

National Pharmaceutical Pricing Authority

Subject: Minutes of the 20th meeting of Multidisciplinary Committee of Experts held on 17.07.2020 at 11:00 AM in NPPA

20th meeting of the “Multidisciplinary Committee of Experts” was held on 17.07.2020 under the Convenorship of Sh. N.I. Chowdhury, Adviser (Cost), in 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 (Academics), AIIMS, New Delhi
2. Dr. Vijay Kumar, Scientist-G and Head (BMS), ICMR, New Delhi
3. Shri A. K. Pradhan, Dy. Drugs Controller, CDSCO
4. Dr. Pooja Gupta, Assoc. Prof., Pharmacology, AIIMS, New Delhi
5. Dr. Rakesh K. Singh, Asstt. Professor, NIPER, Raebareli

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

The Committee was informed that Dr. C.D. Tripathi, Head of the Deptt of Pharmacology, VMMC & Safdarjung Hospital, who was earlier co-opted as a Committee member, intimated about his superannuation.

I. Agenda No. 1 - Retail price fixation each film coated tablet containing Capecitabine IP 700 mg + Cyclophosphamide IP 32.1 mg eq. to Anhydrous Cyclophosphamide 30 mg under Para 5 of DPCO, 2013 for M/s Intas Pharmaceuticals Ltd (manufacturer and marketer).

I.I The Committee deliberated upon the matter in detail and recommended the retail price of film coated tablet containing Capecitabine IP 700 mg + Cyclophosphamide IP 32.1 mg eq. to Anhydrous Cyclophosphamide 30 mg for M/s Intas Pharmaceuticals Ltd (manufacturer and marketer) at Rs. 168.53 per tablet excluding GST as detailed below:

Computation of Retail Price per Tablet	Source/Method	Price excluding GST (Rs.)
Composition – Capecitabine 700mg + Cyclophosphamide 30 mg		
a. Capecitabine 700mg Tablet	Retail Price*	166.33
b. Cyclophosphamide 30mg Tablet	Retail Price*	2.75
Worked out Retail Price		169.08
c. Less 20% of the lowest of (a) and (b) similar to formula recommended in the Pronab Sen Committee report		0.55
Net Retail Price (a+b-c)		168.53
Company Claimed Price		175.00
Recommended price		168.53

* The Price of Capecitabine 700mg Tablet have been worked out as below:-

Ceiling Price of Capecitabine 500mg Tablet = Rs. 126.01

As per report of Pronab Sen Committee the price of other strengths is to be decided as per formula provided below:

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

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.

Price as per above referred formula is $126.01 [1 + 0.80 \{ (700 - 500) / 500 \}] = \text{Rs. } 166.33$ per tablet

* The Price of Cyclophosphamide 30 mg Tablet have been worked out as below

Ceiling Price of Cyclophosphamide 50 mg Tablet = Rs. 4.04

As per report of Pronab Sen Committee the price of other strengths is to be decided as per formula provided below:

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

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.

Price as per above referred formula is $4.04 [1 + 0.80 \{ (30 - 50) / 50 \}] = \text{Rs. } 2.75$ per tablet

2. Agenda No. 2 - Retail price fixation of each film coated tablet containing Capecitabine IP 400 mg and Cyclophosphamide IP 21.4 mg eq. to Anhydrous Cyclophosphamide 20 mg under Para 5 of DPCO, 2013 for M/s Intas Pharmaceuticals Ltd (manufacturer and marketer).

2.1 The Committee deliberated upon the matter in detail and recommended the retail price of film coated tablet containing Capecitabine IP 400 mg + Cyclophosphamide IP 21.4 mg eq. to Anhydrous Cyclophosphamide 20 mg for M/s Intas Pharmaceuticals Ltd (manufacturer and marketer) at Rs. 107.53 per tablet excluding GST as detailed below:

Computation of Retail Price per Tablet	Source/Method	Price excluding GST (Rs.)
Composition – Capecitabine 400mg + Cyclophosphamide 20 mg		
a. Capecitabine 400mg Tablet	Retail Price*	105.85
b. Cyclophosphamide 30mg Tablet	Retail Price*	2.10
Worked out Retail Price		107.95
c. Less 20% of the lowest of (a) and (b) similar to formula recommended in the Pronab Sen Committee report		0.42
Net Retail Price (a+b-c)		107.53
Company Claimed Price		110.00
Recommended price		107.53

* The Price of Capecitabine 400mg Tablet have been worked out as below

Ceiling Price of Capecitabine 500mg Tablet = Rs. 126.01

As per report of Pronab Sen Committee the price of other strengths is to be decided as per formula provided below:

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

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.

Price as per above referred formula is $126.01 [1 + 0.80 \{400 - 500\} / 500] = \text{Rs. } 105.85$ per tablet

* The Price of Cyclophosphamide 20 mg Tablet have been worked out as below

Ceiling Price of Cyclophosphamide 50 mg Tablet = Rs. 4.04

As per report of Pronab Sen Committee the price of other strengths is to be decided as per formula provided below:

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

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.

