मिसिलस.- 8(117)/2023/डी.पी/एनपीपीए-डीवी-II
F. No. 8(117)/2023/DP/NPPA-Div. II

कार्यवाहीस. : 249/117/2023/F
Proceeding No: 249/117/2023/F

Minutes of the 249th (overall) and 117th meeting of the Authority under DPCO, 2013 held on 13.10.2023 at 11:00 AM.

The 249th meeting of the Authority (overall), which is the 117th meeting under the DPCO, 2013 was held on 13th October, 2023 at 11:00 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 also was present.

I. 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 116th Meeting held on 06.09.2023.

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 116thMeeting held on 06.09.2023.

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 30 Form I applications containing retail price fixation of 30 new drug) falling under the purview of Para 2(1)(u) of DPCO, 2013 and approved the retail prices of 29 (twenty 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

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (i)	Paracetamol, Phenylephrine Hydrochloride, Caffeine & Diphenhydramine Hydrochloride Tablets	**Each uncoated tablet contains:** Paracetamol IP 500mg Phenylephrine Hydrochloride IP 5mg Caffeine (Anhydrous) IP 30mg Diphenhydramine Hydrochloride IP 25mg	1 Tablet	M/s Prosperity Drugs Pvt. Ltd. / M/s Torrent Pharmaceuticals Limited	3.85
4 (ii)	Cilnidipine and Telmisartan Tablets	**Each film coated tablet contains:** Cilnidipine IP 20mg Telmisartan IP 40mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Mankind Pharma Ltd.	14.15
4 (iii)	Ibuprofen Solution for Infusion 400mg/100ml	**Each 100ml contains:** Ibuprofen IP 400mg Water for injection IP	1 ML	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Neon Laboratories Limited	2.63
4 (iv)	Phenylephrine Hydrochloride and Chlorpheniramine Maleate Drops IP	**Each ml contains:** Phenylephrine Hydrochloride IP 5mg Chlorpheniramine Maleate IP 2mg	1 ML	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Apex Laboratories Pvt. Ltd.	4.28
4 (v)	Ofloxacin and Dexamethasone Eye / Ear Drops	**Each ml contains:** Ofloxacin IP 0.3% w/v Dexamethasone Sodium Phosphate IP eq. to Dexamethasone Phosphate 0.1% w/v	1 ML	M/s Axa Parenterals Ltd. / M/s Intas Pharmaceuticals Ltd.	6.00

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Benzalkonium Chloride Solution IP 0.02% (As preservative)			
4 (vi)	Montelukast and Fexofenadine Hydrochloride suspension	**Each 5ml contains:** Montelukast Sodium IP eq. to Montelukast 4mg Fexofenadine Hydrochloride IP 60mg	1 ML	M/s Synokem Pharmaceuticals Ltd. / M/s Cipla Ltd.	1.79
4 (vii)	Trastuzumab 150mg	**Each pack contains:** **Vial-1** Lyophilized Powder for concentrate for solution for Intravenous Infusion, Multi use vial **Composition:** Trastuzumab (r-DNA Origin) IH (Active ingredient) 150mg, α,α-Trehalose Dihydrate USP (as Lyoprotectant) 136.2mg L-Histidine Hydrochloride Monohydrate EP (as buffering agent) 3.36mg L-Histidine USP (as buffering agent) 2.16mg Polysorbate 20 IP (as surfactant) 0.6mg Vial -2 Bacteriostatic Water for Injection 10 ml Single use vial Composition: Benzyl Alcohol IP 1.1% V/V Water for Injection	1 Vial	M/s Hetero Biopharma Limited / M/s Mankind Pharma Limited	Deferred **(Note 1)**
4 (viii)	Linagliptin + Metformin Hydrochloride (ER) Tablet	**Each film coated bilayer tablet contains:** Linagliptin 2.5mg Metformin Hydrochloride (as Extended release) IP 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s ERIS Lifesciences Limited	9.60
4 (ix)	Calcium, Magnesium, Vitamin D3 & Zinc Tablets	**Each uncoated tablet contains:** Calcium Citrate USP 1000mg	1 Tablet	M/s Hanuchem Laboratories / M/s Mankind Pharma Ltd.	9.64

