

मिसिल स.- 8(87)/2021/डी.पी/एनपीपीए-डीवी-II

F. No. 8(87)/2021/DP/NPPA-Div. II

कार्यवाही स. : 219/87/2021/F  
Proceeding No: 219/87/2021/F

**Minutes of the 219<sup>th</sup> (overall) and 87<sup>th</sup> meeting of the Authority under DPCO, 2013 held on 27.05.2021 at 11:30 AM**

The 219<sup>th</sup> meeting of the Authority (overall), which is the 87<sup>th</sup> meeting under the DPCO, 2013, was held on 27<sup>th</sup> of May 2021 at 11:30 AM under the Chairmanship of Ms. Shubhra Singh, Chairman, NPPA. The following Authority members of the NPPA were present during the meeting:

- (i) Dr. Vinod Kotwal, Member Secretary, NPPA
- (ii) Shri Amardeep Singh Chowdhary, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure

Shri A. K. Pradhan, Deputy Drug Controller, CDSCO, Ministry of Health & Family Welfare (through Video Conference) represented DCGI

Ms. A. Srija, Economic Advisor, Department of Economic Affairs was granted leave of absence.

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

- (i) Shri N. I. Chowdhury, Advisor
- (ii) Shri S. S. Ojha, Jt. Director (Pricing) (through Video Conference)
- (iii) Shri Prasenjit Das, Deputy Director (Pricing)

1.2 Chairman, NPPA welcomed the new member Shri Amardeep Singh Chowdhary, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure to the Authority who has come in place of Shri A.K. Saha who superannuated on 30<sup>th</sup> April 2021. The Authority placed on record its appreciation of the excellent contribution of the former member Shri A.K. Saha, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure to the work of the Authority. The new Authority member was also briefed about the functioning of the Authority.

## **II. Agenda items**

**1. Agenda item no. 1 - Confirmation of the Minutes of the 86<sup>th</sup> meeting held on 28.04.2021.**

1.1 The Authority confirmed the minutes without any change.

**2. Agenda item no. 2 – Action Taken Report on decisions taken by NPPA in its 86<sup>th</sup> meeting dated 28.04.2021**

2.1 The Authority noted that due action has been taken.

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

3.1 It was noted by the Authority that all cases are being processed in a time-bound manner and normal work is not allowed to get impeded despite the on-going pandemic. The last meeting of the Authority was held on 28<sup>th</sup> April 2021.

**4. Agenda item no. 4 – New Drug application 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(xv) (total 15 Form I applications containing retail price fixation of 15 new drugs) falling under the purview of Para 2(u) of DPCO, 2013 and approved the retail prices of 15 (fourteen) new drugs under Para 5 and 15 of the DPCO 2013, as detailed below:

**A. Retail price fixed under Para 5 and 15 of DPCO, 2013**

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer/ Importer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
1.	Ivabradine Hydrochloride + Metoprolol Tartrate Tablet	<b>Each film coated tablet contains:</b> Ivabradine Hydrochloride eq. to Ivabradine 5 mg + Metoprolol Tartrate IP 25 mg	1 Tablet	M/s Archimedis Healthcare Pvt. Ltd. / M/s Lupin Limited	15.75
2.	Ivabradine Hydrochloride + Metoprolol Tartrate Tablet	<b>Each film coated tablet contains:</b> Ivabradine Hydrochloride eq. to Ivabradine 5 mg + Metoprolol Tartrate IP 50 mg	1 Tablet	M/s Archimedis Healthcare Pvt. Ltd. / M/s Lupin Limited	18.14

