

मिसिल स.- 8(76)/2020/डी.पी/एनपीपीए-डीवी-॥

F. No. 8(76)/2020/DP/NPPA-Div. II

कार्यवाहीस. : 208/76/2020/F

Proceeding No : 208/76/2020/F

Minutes of the 208th (overall) and 76th meeting of the Authority under DPCO, 2013 held on 22.06.2020 at 11:00 AM

The 208th meeting of the Authority (overall), which is the 76th meeting under the DPCO, 2013, was held on the 22nd of June, 2020 at 11:00 AM under the Chairmanship of Ms. Shubhra Singh, Chairman, NPPA. The following Authority members of the NPPA were present:

- (i) Shri A. K. Saha, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure
- (ii) Ms. A. Srija, Economic Advisor, Deptt of Economic Affairs
- (iii) Dr. V. G. Somani, DCG(I), CDSCO

Shri A.K.Pradhan, Deputy Drug Controller, Deptt. 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 N. I. Chowdhury, Advisor
- (ii) Shri S. S. Ojha, Jt. Director (Pricing)
- (iii) Shi Manjesh Porwal, Dy. Director (M&E)
- (iv) Shri Prasenjit Das, Asstt. Director (Pricing)
- (v) Shri Prakash Hemani, Asstt. Director (Pricing)

II. Agenda items

1. Agenda item no. 1 - Confirmation of the Minutes of the 75th meeting held on 20.05.2020.

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 75th meeting dated 20.05.2020

2.1 The Authority noted that due actions have been taken.

3. Agenda item no. 3 - Status of New Drug application

3.1 The Authority noted that applications filed upto first week of June 2020 had been processed and brought before the Authority. The Authority appreciated timely disposal of the applications.

4. Agenda item no. 4 – New Drug application Price fixation under para 5 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(xxi) (total 21 Form I applications) falling under the purview of para 2(u) of DPCO, 2013 and approved the retail prices in 21 (twenty one) cases under para 5 of the DPCO 2013, as detailed below:

A. Retail price fixed under para 5 of DPCO, 2013

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
i.	Clopidogrel Bisulphate + Aspirin Tablet	Each uncoated bilayered tablet contains: Clopidogrel Bisulphate IP Eq. to Clopidogrel 75 mg Aspirin IP 75 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Limited M/s Mylan Pharmaceuticals Pvt. Limited	3.71
ii.	Glimepiride + Metformin Hydrochloride Tablet	Each uncoated bilayered tablet contains: Glimepiride IP 3mg, Metformin Hydrochloride IP 1000mg (as prolonged release form)	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd.M/s Emcure Pharmaceuticals Limited	8.94
iii.	Glimepiride + Metformin Hydrochloride Tablet	Each uncoated bilayered tablet contains: Glimepiride IP 4mg, Metformin Hydrochloride IP 1000mg (as prolonged release form)	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd.M/s Emcure Pharmaceuticals Limited	9.56
iv.	Atorvastatin + Aspirin Capsule	Each Hard Gelatin Capsule contains: Atorvastatin Calcium IP eq. Atorvastatin 10 mg (as Film Coated tablet) Aspirin IP 75mg (as	1 Capsule	M/s Micro Labs Limited	2.42