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Vitamin D3 IP 200IU Magnesium Hydroxide IP eq. to elemental magnesium 100mg Zinc Sulphate Monohydrate IP eq. to elemental Zinc 4mg			
4 (x)	Mefenamic Acid + Paracetamol Suspension	**Each 5ml contains:** Mefenamic Acid IP 50mg Paracetamol IP 125mg	1 ML	M/s Innova Captab Limited / M/s Macleods Pharmaceuticals Limited	0.68
4 (xi)	Mefenamic Acid+ Paracetamol Suspension	**Each 5ml contains:** Mefenamic Acid IP 100mg Paracetamol IP 250mg	1 ML	M/s Innova Captab Limited / M/s Macleods Pharmaceuticals Limited	0.82
4 (xii)	Calcium, Vitamin D3 & Vitamin B12 Tablets	**Each film coated tablet contains:** Calcium Carbonate 1250mg from an organic source (Oyster shell) eq. to Elemental Calcium 500mg Vitamin D3 IP 500 IU Vitamin B12 IP 15mcg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Cipla Ltd.	8.58
4 (xiii)	Atorvastatin, Clopidogrel and Aspirin Capsules	**Each hard gelatin capsule contains:** Atorvastatin Calcium IP eq. to Atorvastatin 40mg (As two film coated tablet) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg, Aspirin IP 75mg (As Gastro-resistant tablet)	1 Capsule	M/s Safetab Life Science / M/s Lupin Limited	13.22
4 (xiv)	Ferrous Ascorbate, Folic Acid, Zinc & Cyanocobalamin Tablets	**Each film coated tablet contains:** Ferrous Ascorbate IP eq. to Elemental Iron 100mg Folic Acid IP 1.5mg Zinc Sulphate Monohydrate IP eq. to Elemental Zinc 22.5mg Cyanocobalamin IP 15mcg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Cipla Ltd.	10.37

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (xv)	Methylcobalamin, Nicotinamide, Pyridoxine Hydrochloride & D-panthenol Injection	**Each 2ml contains:** Methylcobalamin IP 1000mcg, Nicotinamide 100mg, Pyridoxine Hydrochloride IP 100mg, D-panthenol IP 50mg Benzyl Alcohol IP 2% v/v (As preservative)	Per vial of 2ml	M/s Fast Pharma Pvt. Ltd. / M/s German Remedies Pharmaceuticals Pvt. Ltd.	66.50
4 (xvi)	Atorvastatin & Ezetimibe Tablets	**Each film coated tablet contains:** Atorvastatin Calcium IP eq. to Atorvastatin 40mg Ezetimibe IP 10mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Emcure Pharmaceuticals Limited	32.61
4 (xvii)	Glycopyrronium + Formoterol Fumarate + Budesonide powder for Inhalation	**Each capsule contains:** Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate 12mcg Glycopyrrolate IP eq. to Glycopyrronium 25mcg Budesonide IP 400mcg	1 Capsule	M/s Penta Kraft / M/s Mankind Pharma Ltd.	12.98
4 (xviii)	Omeprazole & Domperidone Capsules IP	**Each hard gelatin capsule contains:** Omeprazole IP 20mg (As enteric coated pellets) Domperidone IP 10mg (As coated pellets)	1 Capsule	M/s Prochem Pharmaceuticals Pvt. Ltd. / M/s German Remedies Pharmaceuticals Pvt. Ltd.	6.14
4 (xix)	Nimesulide& Paracetamol tablet	**Each uncoated tablet contains:** Nimesulide BP 100mg Paracetamol IP 325mg	1 Tablet	M/s Lucent Biotech Limited / M/s Torrent Pharmaceuticals Ltd.	3.91
4 (xx)	Sitagliptin Phosphate & Metformin Hydrochloride Tablet	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP 64.25mg eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Windlas Biotech Limited	9.16
4 (xxi)	Sitagliptin Phosphate & Metformin	**Each film coated tablet contains:** Sitagliptin Phosphate	1 Tablet	M/s Windlas Biotech Limited	10.37

