer, and (5) Glucometer as notified vide S.O. 2808 (E) dated 13<sup>th</sup> July 2021, S.O. 401 (E) dated 31<sup>st</sup> January 2022, S.O. 3534 (E) dated 29<sup>th</sup> July 2022 and S.O.6176(E) dated 30<sup>th</sup> December 2022 may be extended till 30<sup>th</sup> June 2023 or till further order, whichever is earlier.

**9. Agenda item no. 9 – Revision of Ceiling Price fixed in 109<sup>th</sup> Authority meeting held on 21.02.2023 for Hormone releasing IUD under Revised Schedule-I (NLEM, 2022).**

9.1 The Authority noted that the methodology for fixation of ceiling price of scheduled formulations under revised Schedule-1 (NLEM) 2022, was deliberated in the 104<sup>th</sup> meeting of Authority held on 23.11.2022. Based on the approved methodology, ceiling prices for Hormone Releasing IUD and IUD containing Copper were uploaded on the NPPA website on 12.01.2023. The ceiling prices were subsequently approved in the 109<sup>th</sup> Authority meeting held on 21.02.2023 and these ceiling prices were notified vide S.O. No. 879(E) dated 24.02.2023.



9.2 However, M/s Bayer Zydus Pharma vide its e-mail dated 28.02.2023 represented that it had sent its representation dated 13.01.2023 against the draft working sheet that was not considered by NPPA while revising the ceiling price of Hormone releasing IUD. The Authority was apprised that representation dated 13.01.2023 was received from M/s Bayer Zydus Pharma and could not be considered earlier wherein it had been informed that in the uploaded draft worksheet, pre-revised PTR of Rs.3255/- of their product "Mirena" was considered as reported by the Pharmatrac and did not capture the post-WPI revised PTR of Rs. 3605/-. The revised PTR was reported to NPPA by the company through Form II filed on 04.04.2022 and Form V on 12.01.2023 through IPDMS within the prescribed time limit.

9.3 The Authority deliberated upon the matter in detail and noted that the company has complied with DPCO provisions and submitted Form II within the prescribed time limit as mentioned in DPCO, 2013. Accordingly, the Authority decided to revise the price in respect of the formulation viz., Hormone releasing IUD, as mentioned in column (6) of the table below.

Table 1

S.No.	Section	Formulation	Dosage form(s) and strength(s)	Ceiling Price notified vide S.O.879(E) dated 24.02.2023	Revised Ceiling Price	Unit
1	2	3	4	5	6	7
1	18.2.2.1	Hormone Releasing IUD	Contains 52 mg of Levonorgestrel	3456.44	3659.68	1 Hormone Releasing IUD

9.4 Further, the Authority also decided that for the period from 24.02.2023 till the date of issue of notification in respect of the above formulation, the prices as notified vide S.O. No. 879(E) dated 24.02.2023 may be treated as operational.

**10. Agenda item no. 10 - Wholesale Price Index as per Para 16 of DPCO 2013 to be applicable from 01.04.2023.**

10.1 The Authority noted that DPIIT, Ministry of Commerce and Industry, Government of India has confirmed the monthly final Wholesale Price Indices (WPI) of all commodities for the year 2022 and 2021 vide O.M. OEA-11025(13)/18/2017-WPD-Part(256) dated 17.03.2023. The Authority deliberated upon the matter in detail and as per provisions of DPCO,2013 approved the WPI @ 12.1218% to be applicable on scheduled formulations w.e.f. 01.04.2023. The Authority further decided to issue an Office Memorandum intimating the WPI to be applicable w.e.f. 01.04.2023 and to issue notification (s) for revised ceiling price of scheduled formulations based on WPI @ 12.1218% to be effective from 01.04.2023.

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

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27/3/2023  
(Dr. Vinod Kotwal)  
Member Secretary