

मिसिलस.- 8(101)/2022/डी.पी/एनपीपीए-डीवी-II
F. No. 8(101)/2022/DP/NPPA-Div. II

कार्यवाहीस. : 233/101/2022/F
Proceeding No: 233/101/2022/F

Minutes of the 233rd(overall) and 101stmeeting of the Authority under DPCO, 2013 held on 07.09.2022 at 11:30 AM

The 233rdmeeting of the Authority (overall), which is the 101stmeeting under the DPCO, 2013, was held on 07th of September at 3:30 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) Ms. Manisha Sensarma, Advisor, Department of Economic Affairs

Shri A. K. Pradhan, Jt. Drug Controller, CDSCO, Ministry of Health & Family Welfare also was present and joined through video-conferencing.

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 (OC & Medical Device)
- (iv) Shri Prasenjit Das, Deputy Director (Pricing)
- (v) Shri Mahaveer Saini, Deputy Director (Pricing)
- (vi) Shri Rajesh Kumar T., Deputy Director (Medical Device, Legal & IT)

1.2 Chairman, NPPA and other Authority members welcomed Shri G. Venkatesh, Advisor (Cost), the new Authority member who joined in place of Shri Amardeep Singh Chowdhury, Advisor (Cost). The excellent contribution made by Shri Amardeep Singh Chowdhury, Advisor (Cost) during his tenure as Authority member was also appreciated.

II. Agenda items

1. Agenda item no. 1 - Confirmation of Minutes of the 100thMeeting held on 05.08.2022

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 100th Meeting held on 05.08.2022

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(xxiii) (n) (total 36 Form I applications containing retail price fixation of 36 new drugs) falling under the purview of Para 2(u) of DPCO, 2013 and approved the retail prices of 36(thirty six) new drugs under Para 5 and 15 of the DPCO 2013, as detailed below:

Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(i)a	Dapagliflozin & Metformin Hydrochloride Extended-Release Tablets	Each film coated tablet contains: Metformin Hydrochloride...500mg (as extended-release form) Dapagliflozin Propanediol Monohydrate eq to Dapagliflozin 10mg	1 Tablet	M/s Synokem Pharmaceutical Ltd. / M/s Hetero Healthcare Ltd.	9.27 (Note 1)
4(ii)	Sodium Alginate, Sodium Bicarbonate & Calcium Carbonate Oral Suspension	Each 5ml Contains: Sodium Alginate IP 250mg, Sodium Bicarbonate IP 133.5mg, Calcium Carbonate IP 80mg	1 ml	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Cadila Pharmaceuticals Ltd.	0.88
4(iii)	Cilnidipine & Metoprolol Succinate (ER) Tablets	Each film coated bilayered tablet contains: Cilnidipine IP 10mg Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate 25mg (as extended-release form)	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Troikaa Pharmaceuticals Ltd.	7.22
4(iv)	Cilnidipine & Metoprolol Succinate (ER) Tablets	Each film coated bilayered tablet contains: Cilnidipine IP 10mg Metoprolol Succinate IP eq. to Metoprolol Tartrate 50mg (as extended-release form)	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Troikaa Pharmaceuticals Ltd.	9.25
4(v)	Paracetamol Infusion IP (1%w/v)	Each 100ml contains: Paracetamol IP 1000mg water for Injection IPq.s.	1 ml	M/s R. K. Laboratories (P) Ltd. / M/s Mankind Prime Labs Pvt. Ltd.	3.02
4(vi)	Telmisartan & Metoprolol Succinate (ER) Tablets	Each film coated tablets contains: Telmisartan IP 40mg Metoprolol Succinate IP 25mg (As Extended-release form)	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Indchemie Health Specialities Pvt. Ltd.	12.01

Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(vii)	Telmisartan, Amlodipine & Hydrochlorothiazide Tablets	Each film coated tablets contains: Telmisartan IP 80mg Amlodipine Besilate IP eq. to Amlodipine 5mg Hydrochlorothiazide IP 12.5mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Cipla Ltd.	15.15
4(viii)	Telmisartan & Metoprolol Succinate (ER) Tablets	Each film coated tablets contains: Telmisartan IP 40mg Metoprolol Succinate IP 50mg (As Extended-release form)	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Indchemie Health Specialities Pvt. Ltd.	14.03
4(ix)	Etoricoxib and Paracetamol Tablets	Each Film Coated tablet contains: Etoricoxib IP 60 mg Paracetamol IP 325 mg	1 Tablet	M/s Theon Pharmaceuticals Ltd. / M/s Wockhardt Limited	8.03
4(x)	Amoxycillin & Potassium Clavulanate Oral Suspension IP	Each 5ml of constituted suspension contains: Amoxycillin Trihydrate IP eq. to Amoxycillin 600mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 42.9mg	1 ml	M/s Malik Lifesciences Pvt. Ltd. / M/s Mankind Pharma Ltd.	3.24
4(xi)	Aspirin Gastro-resistant and Atorvastatin Capsules	Each hard gelatin capsule contains: Aspirin IP (as Gastro-resistant Tablet IP) 75mg Atorvastatin Calcium IP eq. To Atorvastatin IP 20mg	1 Capsule	M/s Tristar Formulations Pvt. Ltd. / M/s Mankind Pharma Limited	2.93
4(xii)	Metoprolol Succinate (As Extended Release), Cilnidipine & Telmisartan Tablets	Each film coated tablet contains: Metoprolol Succinate IP 23.75mg eq. to Metoprolol tartrate 25mg (As Extended Release) Cilnidipine IP 10mg Telmisartan IP 40mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Cipla Ltd.	10.04
4(xiii)	Metoprolol tartrate and Ivabradine Tablets	Each film coated tablet contains: Metoprolol tartrate IP 50mg Ivabradine Hydrochloride eq. to Ivabradine 5mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Cipla Ltd.	16.70
4(xiv)	Beclomethasone Dipropionate, Neomycin Sulphate & Clotrimazole Cream	Composition: Beclomethasone Dipropionate IP 0.025% w/w Neomycin Sulphate IP eq. to Neomycin 0.50% w/w Clotrimazole IP 1.00% w/w	1 gm	M/s Curetech Skincare / M/s Eris Healthcare Pvt. Ltd.	5.65

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Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(xv)	Metoprolol tartrate and Ivabradine Tablets	Each film coated tablet contains: Metoprolol tartrate IP 25mg Ivabradine Hydrochloride eq. to Ivabradine 5mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Cipla Ltd.	14.56
4(xvi)	Thiocolchicisid, Aceclofenac and Paracetamol Tablets	Each film coated tablet contains: Thiocolchiciside IP 8mg Aceclofenac IP 100mg Paracetamol IP 325mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Micro Labs Ltd.	18.75
4(xvii)	Thiocolchicisid, Aceclofenac and Paracetamol Tablets	Each film coated tablet contains: Thiocolchiciside IP 4mg Aceclofenac IP 100mg Paracetamol IP 325mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Micro Labs Ltd.	16.07
4(xviii)	Tranexamic Acid & Mefenamic Acid tablets	Each film coated tablet contains: Tranexamic Acid IP 500mg Mefenamic Acid IP 250mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Micro Labs Ltd.	26.79
4(xix)	Telmisartan, Chlorthalidone & Metoprolol (ER) Tablets	Each film coated bilayered tablet contains: Telmisartan IP 40mg, Chlorthalidone IP 12.5mg Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate 50mg (as extended release)	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Mankind Pharma Ltd.	13.40
4(xx)	Metoprolol Succinate (As Extended Release), Cilnidipine & Telmisartan Tablets	Each film coated tablet contains: Metoprolol Succinate IP 47.50mg eq. to Metoprolol tartrate 50mg (As Extended Release) Cilnidipine IP 10mg Telmisartan IP 40mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Cipla Ltd.	12.46
4(xxi)	Povidone-Iodine Ointment USP	Composition: Povidone-Iodine IP 5%w/w (Available Iodine 0.5%w/w)	1 gm	M/s Nanz Med Science Pharma Pvt. Ltd. / M/s Torrent Pharmaceuticals Ltd.	1.66
4(xxii)	Esomeprazole and Domperidone Sustained Release capsule	Each Hard Gelatin Capsule Contains: Esomeprazole Magnesium Trihydrate IP eq. to Esomeprazole 40mg (as enteric coated pellets) Domperidone IP 30mg (as sustained release pellets)	1 Capsule	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Cadila Pharmaceuticals Ltd.	11.32
4(xxiii)a	Sitagliptin Phosphate and Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Aprica Healthcare Limited	18.34 (Note 2)
	Sitagliptin and	Each film coated	1 Tablet	M/s Mascot Health	18.67



Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(xxiii)b	Metformin Hydrochloride (SR) Tablets	bilayered tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg (As Sustained release)		Series Pvt. Ltd. / M/s Aprica Healthcare Limited	(Note 2)
4(xxiii)c	Sitagliptin and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg (As Sustained release)	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Aprica Healthcare Limited	20.06 (Note 2)
4(xxiii)d	Sitagliptin Phosphate and Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Aprica Healthcare Limited	20.02 (Note 2)
4(xxiii)e	Sitagliptin and Metformin Hydrochloride (ER) Tablets	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg (as Extended-Release Form)	1 Tablet	M/s Theon Pharmaceuticals Ltd. / M/s German Remedies Pharmaceuticals Pvt. Ltd.	18.67 (Note 2)
4(xxiii)f	Sitagliptin and Metformin Hydrochloride (ER) Tablets	Each bilayered film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (as Extended-Release Form)	1 Tablet	M/s Theon Pharmaceuticals Ltd. / M/s German Remedies Pharmaceuticals Pvt. Ltd.	20.17 (Note 2)
4(xxiii)g	Sitagliptin and Metformin Hydrochloride (ER) Tablets	Each bilayered film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (as Extended-Release Form)	1 Tablet	M/s Theon Pharmaceuticals Ltd. / M/s German Remedies Pharmaceuticals Pvt. Ltd.	21.56 (Note 2)
4(xxiii)h	Sitagliptin and Metformin Hydrochloride (ER) Tablets	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg (as Extended-	1 Tablet	M/s Theon Pharmaceuticals Ltd. / M/s German Remedies Pharmaceuticals Pvt. Ltd.	20.06 (Note 2)



Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Release Form)			
4(xxiii)i	Sitagliptin and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (As Sustained release)	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	20.17 (Note 2)
4(xxiii)j	Sitagliptin and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (As Sustained release)	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	21.56 (Note 2)
4(xxiii)k	Sitagliptin and Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Hetero Labs Ltd. / M/s Hetero Healthcare Ltd.	14.28 (Note 2)
4(xxiii)l	Sitagliptin and Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Hetero Labs Ltd. / M/s Hetero Healthcare Ltd.	15.17 (Note 2)
4(xxiii)m	Sitagliptin Phosphate and Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Psychotropics India Limited	17.87 (Note 2)
4(xxiii)n	Sitagliptin Phosphate and Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Psychotropics India Limited	16.37 (Note 2)

Note 1. The Authority deliberated upon the matter in detail and decided to approve the retail price in line with the decision as recorded in Note 5 of Para 4.1 of the Minutes of the 96th Authority meeting dated 24.03.2022



Note 2. The Authority deliberated upon the matter in detail and decided to approve the retail price in line with the decision as recorded in Note 7 of Para 4.1 of the Minutes of the 96th Authority meeting dated 24.03.2022.

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

5.1 Noted.

6. Agenda item no. 6 –Minutes of 44thmeeting of Multidisciplinary Committee of Experts held on 04.08.2022.

6.1 Noted.

6.2 The Minutes of the meeting regarding applications for special price for incremental innovations pending before the Multidisciplinary Committee of Experts are brought to the notice of Authority. The Authority noted the minutes and stressed the need for disposing the applications expeditiously.