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Hydrochloride Tablet	Monohydrate IP 64.25mg eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg			
4 (xxii) a	Sitagliptin, Pioglitazone and Metformin Hydrochloride (Sustained Released) Tablet	**Each film coated Bilayered Tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg Metformin Hydrochloride IP 1000mg (Sustained Release Form)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Zuventus Healthcare Limited	17.16
4 (xxii) b	Sitagliptin, Pioglitazone and Metformin Hydrochloride (Sustained Released) Tablet	**Each film coated Bilayered Tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg Metformin Hydrochloride IP 500mg (Sustained Release Form)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Zuventus Healthcare Limited	16.09
4 (xxii) c	Sitagliptin, Pioglitazone and Metformin Hydrochloride (Sustained Released) Tablet	**Each film coated Bilayered Tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg Metformin Hydrochloride IP 1000mg (Sustained Release Form)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Primus Remedies Pvt. Ltd.	17.16
4 (xxii) d	Sitagliptin, Pioglitazone and Metformin	**Each film coated Bilayered Tablet contains:**	1 Tablet	M/s Akums Drugs & Pharmaceuticals	16.09

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Hydrochloride (Sustained Released) Tablet	Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg Metformin Hydrochloride IP 500mg (Sustained Release Form)		Ltd. / M/s Primus Remedies Pvt. Ltd.	
4 (xxiii) a	Linagliptin + Metformin Hydrochloride (ER) Tablet	**Each film bilayer coated tablet contains:** Linagliptin 5mg Metformin Hydrochloride (as Extended release) IP 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s ERIS Lifesciences Limited	14.37
4 (xxiii) b	Linagliptin + Metformin Hydrochloride (ER) Tablet	**Each film coated Bilayered tablet contains:** Linagliptin 5mg Metformin IP 1000mg Hydrochloride (as Extended release)	1 Tablet	M/s Alkem Health Science (A unit of Alkem Laboratories Ltd.) / M/s Alkem Laboratories Ltd.	14.37
4 (xxiii) c	Linagliptin + Metformin Hydrochloride (ER) Tablet	**Each film coated Bilayered tablet contains:** Linagliptin 5mg Metformin Hydrochloride IP 500mg (as Extended release)	1 Tablet	M/s Alkem Health Science (A unit of Alkem Laboratories Ltd.) / M/s Alkem Laboratories Ltd.	12.92
4 (xxiv) a	Dapagliflozin, Sitagliptin and Metformin Hydrochloride Tablets	**Each film coated tablet contains:** Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Eris Lifesciences Limited	14.62
4 (xxiv) b	Dapagliflozin, Sitagliptin and Metformin	**Each film coated tablet contains:** Dapagliflozin	1 Tablet	M/s Exemed Pharmaceuticals / M/s Eris	13.55

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Hydrochloride Tablets	Propanediol Monohydrate eq. to Dapagliflozin 5mg Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg		Lifesciences Limited	

Note 1: The Authority deliberated on the agenda item and observed that further necessary clarifications are required from the company regarding per ml composition, pack size etc. of the subject formulation. Hence, agreed to defer the agenda item.

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

5.1 Noted

6. Agenda item no. 6 –Minutes of 54thmeeting of Multidisciplinary Committee of Experts held on 15.09.2023.

6.1 Noted

7. Agenda item no. 7 –Application by M/s Cadila Pharmaceuticals Limited for exemption from the provisions of Drug Price Control Order 2013 under Para 32 (i) & (ii) for their product Cholecalciferol Aqueous Injection 6,00,000 IU/2ml (Vitamin D3 Injection)".

7.1 The Authority noted that M/s Cadila Pharmaceuticals Limited has applied for exemption from the provisions of Drug Price Control Order 2013 under Para 32 (i) & (ii) for their product Cholecalciferol Aqueous Injection 6,00,000 IU/2ml (Vitamin D3 Injection).

7.2 The Authority noted that the matter was deliberated in 54th meeting of MDC held on 15.09.2023 wherein the Committee examined the submission of the applicant with respect to the need, benefits, and superiority of an Aqueous Parenteral composition of Vitamin D3 claimed and recommended that exemption may be granted to M/S Cadila Pharmaceuticals Ltd under Para 32 (i) and (ii) based on the inputs of the Patent Office.