		Gastro Resistant Tablet IP)			
v.	Atorvastatin + Aspirin Capsule	Each Hard Gelatin Capsule contains: Atorvastatin Calcium IP eq. Atorvastatin 10 mg (as Film Coated tablet) Aspirin IP 150mg (as two Gastro Resistant Tablet IP each 75mg)	1 Capsule	M/s Micro Labs Limited	2.54
vi.	Cilnidipine + Telmisartan Tablet (Telsartan -LN 80)	Each film coated tablet contains: Cilnidipine IP 10 mg, Telmisartan IP 80 mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ Dr. Reddy's Laboratories Limited	13.12
vii.	Cilnidipine + Telmisartan Tablet (Telsartan -LN 40)	Each film coated tablet contains: Cilnidipine IP 10 mg, Telmisartan IP 40 mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ Dr. Reddy's Laboratories Limited	8.65
viii.	Rosuvastatin + Aspirin + Clopidogrel Capsule (Rozat Gold 10mg)	Each hard gelatine capsule contains: Rosuvastatin Calcium IP Eq. to Rosuvastatin 10mg (As film coated Rosuvastatin Tablets IP) Aspirin IP 75mg (As Aspirin Gastro-Resistant Tablets IP) Clopidogrel Bisulphate IP Eq. to Clopidogrel 75mg (As film coated Clopidogrel Tablets IP)	1 Capsule	M/s Akums Drugs and Pharmaceuticals / Dr. Reddy's Laboratories Limited	11.48
ix.	Rosuvastatin + Aspirin + Clopidogrel Capsule (Rozat Gold 20mg)	Each hard gelatine capsule contains: Rosuvastatin Calcium IP Eq. to Rosuvastatin 20mg (As film coated Rosuvastatin Tablets IP) Aspirin IP 75mg (As Aspirin Gastro-Resistant Tablets IP) Clopidogrel Bisulphate IP Eq. to Clopidogrel 75mg (As film coated Clopidogrel Tablets IP)	1 Capsule	M/s Akums Drugs and Pharmaceuticals / Dr. Reddy's Laboratories Limited	17.46
x.	Glimepiride +	Each uncoated	1	M/s Akums Drugs	8.94

	Metformin Hydrochloride Tablet (Glimy M3 Forte)	bilayered tablet contains: Glimpiride IP 3mg, Metformin Hydrochloride IP 1000mg(as prolonged release form)	Tablet	and Pharmaceuticals / Dr. Reddy's Laboratories Limited	
xi.	Glimpiride + Metformin Hydrochloride Tablet (Glimy M4 Forte)	Each uncoated bilayered tablet contains: Glimpiride IP 4mg, Metformin Hydrochloride IP 1000mg(as prolonged release form)	1 Tablet	M/s Akums Drugs and Pharmaceuticals / Dr. Reddy's Laboratories Limited	9.56
xii.	Etoricoxib + Paracetamol Tablet	Each film coated tablet contains: Etoricoxib IP 60mg, Paracetamol IP 325mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Zuventus Healthcare Limited	5.58
xiii.	Tolperisone Hydrochloride + Diclofenac Sodium Tablet	Each film coated bilayered tablet contains: Tolperisone Hydrochloride IP 150mg, Diclofenac Sodium IP 50mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Zuventus Healthcare Limited	13.42
xiv.	Cilnidipine + Metoprolol Succinate Tablet	Each film coated bilayered tablet contains: Cilnidipine IP 10mg, Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate 25mg (in extended release form)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. /M/s Intas Pharmaceuticals Limited	7.11
xv.	Nebivolol + Telmisartan Tablet	Each uncoated bilayered tablet contains: Nebivolol hydrochloride IP eq. to Nebivolol 5 mg, Telmisartan IP 40mg	1 Tablet	M/s Lupin Limited	12.59
xvi.	Levetiracetam + Sodium Chloride Infusion	Each 100 ml contains: Levetiracetam IP 500mg, Sodium Chloride IP 820mg, Water for injection IP	100ml Pack	M/s Akums Drugs & Pharmaceuticals Limited/M/s Lupin Limited	91.56

		q.s.			
xvii.	Levetiracetam + Sodium Chloride Infusion	Each 100 ml contains: Levetiracetam IP 1000mg, Sodium Chloride IP 750mg, Water for injection IP q.s.	Per 100ml Pack	M/s Akums Drugs & Pharmaceuticals Limited/M/s Lupin Limited	148.72
xviii.	Levetiracetam + Sodium Chloride Infusion	Each 100 ml contains: Levetiracetam IP 1500mg, Sodium Chloride IP 540mg, Water for injection IP q.s.	Per 100ml Pack	M/s Akums Drugs & Pharmaceuticals Limited/M/s Lupin Limited	206.32
xix.	Norethisterone Acetate tablet	Each film coated controlled release tablet contains: Norethisterone Acetate BP 15mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd./M/s Torrent Pharmaceuticals Limited	17.83
xx.	Norethisterone Acetate Tablet	Each film coated controlled release tablet contains: Norethisterone Acetate BP 10mg	1 Tablet	M/s Zydus Healthcare Limited	15.40
xxi.	Norethisterone Acetate Tablet	Each film coated controlled release tablet contains: Norethisterone Acetate BP 15mg	1 Tablet	M/s Zydus Healthcare Limited	17.83

Note: The retail prices are to be notified after 10 working days from uploading of draft working sheet on NPPA's website.