7. Agenda item no. 7 - Launch of “Each hard gelatin capsules containing Rosuvastatin 10mg + Clopidogrel 75mg” by M/s Sun Pharmaceutical Industries Ltd without obtaining prior price approval –Fixation of Retail price thereon.

7.1 The Authority deliberated upon the matter in detail regarding the need for price fixation of each hard gelatin capsules containing Rosuvastatin 10mg + Clopidogrel 75mg” due to launch of the same by M/s Sun Pharmaceutical Industries Ltd without obtaining prior price approval. Accordingly, the Authority approved the retail price of ‘each hard gelatin capsules containing Rosuvastatin 10mg + Clopidogrel 75mg’ for M/s Sun Pharmaceutical Industries Ltd at Rs. 13.02 per capsules excluding GST.

8. Agenda item no. 8 - Application by M/s Axa Parenterals Ltd. for separate price of non-glass innovative single use eye drops (preservative free)

8.1 The Authority noted the applications filed by M/s Axa Parenterals Ltd for separate price for non-glass innovative single use eye drops (preservative free) of various formulations. The Authority also noted that the Multidisciplinary Committee of Experts in its 44th meeting dated 04.08.2022 recommended for rejection of the application since the requisite data specific to the product under reference, *inter-alia*, including harmful effects of using preservatives as sought by the Committee could not be provided by M/s Axa Parenterals Ltd. The Authority deliberated upon the matter in detail and agreed with the recommendations of Multidisciplinary Committee to reject the application of M/s Axa Parenterals Ltd for separate price of non-glass innovative single use eye drops (preservative free). In this connection, Authority also noted that in the cases where pharma companies are claiming improved therapeutic efficacy, such

claims should be endorsed from the competent authorities like Central Drugs Standard Control Organisation (CDSCO).

9. Agenda item no. 9 - Ceiling Prices of Orthopaedic Knee Implants for Knee Replacement System.

9.1 The Authority noted that the knee implants ceiling prices were notified vide notification S.O 3670(E) dated 10th September 2021 which is in force up to 15th September 2022. The Authority deliberated upon the matter in detail and noted the following requests made by various industry associations:

(i) For a one-time relief in the pricing of Knee Implant by invoking Para 19 of DPCO; and
(ii) To consider 20% increase in the ceiling price of knee implants on account of fluctuations in foreign exchange; increase in manpower cost, freight cost, WPI; and supply chain problems because of on-going Russia-Ukraine war.

9.2 The Authority observed that the annual WPI w.e.f. 01.04.2020, 01.04.2021, & 01.04.2022 was 1.88468%, 0.53638% & 10.76607%, respectively. The prices were reviewed in consonance with the prevailing annual WPI which is 10.76607%. The Authority also observed that the non-scheduled medical devices/drugs are monitored under para 20(1) of DPCO, 2013 and the Knee Implants are non-scheduled devices/drugs. No annual increase was allowed in year 2020-21 and 2021-22 and companies were required to maintain the MRP prevailing during the year 2019-20 in the years 2020-21 and 2021-22.

9.3 After taking all the above into consideration, the Authority decided that in continuation to the notifications S.O. 2668(E) dated 16th August, 2017, S.O. 298(E) dated 13th August, 2018, S.O. 2934(E) dated 13th August 2019, S.O. 2764(E) dated 14th August 2020, S.O. 3147 (E) dated 15th September 2020 and S.O 3670(E) dated 10th Sept 2021 regarding fixation of ceiling prices of orthopedics' knee implants under para 19 of DPCO, 2013, the ceiling price shall continue and be further monitored as per the provisions of paragraph 20(1) of DPCO, 2013. The notes (b) to (t) of the notification S.O. 2668 (E) dated 16.08.2017 shall remain in force during the currency of this order. Further, the ceiling price of orthopedics' knee implants will be reviewed after a period of one year.

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


(Dr. Vinod Kotwal)
Member Secretary