7.3 The Authority also noted the inputs from Patent Office received vide mail dated 15.08.2023 which are reproduced below:

Analysis of the granted Patent No. 431119:
"A stable aqueous parenteral composition comprising 300000 to 600000 IU/ml of Vitamin D3 along with other excipients as well as a process for preparation of

the same has been granted a patent (Patent No. 431119). The title of the specification is AN AQUEOUS PARENTERAL COMPOSITION OF VITAMIN D3.

As sought to provide confirmation as per the letter dated 20.07.2023 of NPPA, the formulation i.e., Cholecalciferol aqueous injection 6,00,000 IU/2ml (Vitamin D3 injection) and the process through which it is developed are covered under the scope of Patent granted for "AN AQUEOUS PARENTERAL COMPOSITION OF VITAMIN D3" to M/s Cadila Pharmaceuticals Limited, it is informed that the same is within the scope of the patent granted.

Vitamin D3 is otherwise known as cholecalciferol and the composition comprising the same as granted is 300000 to 600000 IU/ml of Vitamin D3 or 600000 IU/2ml if the lower side range is considered."

7.4 The Authority deliberated upon the inputs of the Patent office and the recommendation of the MDC that exemption may be granted to M/s Cadila Pharmaceuticals Limited under Para 32(i) and 32(ii) of DPCO, 2013 with respect to the formulation "Cholecalciferol Aqueous Injection 6,00,000 IU/2ml (Vitamin D3 Injection)" as the same is covered under the scope of patent granted by the Patent Office. Accordingly, it was agreed that since M/s Cadila Pharmaceuticals Limited fulfills the conditions as per Para 32(i) & 32 (ii) of DPCO, 2013 w.r.t. the formulation and the process for "Cholecalciferol Aqueous Injection 6,00,000 IU/2ml (Vitamin D3 Injection)" exemption be granted to M/s Cadila Pharmaceuticals Limited under Para 32(i) & (ii) of DPCO, 2013 for the said formulation for a period of five years from the date of commencement of its commercial marketing by the manufacturer in the country or expiry of Indian Patent, whichever is earlier.

7.5 The Authority further directed that M/s Cadila Pharmaceuticals Limited shall intimate the date of commercial marketing of the said formulation in the country, the Price to Retailer (PTR) and Maximum Retail Price fixed by the company in respect of above formulation by issuing a price list in Form V under DPCO, 2013.

7.6 The Authority also directed that M/s Cadila Pharmaceuticals Limited shall seek retail price approval for the formulation, if applicable, three months before the expiry of the exemption period of five years granted under Para 32(i) & 32(ii) of DPCO 2013.

8. Agenda item no. 8 –Application filed by M/s Panacea Biotec Limited for exemption under para 32 (i) to (iii) of DPCO, 2013 for their product EasyfourPol (DTwP-Hib-IPV) Vaccine.

8.1 The Authority noted that M/s Panacea Biotec Limited had filed Form I application dated 22.09.2022 for retail price approval for their product Easy fourPol (DTwP-Hib-IPV) Vaccine each dose of 0.5ml containing Diphtheria Toxoid ≥ 30IU, Tetanus Toxoid ≥ 60IU, Inactivated w-B.pertussis ≥4 IU Purified capsular polysaccharide of Haemophilus influenza type b conjugated to 18-33 µg of Tetanus Toxoid (carrier protein) 10 µg, Inactivated Salk Poliovirus Type1* 40 DU**,Inactivated Salk Poliovirus Type2*8 DU**, Inactivated Salk Poliovirus Type 3*32 DU**,Aluminum content(AI+++) (As Aluminum Phosphate gel NMT 1.25mg, 2-Phenoxyethanol 3.3mg and Physiological saline q.s for the said vaccine.

8.2 It was noted that the said vaccine is not covered under UIP as per confirmation received from MoH&FW vide their letter dated 11.11.2022.

8.3 When the matter was under consideration by MDC, the applicant vide letter dated 10.02.2023 stated that they have inadvertently applied for the retail price fixation & their product is covered under Patent granted by Indian patent office and requested to consider the same under Para 32 of DPCO, 2013.

8.4 The matter was deliberated in the 49th meeting of MDC held on 23.02.2023 wherein Committee directed the applicant to apply afresh under Para 32 of DPCO, 2013 with all the requisite documents.