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer/ Importer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
3.	Telmisartan, Cilnidipine & Metoprolol (ER) Tablet	<b>Each film coated tablet contains:</b> Telmisartan IP 40mg, Cilnidipine IP 10mg Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate (as extended release) 25mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Neomac Pharmaceuticals Pvt. Ltd.	10.16
4.	Telmisartan, Cilnidipine & Metoprolol (ER) Tablet	<b>Each film coated tablet contains:</b> Telmisartan IP 40mg, Cilnidipine IP 10mg Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate (as extended release) 50mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Neomac Pharmaceuticals Pvt. Ltd.	12.41
5.	Doxycycline & Lactic Acid Bacillus Capsule	<b>Each hard gelatin capsule contains:</b> Doxycycline hyclate IP eq. to Doxycycline (as pellets) 100mg Lactic Acid Bacillus (As enteric coated pellets) 5 Billion Spores	1 Capsule	M/s Skymap Pharmaceuticals Pvt. Ltd.	6.94
6.	Doxycycline & Lactic Acid Bacillus Capsule	<b>Each hard gelatin capsule contains:</b> Doxycycline hyclate IP eq. to Doxycycline (as pellets) 100mg Lactic Acid Bacillus (As enteric coated pellets) 5 Billion Spores	1 Capsule	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s Glensmith Labs Pvt. Ltd.	6.94
7.	Darunavir + Ritonavir Tablet	<b>Each film coated tablet contains:</b> Darunavir Ethanolate eq. Darunavir IP 600mg Ritonavir IP 100mg	1 Tablet	M/s Hetero Labs Ltd. / M/ Cipla Limited	145.70

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer/ Importer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
8.	Povidone-Iodine gargle 0.5% w/v	<b>Contains:</b> Povidone Iodine IP 0.5% w/v (available Iodine 0.05% w/v)	1 ML	M/s Stedman Pharmaceuticals Pct. Ltd.	0.66
9.	Teneligliptin + Metformin Hydrochloride IP (SR) Tablet	<b>Each uncoated bilayered tablet contains:</b> Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg Metformin Hydrochloride IP (As Sustained Release) IP 500mg	1 Tablet	M/s Windlas Biotech Pvt. Limited / M/s Abbott Healthcare Limited	11.00
10.	Teneligliptin + Metformin HCL (ER) Tablet	<b>Each uncoated bilayered tablet contains:</b> Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg Metformin hydrochloride (As Extended Release) IP 500mg	1 Tablet	M/s Morepen Laboratories Limited	10.96
11.	Teneligliptin + Metformin HCL (ER) Tablet	<b>Each uncoated bilayered tablet contains:</b> Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg Metformin hydrochloride (As Extended Release) IP 1000mg	1 Tablet	M/s Morepen Laboratories Limited	11.48
12.	Teneligliptin + Metformin Hydrochloride IP (SR) Tablet	<b>Each uncoated bilayered tablet contains:</b> Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg Metformin Hydrochloride (As Sustained Release) IP 1000mg	1 Tablet	M/s Windlas Biotech Pvt. Limited / M/s Abbott Healthcare Limited	11.48
13.	Ivabradine	Each film coated tablet	1 Tablet	M/s Archimedis	20.68

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer/ Importer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Hydrochloride + Metoprolol Tartrate Tablet	<b>contains:</b> Ivabradine Hydrochloride eq. to Ivabradine 7.5 mg + Metoprolol Tartrate 25 mg		Healthcare Pvt. Ltd. / M/s Lupin Limited	
14.	Darunavir + Ritonavir Tablet	<b>Each film coated tablet contains:</b> Darunavir Ethanolate eq. Darunavir IP 800mg Ritonavir IP 100mg	1 Tablet	M/s Hetero Labs Ltd. / M/ Cipla limited	190.44
15.	Trastuzumab Concentrate for solution for Infusion in vials	<b>Each vial contains:</b> Trastuzumab 150 mg	Each vial	M/s Roche Products (India) Pvt. Ltd/ M/s Cipla Ltd	15526.97

**Note 1.** The retail prices are to be notified after 10 working days from uploading of draft working sheet/Minutes of the Multidisciplinary Committee of Experts/ Minutes of the Authority Meeting on NPPA's website, as applicable.

**Note 2.** The Authority noted that the formulation at S.No. 15 is an anti-cancer drug and its availability is of essence. Representative of DCGI intimated that the subject formulation is an approved formulation. The Authority also noted the draft working sheet. The Authority deliberated upon the matter in detail and approved the retail price of the formulation subject to fulfillment of all the applicable statutory requirements as laid down by the Govt. under relevant statutes/ rules, including manufacturing license permission from the Competent Authority i.e. the Central/State Licensing Authority, as may be applicable, by the concerned manufacturer/marketing companies. It was decided that the retail price would be notified after uploading the draft working for ten working days.

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

5.1 Noted.

**6. Agenda item no. 6 - Intimation of Minutes of 32<sup>nd</sup> meeting of Multidisciplinary Committee of Experts held on 23.05.2021.**

6.1 Noted.

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

**Sd/-**  
**(Dr. Vinod Kotwal)**  
Member Secretary