

National Pharmaceutical Pricing Authority

**Subject: Minutes of the 18<sup>th</sup> meeting of Multidisciplinary Committee of Experts held on 08.05.2020 at 11:00 AM in NPPA**

18<sup>th</sup> meeting of the “Multidisciplinary Committee of Experts” was held on 08.05.2020 under the Convenorship of the Sh. N.I. Chowdhury, Adviser (Cost), in the Conference Room of NPPA. The following members attended the meeting through video conferencing:-

1. Prof. Y. K. Gupta, Principal Scientific Advisor (Projects), THSTI-DBT, Gol & Ex-HoD, Pharmacology & Dean, AIIMS, New Delhi
2. Dr. C. D. Tripathi, Head Department of Pharmacology, VMMC & Safdarjung Hospital
3. Dr. K. Bangarurajan, JDC(I), CDSCO
4. Dr. Vijay Kumar, Scientist-G and Head (BMS), ICMR, New Delhi
5. Dr. Gaurav Pratap Singh, Sr. Scientific Officer, Indian Pharmacopoeia Commission

The following officers of NPPA attended and presented the cases to the Committee

1. Sh. S. S. Ojha, Jt. Director (Pricing), NPPA
2. Sh. Prasenjit Das, Assistant Director (Pricing), NPPA
3. Sh. Prakash Hemani, Assistant Director (Pricing), NPPA

**1. Agenda No. 1 - Retail price fixation of Syrup in which each 15 ml syrup containing Ferric Ammonium Citrate IP 160mg, Vitamin B12 IP 5mcg , Folic Acid IP 1 mg , Zinc Sulphate Monohydrate IP 30mg under Para 5 of DPCO, 2013 for M/s Zydus Healthcare Ltd (marketer) and M/s Zydus Healthcare Ltd (manufacturer/ importer)**

1.1 The Committee observed that the representative of the office of DCGI clarified that the subject formulation is approved by DCGI on 03.02.2016 under 18 month policy (Kokate Committee rational FDC List) decision.

1.2 The deliberated upon the matter in detail and decided to calculate the price of the syrup by taking available data as per Pharmatrac for the month of May 2019 in respect of syrup having ferrous combinations with ferrous strength of 160 mg under para 4 of DPCO 2013. The calculation came to Rs. 0.50 per ml and accordingly the Committee recommended the retail of syrup containing Ferric Ammonium Citrate IP 160mg, Vitamin B12 IP 5mcg, Folic Acid IP 1 mg , Zinc Sulphate Monohydrate IP 30mg under Para 5 of DPCO, 2013 for M/s Zydus Healthcare Ltd (marketer) and M/s Zydus Healthcare Ltd (manufacturer/ importer) at Rs. 0.50 per ml excluding GST.

**2. Agenda No. 2 Retail price fixation of Docaravimab and Miromavimab combination Injections under Para 5 of DPCO, 2013 for M/s Cadila Healthcare Ltd (marketer) and M/s Cadila Healthcare Ltd (manufacturer/ importer)**

2.1 The Committee noted that applicant company has claimed the retail price for various packs and strength of Docaravimab and Miromavimab combination Injections as detailed below:

Sl. No.	Name	Compositions	Claimed retail price per pack (ex. GST)
1	Docaravimab and Miromavimab Injection 3000IU /5 ml	Each 1ml injection contains: Docaravimab (r-DNA Origin) (INH) 300 IU Miromavimab (r-DNA Origin) (INH) 300 IU	Rs. 32580/-
2	<b>Docaravimab and Miromavimab Injection 3000 IU /10 ml</b>	Each 1ml injection contains: Docaravimab (r-DNA Origin) (INH) 150 IU Miromavimab (r-DNA Origin) (INH) 150 IU	Rs. 32580/-
3	<b>Docaravimab and Miromavimab Injection 1500 IU /2.5 ml</b>	Each 1ml injection contains: Docaravimab (r-DNA Origin) (INH) 300 IU Miromavimab (r-DNA Origin) (INH) 300 IU	Rs. 13032/- per pack
4	<b>Docaravimab and Miromavimab Injection 600 IU / ml</b>	Each 1ml injection contains: Docaravimab (r-DNA Origin) (INH) 300 IU Miromavimab (r-DNA Origin) (INH) 300 IU	Rs. 6516/- per pack