8.5 The Authority noted that M/s Panacea Biotech Limited vide e-mail dated 06.03.2023 applied for the exemption under Para 32 for the said vaccine & further submitted on 29.06.2023 that exemption may be granted under Para 32(i).

8.6 The Authority observed the Patent issued by the Patent Office under Indian Patent Act, 1970 dated 30.03.2016 for "Novel Combination Vaccines with Whole Cell Perutssis and method of manufacturing the same" bearing registration no. 272351 along with the claim filed with Patent Office (Application No. 2437/DEL/2008) as provided by M/S Panacea Biotech Limited. The Authority deliberated upon the inputs from Patent office as received vide mail dated 23.06.2023 which read as below:

> *".....and to inform you that the product for which the exemption is applied, i.e.EasyfourPol Vaccine, containing "Adsorbed Diphtheria, Tetanus, Pertussis, Poliomyelitis (Inactivated) and Haemophilus Influenzae Type b Conjugate Vaccine IP" is covered under the scope of Patent No. 272351 granted for "Novel Combination Vaccines with Whole Cell Perutssis and method of manufacturing the same" to M/s Panacea Biotech Limited."*

8.7 The Authority also noted that the matter was placed in the 54thmeeting of MDC held on 15.09.2023, wherein the Committee deliberated upon the inputs of the Patent office in detail and observed that M/s Panacea Biotech Limited fulfills the conditions of Para 32(i) of DPCO, 2013 with respect to the formulation EasyfourPol Vaccine containing "Adsorbed Diphtheria, Tetanus, Pertussis, Poliomyelitis (Inactivated) and Haemophilus Influenza Type b Conjugate Vaccine IP". Hence, the Committee recommended that exemption may be granted to M/s Panacea Biotech Limited under Para 32(i) of DPCO, 2013 with respect to the formulation EasyfourPol Vaccine containing "Adsorbed Diphtheria, Tetanus, Pertussis, Poliomyelitis (Inactivated) and Haemophilus Influenzae Type b Conjugate Vaccine IP".

8.8 The Authority deliberated on the matter in detail and based on the recommendation of Multi Disciplinary Committee & inputs of the Patent office decided that exemption may be granted to M/S Panacea Biotech Limited for the said vaccine under Para 32 (i) of DPCO 2013 for a period of five years from the date of commencement of its commercial marketing by the manufacturer in the country or expiry of Indian Patent, whichever is earlier.

8.9 The Authority further directed that M/s Panacea Biotech Limited shall intimate the date of commercial marketing of the said vaccine in the country, the Price to Retailer (PTR) and Maximum Retail Price fixed by the company in respect of above said vaccine by issuing a price list in Form V under DPCO, 2013.

8.10 The Authority also directed that M/s Panacea Biotech Limited shall seek retail price approval for the said vaccine if applicable, three months before the expiry of the exemption period of five years granted under Para 32(i) of DPCO 2013.

9. Agenda item no. 9 – Retail Price fixation of formulation "Formoterol Fumarate Dihydrate 6mcg + Beclomethasone Dipropionate IP 100 mcg Inhaler (MDI) for M/s Cipla Limited in view of DoP's Review Order dated 03.10.2022.

9.1 The Authority noted that DoP has issued review order dated 3.10.2022 wherein it was stated that the matter requires remand for fresh orders on merits by MDC and NPPA after analysis of entire facts to avoid miscarriage of justice. Accordingly, the matter was referred back to NPPA to consider the issues raised by the applicant and to pass an appropriate order.

9.2 The Authority recalled that the matter was placed in 47th and 49th meeting of MDC held on 2.12.2022 and 23.02.2023 respectively. The MDC had directed M/s Cipla to provide the requisite documents (published literature, product duly approved by regulator/ licensing authority and proper label claim demonstrating the efficacy of the product) within one week and if the same were not received within due time, the matter would be treated as closed. M/S Cipla did not submit the documents. The matter was accordingly, placed in the 112th Authority meeting held on 01.05.2023. Since the recommendation by the MDC were conditional, the Authority referred the matter back to MDC to provide clear recommendations in the matter.