Price as per above referred formula is $4.04 [1 + 0.80 \{20 - 50\} / 50] = \text{Rs. } 2.10$ per tablet

3. Agenda no. 3 - Retail price fixation of each soft gelatin capsule containing Methylcobalamin IP 1500 mcg , Alpha Lipoic Acid USP 100 mg , Pyridoxine Hydrochloride IP 3 mg and Folic Acid IP 1.5 mg under Para 5 of DPCO, 2013 for M/s Mylan Pharmaceuticals Pvt. Ltd (marketer) and M/s Akum Drugs & Pharmaceuticals Ltd (manufacturer/ importer).

3.1 The Committee deliberated upon the matter in detail and noted that main constituent in the formulation is Methylcobalamin 1500 mcg and recommended that the price of this formulation may be fixed under para 5 of DPCO 2013 on the basis of similar drugs having Methylcobalamin 1500 mcg. The retail price was calculated under para 5 of DPCO 2013 by taking data of the similar drugs having Methylcobalamin 1500 mcg for the month of August 2019 and it came to Rs. 12.37 per capsule excluding GST. The Committee also observed that the company claimed retail price at Rs. 17.00 per capsule. Accordingly, the Committee recommended the retail price of soft gelatin capsule containing Methylcobalamin IP 1500 mcg , Alpha Lipoic Acid USP 100 mg , Pyridoxine Hydrochloride IP 3 mg and Folic Acid IP 1.5 mg for M/s Mylan Pharmaceuticals Pvt. Ltd (marketer) and M/s Akum Drugs & Pharmaceuticals Ltd (manufacturer/ importer) at Rs. 12.37 per capsule excluding GST.

4. Agenda no. 4 - Retail price fixation of each film coated tablet containing Methylcobalamin IP 1500 mcg , Folic Acid IP 5 mg and Pyridoxine Hydrochloride IP 20 mg under Para 5 of DPCO, 2013 for M/s Unison Pharmaceuticals Pvt. Ltd (manufacturer and marketer).

4.1 The Committee deliberated upon the matter in detail and noted that main constituent in the formulation is Methylcobalamin 1500 mcg and recommended that the price of this formulation may be fixed under para 5 of DPCO 2013 on the basis of similar drugs having Methylcobalamin 1500 mcg. The retail price was calculated under para 5 of DPCO 2013 by taking data of the similar drugs having Methylcobalamin 1500 mcg for the month of November 2019 and it came to Rs. 9.30 per tablet excluding GST. The Committee also observed that the company claimed retail price at Rs. 3.87 per tablet excluding GST. Accordingly, the Committee recommended the retail price of each film coated tablet containing Methylcobalamin IP 1500 mcg , Folic Acid IP 5 mg and Pyridoxine Hydrochloride IP 20 mg under Para 5 of DPCO, 2013 for M/s Unison Pharmaceuticals Pvt. Ltd (manufacturer and marketer) at Rs. 3.87 per tablet excluding GST.

5. Agenda no. 5 - Retail price fixation of Chlorhexidine and Isopropyl Alcohol Topical Solution in which each ml solution containing Chlorhexidine Gluconate Solution IP 2.5% v/v eq to Chlorhexidine Gluconate 0.5% w/v + Isopropyl Alcohol IP 70% v/v under Para 5 of DPCO, 2013 for M/s Stedman Pharmaceuticals Pvt. Ltd (manufacturer and marketer) in 100 ml, 200ml, 500 ml and 5 litre pack

5.1 The Committee deliberated upon the matter in detail and recommended the retail price of Chlorhexidine and Isopropyl Alcohol Topical Solution in which each ml solution containing Chlorhexidine Gluconate Solution IP 2.5% v/v eq to Chlorhexidine Gluconate 0.5% w/v + Isopropyl Alcohol IP 70% v/v under Para 5 of DPCO, 2013 for M/s Stedman Pharmaceuticals Pvt. Ltd (manufacturer and marketer) at Rs. 42.37 (excluding GST), Rs. 84.75 (excluding GST), Rs. 211.87 (excluding GST) and Rs. 2118.64 (excluding GST) for 100 ml pack, 200 ml pack, 500 ml pack and 5 litre pack respectively as detailed below:

Computation of Retail Price per ml	Source/Method	Amount excluding GST (Rs.)
Composition – Chlorhexidine Gluconate Solution 2.5% v/v eq. to Chlorhexidine 0.5% w/v + Isopropyl Alcohol 70% v/v		
a. Chlorhexidine Gluconate Solution 2.5% v/v eq. to Chlorhexidine 0.5%	Derived Retail price	0.06
b. Isopropyl Alcohol 70% v/v	Ceiling Price of Ethyl Alcohol 70% (Data of Isopropyl Alcohol not available)	0.42
Worked out Retail Price		0.48
d. Less 30% of the lowest of (a) to (b) as recommended in the Pronab Sen Committee report		0.02
Net Retail Price (a+b-c)		0.46

Worked out Retail Price for 100ml pack	46.00
Company Claimed Price for 100ml pack	42.37
Recommended price for 100ml Pack	42.37
Worked out Retail Price for 200ml pack	92.00
Company Claimed Price for 200ml pack	84.75
Recommended price for 200ml Pack	84.75
Worked out Retail Price for 500ml pack	230.00
Company Claimed Price for 500ml pack	211.87
Recommended price for 500ml Pack	211.87
Worked out Retail Price for 5000ml pack	2300.00
Company Claimed Price for 5000ml pack	2118.64
Recommended price for 5000ml Pack	2118.64

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.