2.2 M/s Cadila Healthcare Ltd made a presentation before the Committee. The Committee deliberated upon the matter in detail and observed that the novel cocktails of two murine monoclonal anti-bodies namely Docaravimab and Miromavimab is used against rabies as Antirabies Immunoglobulin and the same are approved by DCGI as an Investigational New Drug (IND). IND Committee constituted at ICMR has vetted the result of comparative phase 3 clinical trial with Human rabies Immunoglobulin (HRI) and found the results acceptable and recommended for marketing authorization. Accordingly, based on the recommendation of IND, DCGI has issued the necessary permission in Form 46.

2.3 The committee observed the justification of price submitted by company based on therapeutic benchmark cum incremental innovation and recommended the retail price as detailed below:

**Price for Docaravimab and Miromavimab Injection 1500 IU /2.5 ml**

Particulars	Price
For an adult of with requirement of Human Anti-rabies Immunoglobulin (HRI) of 750IU, the product of the company requirement will be 1500IU.	
Ceiling Price of (HRI) 150IU / ml	Rs. 2,715 per ml
Price for 750IU in 5ml pack	Rs. 13,575/-
Add : Incremental Innovation 20%	Rs. 2,715/-
Worked out price for 1500IU / 2.5ml of Docaravimab and Miromavimab	Rs. 16,290/-
Price Claimed by company	Rs. 13,032/-
Recommended Price for 1500IU / 2.5ml	<b>Rs. 13,032/-</b>

**Price for Docaravimab and Miromavimab Injection 600 IU /ml**

Particulars	Price
Recommended Price for 1500IU / 2.5ml	<b>Rs. 13,032/-</b>
Pro-rata Price for 600IU / ml (13032/2.5)	Rs. 5,212.80
Price Claimed by company	Rs. 6,516/-
Recommended Price for 600IU / ml	<b>Rs. 5,212.80/-</b>

Price for **Docaravimab and Miromavimab Injection 3000IU / 5ml**

Particulars	Price
Recommended Price for 1500IU / 2.5ml	<b>Rs. 13,032/-</b>
Pro-rata Price for 3000IU / 5ml (13032x2)	Rs. 26,064/-
Price Claimed by company	Rs. 32,580/-
Recommended Price for 3000IU / 5ml	<b>Rs. 26,064/-</b>

Price for **Docaravimab and Miromavimab Injection 3000 IU /10ml**

Particulars	Price
Recommended Price for 1500IU / 2.5ml	<b>Rs. 13,032/-</b>
Pro-rata Price for 3000IU / 10ml (13032x2)	Rs. 26,064/-
Price Claimed by company	Rs. 32,580/-
Recommended Price for 3000IU / 10ml	<b>Rs. 26,064/-</b>

**3. Agenda no. 3 Retail price fixation of each film coated tablet containing Alpha Lipoic Acid 100mg, Folic Acid 1.5mg, Methylcobalamin 1500mcg, Vitamin D3 1000IU, Pyridoxine Hydrochloride 3mg under Para 5 of DPCO, 2013 for M/s Cadila Pharmaceuticals Limited (marketer) and M/s East African (India) Overseas (Manufacturer)**

3.1 The Committee deliberated upon the matter in detail and decided to recommended the retail price of each film coated tablet containing Alpha Lipoic Acid 100mg, Folic Acid 1.5mg, Methylcobalamin 1500mcg, Vitamin D3 1000IU, Pyridoxine Hydrochloride 3mg under Para 5 of DPCO, 2013 for M/s Cadila Pharmaceuticals Limited (marketer) and M/s East African (India) Overseas (Manufacturer) at Rs. 13.33 per tablet excluding GST as detailed below:

Computation of Retail Price per Tablet	Source/Method	Amount (Rs.)
Composition – Alpha Liopic Acid 100mg + Folic Acid 1.5mg + Methylcobalamin 1500mcg + Vitamin D3 1000IU + Pyridoxine Hydrochloride 3mg		
a. Methylcobalamin 1500 mcg	Retail price	8.94
b. Folic Acid 1.5mg	Retail Price as per Pronab Sen Committee Report	0.60
c. Vitamin D3 1000IU	Ceiling Price	3.74
d. Pyridoxine Hydrochloride 3mg	Retail Price as per Pronab Sen Committee Report	0.05
e. Alpha Lipoic Acid 100mg	Data not available	-
Worked out Retail Price		13.33
d. Less 20% of the lowest of (a) to (e) as		0.00

recommended in the Pronab Sen Committee report		
Net Retail Price (a+b-c)		13.33
Company Claimed Price		16.00
Recommended price		13.33

Derived retail price as per recommendation of pronab sen committee :

$$P(s) = P^*.[1+a.\{(s-s^*)/s^*\}]$$

Where : P(s) = Price ceiling of the strength s

P\* = price ceiling for reference strength s\*

s = strength in terms of API content

s\* = reference strength

a= 0.8 for tablet / capsule and 0.7 for injectibles.

Derived Retail price for Folic Acid 1.5mg =  $1.36[1+0.80\{1.5-5\}/5]$  = Rs. 0.60 per tablet

Derived Retail price for Pyridoxine Hydrochloride 3mg =  $0.11[1+0.80\{3-10\}/10]$  = Rs. 0.05 per tablet

**4. Agenda no. 4 Retail price fixation of each film coated tablet containing Calcium Carbonate IP 1250 mg eq to elemental calcium 500 mg, Vitamin D3 IP 2000 IU, Mecobalamin IP (Methylcobalamin) 1500 mcg, L-Methylfolate Calcium 1 mg, Pyridoxal -5 Phosphate 20 mg under Para 5 of DPCO, 2013 for M/s Cadila Pharmaceuticals Ltd (marketer) and M/s Akum Drugs & Pharmaceuticals Pvt. Ltd (manufacturer/ importer)**

4.1 The Committee deliberated upon the matter in detail and decided to recommended the retail price of each film coated tablet containing Calcium Carbonate IP 1250 mg eq to elemental calcium 500 mg, Vitamin D3 IP 2000 IU, Mecobalamin IP (Methylcobalamin) 1500 mcg, L-Methylfolate Calcium 1 mg, Pyridoxal -5 Phosphate 20 mg under Para 5 of DPCO, 2013 for M/s Cadila Pharmaceuticals Ltd (marketer) and M/s Akum Drugs & Pharmaceuticals Pvt. Ltd (manufacturer/ importer) at Rs. 17.59 per tablet excluding GST as detailed below:

Computation of Retail Price per Tablet	Source/Method	Amount (Rs.)
Composition – Calcium 500mg + L-Methylfolate Calcium 1 mg + Pyridoxal -5 Phosphate 20 mg + Methylcobalamin 1500mcg + Vitamin D3 2000IU		
a. Methylcobalamin 1500 mcg	Retail price	8.94
b. Calcium 500mg	Ceiling Price	1.72
c. Vitamin D3 2000IU	Retail Price as per Pronab Sen Committee Report	6.73
d. Pyridoxal -5 Phosphate 20 mg	Retail Price as per Pronab Sen Committee Report	0.20

e. L-Methylfolate Calcium 1 mg	Data not available	-
Worked out Retail Price		17.59
d. Less 20% of the lowest of (a) to (e) as recommended in the Pronab Sen Committee report		0.00
Net Retail Price (a+b-c)		17.59
Company Claimed Price		25.00
Recommended price		17.59

Derived retail price as per recommendation of pronab sen committee :

$$P(s) = P^* \cdot [1 + a \cdot \{(s - s^*) / s^*\}]$$

Where :  
P(s) = Price ceiling of the strength s  
P\* = price ceiling for reference strength s\*  
s = strength in terms of API content  
s\* = reference strength  
a = 0.8 for tablet / capsule and 0.7 for injectibles.

Derived Retail price for Vitamin D3 =  $3.74[1 + 0.80\{20 - 10\}/10]$  = Rs. 6.73 per tablet

Derived Retail price for Pyridoxal -5 Phosphate 20 mg =  $0.11[1 + 0.80\{20 - 10\}/10]$  = Rs. 0.20 per tablet

Sd/-  
(S. S. Ojha)  
Jt. Director (Pricing)

Copy to:  
All members of the Committee.