9.3 The matter was deliberated again by MDC in its 52ndand 53rd meeting held on 11.07.2023 and 8.08.2023 respectively wherein the committee undertook point-wise examination of the issue placed before it and also directed that Writ Petitions (W.P.) filed by the applicant and counter affidavit (if any) filed by NPPA may be examined and placed in MDC meeting. The Authority noted that the detailed examination of the W.P.s filed by the applicant was placed in 54th meeting of the MDC held on 15.09.2023.

9.4 The MDC deliberated and examined in detail the issues raised by M/s Cipla in the W.Ps relating to product having extra fine particles, development of the formulation by a complex manufacturing process compared to the competitor, additional price on account of digital counter, and issue related to non-filing of application for separate price under para 11 (3) by M/S Cipla. It was observed that M/s Cipla has neither provided the requisite DCGI approval for the product with extra features nor submitted till date the documents as were requested in the 47th MDC meeting. Hence, after detailed deliberations, MDC did not find any merit and recommended that the matter may be treated as closed.

9.5 The Authority deliberated in detail on the above recommendation of the MDC made in its 54th meeting held on 15.9.2023 and decided that the matter may be treated as closed

10. Agenda item no. 10 – Retail Price fixation of new drugs for which MDC has already recommended a methodology

10.1 The applications for retail price fixation of the new drugs for which market-based data is not available are placed before MDC as per provisions of Para 5(2) of DPCO, 2013. The prices recommended by the MDC are placed for approval of the Authority.

10.2 The Authority observed that MDC in its 53rd meeting held on 08.8.2023 observed that in some cases, similar procedure is being followed for fixing the price of same formulations with only change of month when a new application is received. The retail price recommended in earlier meetings for a particular formulation for a specific company is being placed again before the MDC with data of new month for a new applicant. In such cases, the MDC has recommended as below:

> *"The Committee has observed that retail price recommended in earlier meetings for a particular formulation for a specific company are being again placed before the MDC in case of different applicant. Since, the basic methodology followed is same and only the data of calculations changes, the Committee is of the view that for the formulations for which once the retail price is recommended by the MDC, other applications may be placed before the committee, when change in circumstances requires deliberations. Accordingly, MDC recommends that the matter may be placed before the Authority for consideration."*

10.3 The Authority noted that as per the present practice, if the data of requisite month i.e. data of the month ending immediately before six months of receipt of application is not available in Pharmatrac, such cases are referred to MDC even if, the price of same formulation has been fixed earlier for other applicants based on recommendation of MDC. The retail price calculated may be different from the earlier recommended price for other applicants due to change in data to be considered i.e., 6 months prior to the date of application.

10.4 The Authority discussed the recommendation of MDC as mentioned in para 10.2 above and it was decided that the matter needs further deliberation.

11. Agenda item no. 11 – Issue related to the Ceiling Price Notifications after considering WPI @ 12.1218%increase, released on 31.03.2023 (S.O. No. 1568(E) to 1580(E) wherein, NPPA has rounding off to the bottom zero instead of rounding off to the nearest zero.

11.1 The Authority noted that Ceiling prices of the scheduled formulations were revised by NPPA based on Wholesale Price index @ 12.1218% for the year 2023 vide notification No. 1568 (E) to 1580(E) dated 31.03.2023.

11.2 Review applications have been filed by two companies before DoP stating that while revising the ceiling prices in the said notifications, the ceiling price for all

formulations has been incorrectly rounded down by NPPA rather than to the nearest zero.

11.3 The Authority noted that in the past, the ceiling prices of formulations have been revised by considering rounding off up to two decimal points i.e. second decimal point rounded off based on third decimal figure. However, inadvertently the same practice has not been followed for the year 2023 and NPPA while revising the ceiling prices has ignored the third digit. This has resulted in lower/decreased ceiling price for some formulations by Rs.0.01 per unit. The Authority noted that the ceiling prices of 905 scheduled formulations (651 fixed under NLEM 2022 & 254 fixed under earlier NLEMs) were revised based on change in WPI of 12.1218% with effect from 01.04.2023.

11.5 The Authority deliberated upon the matter in detail and it was decided that ceiling prices as notified vide SO no. 1568 (E) to 1580(E) dated 31.03.2023 may be amended in r/o those formulations where non-consideration of third decimal figure has resulted in lower/decreased ceiling price for some formulations by Rs.0.01 per unit.