5. Agenda item no. 5 - Ceiling Price fixation of Tetanus + Diphtheria (TD) Vaccine

5.1 The Authority deliberated upon the matter in detail and approved the ceiling price of TD vaccine at Rs. 17.11 per 0.5 ml pack excluding GST and TD vaccine at Rs. 118.11 per 5 ml pack excluding GST.

6.1 Agenda item no. 6(i) - Status of implementation of Review cases

6.1.1 It was noted that there was only one review order pending for implementation as on 15.06.2020 and the same had been processed and brought before the Authority.

6.2 Agenda item no. 6(ii) – Review application filed by M/s Cipla Ltd in connection with ceiling price fixation of Budesonide 200 MCG/dose inhaler (MDI) vide SO. 1028(E) dated 26.02.2019.

6.2.1 The Authority deliberated upon the matter in detail and revised the ceiling price of Budesonide 200MCG/ dose inhaler (MDI) at Rs. 1.76 per MDI excluding GST towards implementation of review order no. 31015/5/2019-Pricing dated 01.05.2020. The revised ceiling price is to be notified after 10 working days from uploading of draft working sheet.

7. Agenda item no. 7 - Application of M/s s Gilead Sciences for exemption from fixation ceiling price in respect of Tenofovir Alafenamide tablets for the treatment of chronic Hepatitis B (registered Trade/ Brand name Vemlidy) under paragraph 32 of Drug (Prices Control) Order, 2013 read with Drugs (Prices Control) Amendment Order, 2019.

7.1 The Authority deliberated upon the matter in detail and decided to defer.

8. Agenda item no. 8 - Price fixation as per Pharmaceuticals Purchase Policy (PPP) for products of Pharma Central Public Sector Enterprises (CPSEs) and their subsidiaries.

Record note of Discussion to be circulated separately to the members.

9. Agenda item no. 9 - Revision of Ceiling Price of Diclofenac Injection 25mg/ml.

9.1 The Authority deliberated upon the matter in detail and noted that ceiling price of Diclofenac injection 25mg/ml has been fixed in December 2016 under NLEM 2015. The Authority observed that the matter regarding non-consideration of one formulation while calculating the ceiling price of Diclofenac Injection 25mg/ml, as represented by M/s Blue Cross Laboratories Ltd, should have been represented by the company under para 31 of DPCO 2013. Thus, the company had ceased its right as available under para 31 of DPCO 2013. Recourse to upward price revision under para 19 of DPCO 2013 at a later date cannot be justified in such case. Accordingly, the Authority decided to dispose off the matter.

10. Agenda item no. 10 - Application for exemption under para 32(i) of DPCO 2013 for KEYTRUDA (Pembrolizumab Injection) filed by M/s MSD Pharmaceuticals Pvt. Ltd

10.1 The Authority deliberated upon the matter in detail and decided to defer.

11. Agenda item no. 11 - Application for upward price revision of Heparin Injection under para 19 of DPCO 2013

11.1 The Authority deliberated upon the matter in detail and noted that various companies representing major market share have applied for price revision of Heparin Injection 1000IU/ ml and Heparin Injection 5000IU/ ml under para 19 of DPCO 2013. Both Heparin Injection 1000IU/ ml and Heparin Injection 5000IU/ ml are scheduled formulations under DPCO 2013.

11.2 The Authority further noted that Heparin injection 5000IU/ml has also been included in list of medicine essential for patients admitted in ICU and Hospitalization due to COVID-19 circulated by Ministry of Health & Family Welfare (MoH&FW). Uninterrupted supply of such medicines is essential for management of COVID-19. Further, reports of shortage have also been received for Heparin Injection.