Ceiling Price for Chlorhexidine 5% Solution = 0.15 per ml

Derived Retail price for Chlorhexidine 0.5% = $0.15[1 + 0.70\{(0.5 - 5)/5\}] = \text{Rs. } 0.06 \text{ per ml}$

6. Agenda no. 6 - Application for extension of ceiling price for I.V. Fluids with packaging in Non-glass with special feature.

6.1 The Committee deliberated upon the matter in detail and noted that 5 companies namely, M/s Realcade Lifesciences Ltd, M/s Rusoma Laboratories Pvt. Ltd, M/s Shree Krishna Keshav Laboratories Ltd, M/s Axa Parentals Ltd and M/s Eurolife Healthcare Pvt. Ltd have applied for separate ceiling price for IV fluids with packaging in non-glass with special features in line with S.O. 1215(E) dated 25.03.2020. The three companies (except M/s Realcade Lifesciences Ltd and M/s Rusoma Laboratories Ltd) made demonstration before the members. The Committee observed that the non-glass packages of I.V. fluids of the two companies namely, M/s Shree Krishna Keshav Laboratories Ltd and M/s Axa Parentals Ltd have special features as (i) Self Collapsibility and self-seal ability, (ii) not having air-vent and (iii) having no chance of contamination during manufacture / infusion / admixing levels. Accordingly, the Committee recommended to extend the ceiling prices and the formulations mentioned in SO. 1215(E) dated 25.03.2020 to the two companies namely, M/s Shree Krishna Keshav Laboratories Ltd and M/s Axa Parentals Ltd for I.V. fluids in packages in non-glass with special features.

6.2 M/s Eurolife Healthcare Pvt. Ltd made a demonstration before the Committee regarding the packages in non-glass of IV fluid having special features like (i) Self Collapsibility and self-seal ability, (ii) not having air-vent and (iii) having no chance of contamination during manufacture / infusion / admixing levels. A member of the Committee sought information from M/s Eurolife Healthcare Pvt. Ltd regarding the availability of licence for manufacturing of IV fluids with packaging in non-glass having special features in which the company replied that the same would be provided in due course. Hence, the Committee decided to defer the representation of M/s Eurolife Healthcare Pvt. Ltd for further examination.

7. Agenda no. 7 - Application for extension of ceiling price for Ringer lactate injection in packaging with special feature.

7.1 The Committee deliberated upon the matter in detail and noted that 3 companies namely, M/s Denis Chem lab Ltd, M/s Amanta Healthcare Ltd and M/s Shree Krishna Keshav Laboratories Ltd have applied for separate ceiling price for ringer lactate injection in packages with special features in line with S.O. 1216(E) dated 25.03.2020. The three companies made demonstration before the members. The Committee observed that the packages of ringer lactate injection of the three companies namely, M/s Denis Chem lab Ltd, M/s Amanta Healthcare Ltd and M/s Shree Krishna Keshav Laboratories Ltd have special features as (i) Self Collapsibility and self-seal ability, (ii) not having air-vent and (iii) having no chance of contamination during manufacture / infusion / admixing levels. Accordingly, the Committee recommended to extend the ceiling prices and the formulations mentioned in SO. 1216(E) dated 25.03.2020 to the three companies namely, M/s Denis Chem lab Ltd, M/s Amanta Healthcare Ltd and M/s Shree Krishna Keshav Laboratories Ltd for ringer lactate injection for packages with special features.

8. Agenda no. 8 - Application for separate price under para 11(3) of DPCO 2013 filed by M/s Abbott India Ltd in respect of Digene Stickpack

8.1 The Committee deliberated upon the matter in detail and observed the demonstration made by M/s Abbott India Ltd. The Committee observed that the formulation is a non-scheduled formulation and NPPA monitors its price. The Committee further observed that application for separate price is only for change in packaging and there is no incremental innovation or significant therapeutic efficacy. Accordingly, the Committee decided to reject the application of M/s Abbott India Ltd for separate price of Digene Stickpack under para 11(3) of DPCO 2013.

9. Agenda no. 9 - Application for upward price revision of Ibuprofen 200 mg and 400 mg tablet under para 19 of DPCO 2013 by M/s Abbott India Ltd

Record note of discussion to be circulated separately to the members

10. Agenda no. 10 - Application for upward price revision of Mannitol Injection 20% under para 19 of DPCO 2013 by Rusuma Laboratories Ltd

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

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

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

Copy to:
All members of the Committee.