12. Agenda item no. 12 - Application received from the marketers for continuation of prevailing prices after change of manufacturer for the formulations for which retail price already notified and launched in the market.

12.1 The Authority in its 113th and 115th meeting held 26.05.2023 and 31.07.2023 respectively had framed the guidelines for examining the cases of continuation of same retail price by the marketers, in case of change of manufacturer by them for formulations for which retail price has been already notified by NPPA. Further, the formulation were launched in the market under a specified brand. The guidelines were framed to ensure consistency and predictability in examination of such cases.

12.2 The Authority noted that applications have been received from marketing companies wherein they have proposed to manufacture the formulations (as per Table 2 below) at their own manufacturing plant rather than with their present manufacturers and market under the same brand name at current MRP. Hence, the marketing companies have requested for allowing continuation of retail price already approved on change of manufacturer.

12.3 The Authority deliberated upon the matter in detail noted that the marketing companies who intend to shift the manufacturing activity to their own plant have already launched the formulations and have approved and notified retail price from NPPA. Hence, the Authority approved that such marketers may be permitted to manufacture and market the formulations under their existing (same) brand at the NPPA approved retail price not exceeding the present applicable retail price for already launched formulations.

Table 2

S.No	Formulation	S. O. No	Present Marketer and Manufacturer	Proposed Marketer and Manufacturer
1	Each uncoated bilayered tablet contains Glimepiride 3mg + Metformin HCl 500mg (in sustained release form) under the brand name "Azulix 3MF"	S.O No. 2105(E) dated 20.08.2014	M/s Torrent Pharmaceuticals (Marketer) Ltd. and M/s Windlas Biotech Limited (Manufacturer)	M/s Torrent Pharmaceuticals Ltd.
2	Each uncoated bilayered tablet contains Glimepiride 4mg + Metformin HCl 500mg (in sustained release form) under the brand name "Azulix 4 MF"	S.O No. 2105(E) dated 20.08.2014	M/s Torrent Pharmaceuticals (Marketer) Ltd. and M/s Windlas Biotech Limited (Manufacturer)	M/s Torrent Pharmaceuticals Ltd
3	Each hard gelatin capsule containing Rosuvastatin Calcium eq. to Rosuvastatin 10mg (as pellets] Aspirin IP 75mg (as enteric coated pellets) Clopidogrel BisulphateIP eq. to Clopidogrel 75mg (as pellets)under the brand name "Unistar Gold 10"	S. O No. 3982(E) dated 13.08.2018	M/s Torrent Pharmaceuticals (Marketer)Ltd. And M/s Synokem Pharmaceuticals Ltd. (Manufacturer)	M/s Torrent Pharmaceuticals Ltd.
4	Each hard gelatin capsule containing Rosuvastatin Calcium eq. to Rosuvastatin 20mg (as pellets). Aspirin IP 75mg (as enteric coated pellets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (as pellets) under the brand name "Unistar Gold 20"	S. O No. 3982(E) dated 13.08.2018	M/s Torrent Pharmaceuticals (Marketer) Ltd. and M/s Synokem Pharmaceuticals Ltd. (Manufacturer)	M/s Torrent Pharmaceuticals Ltd.

S.No	Formulation	S. O. No	Present Marketer and Manufacturer	Proposed Marketer and Manufacturer
5	Each hard gelatine capsule contains: Rosuvastatin Calcium eq. to Rosuvastatin 10mg (As pellets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (as pellets) under the brand name "Rozuplatt Capsules"	S.O No. 1689(E) dated 24.05.2017	M/s Torrent Pharmaceuticals (Marketer)and M/s Synokem Pharmaceuticals Ltd. (Manufacturer)	M/s Torrent Pharmaceuticals Ltd.
6	Each film coated tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg + Metformin Hydrochloride IP 500mg (as Extended Release) under the brand name "Istamet D-XR 500 MG tablet", " Oxramet-S XR 500 MG tablet", " Sitared-MD XR 500 MG tablet"	S.O No. 878(E) dated 24.02.2023	M/s Sun Pharma Laboratories Limited (Marketer) and M/s Exemed Pharmaceuticals (Manufacturer)	M/s Sun Pharma Laboratories Limited

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

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19/10/2023

(Dr. Vinod Kotwal)
Member Secretary