11.3 The Committee headed by Dr. S. Eswara Reddy, Jt Drug Controller, CDSCO vide its report communicated through letter dated 19th June, 2020 has informed that there has been an increase of 211% in the price of API Heparin when compared to base year of September 2018. The Committee had opined that *“NPPA may consider to increase the ceiling price of Heparin Injection 5000IU/ ml by 50% to ensure continuous availability of the essential drugs in public interest. The Committee also recommends that increase in ceiling price may be considered for only a fixed duration, say for about six to nine months, after which the situation may be reviewed and further necessary action can be taken as deemed fit.”*

11.4 The Authority considered the aspect of availability of Heparin Injection 1000IU/ ml and Heparin Injection 5000IU/ ml, a scheduled formulation, especially during the pandemic situation of COVID-19 and opined that any situation of non-availability due to increase in the price of API needs to be seen from a public interest perspective. Therefore, due to extra-ordinary situation, the Authority invoked Para 19 of DPCO 2013 in public interest for upward revision of the ceiling prices of Heparin Injection 1000IU/ ml and

Heparin Injection 5000IU/ ml, being the essential medicines, by giving an increase of 50% from the present ceiling price to be applicable upto 31st December 2020, as detailed below:

Name of the Scheduled Formulation	Dosage form & Strength	Unit	Approved Ceiling Price (excluding GST) (Rs.)
Heparin	Injection 5000 IU/ml	1 ml	60.54
Heparin	Injection 1000 IU/ml	1 ml	24.39

11.5 The Authority further directed that the provisions of para 13(2) of DPCO 2013 would not be applicable on the revised ceiling price of Heparin 1000IU/ml Injection and Heparin 5000IU/ml Injection mentioned in para 11.4 above upto 31st December 2020 for which the revised price is applicable.

11.6 The Authority further directed for monthly monitoring of price of Heparin Sodium API.

12. Agenda item no. 12 – Application for upward price revision under para 19 of DPCO 2013

Record note of Discussion to be circulated separately to the members.

13. Agenda item no. 13 – Withdrawn.

14. Agenda item no. 14 – Submission of Form-IV intimation by M/s GlaxoSmithKline Pharmaceuticals Limited for discontinuation of scheduled formulation Ranitidine Tablet (Zinetac 150mg) under para 21(2) of DPCO, 2013-reg.

14.1 The Authority deliberated upon the matter in detail and noted that M/s GlaxoSmithKline Pharmaceuticals Limited has informed about discontinuation of Ranitidine 150 mg tablet in the country stating that they have made a decision to discontinue the manufacture and supply of the Ranitidine brand globally.

14.2 The Authority observed that there are other major market players of the said formulation.

14.3 Accordingly the Authority decided that M/s GlaxoSmithKline Pharmaceuticals Limited may be allowed to discontinue Ranitidine 150 mg tablet (Zinetac 150mg) with immediate effect.

15. Agenda item no. 15 - Intimation of Minutes of 19th meeting of Multidisciplinary Committee of Experts held on 17.06.2020.

15.1 The Authority noted the minutes and observed that the Committee had sought information for examining the scientific rationality and therapeutic justification in respect of the application for retail price fixation of new drugs. The Authority was of the view that examination of the scientific rationality and therapeutic justification is the domain of Central Drugs Standards Control Organisation (CDSCO)/ State Licensing Authority. The Authority also observed that as per the ecosystem being developed, the retail price approval of new drugs is to be given within a scheduled time. Accordingly, the Authority desired that the Committee may recommend the retail price of new drugs being brought before it within a reasonable time.

16. Matter relating to availability of N-95 mask

16.1 The Authority was apprised that N-95 masks had come under notified drugs w.e.f. 01.04.2020. NPPA has examined issues related to availability & pricing of N95 mask and for this purpose NPPA has collected the relevant data from various sources. Inter Ministerial consultations also took place in this regard. It was observed that there continued to be a mismatch between demand and supply of N95 masks in the country. On the advisory issued by NPPA, the price of N95 mask had been rolled back by manufacturers/ importers upto 67%. NPPA had also issued another advisory on 23.06.2020 to manufacturers/ importers for compliance of Para 20 of DPCO 2013. Simultaneously NPPA is monitoring price rise during the next twelve months so that it may not be more than 10% of MRP as on 01.04.2020. NPPA has also issued proforma asking the manufacturers/ importers to provide their price maintained during the period starting from 1st April 2020 till date. The Authority noted and concurred with the above course of action.

The meeting ended with a vote of thanks to the Chair.

Sd/-
(N.I. Chowdhury)
Advisor (Cost)