

National Pharmaceutical Pricing Authority**Subject: Minutes of the 21st meeting of Multidisciplinary Committee of Experts held on 28.08.2020 at 02:30 PM in NPPA**

21st meeting of the “Multidisciplinary Committee of Experts” was held on 28.08.2020 under the Convenorship of Sh. N.I. Chowdhury, Adviser (Cost), in NPPA. The following members attended the meeting through video conferencing:-

1. Dr. Vijay Kumar, Scientist-G and Head (BMS), ICMR, New Delhi
2. Dr. Jai Prakash, Sr. Principal Scientific Officer, IPC
3. Dr. Pooja Gupta, Assoc. Prof., Pharmacology, AIIMS, New Delhi
4. Dr. Rakesh K. Singh, Assoc. Professor, NIPER, Raebareli
5. Shri A. K. Pradhan, Dy. Drugs Controller, CDSCO

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

I. Agenda No. 1 - Retail price fixation under Para 5 of DPCO, 2013 - Human Prothrombin Complex IP-250 IU in which each vial containing Human Coagulation Factor II 175-412 IU, Human Coagulation Factor VII 40-260 IU, Human Coagulation Factor IX 250 IU, Human Coagulation Factor X 150-530 IU, Protein C 230-450 IU, Protein S 220-440 IU, Heparin 15-30 IU, Total protein not more than 52g/l 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 Human Prothrombin Complex IP-250 IU in which each vial containing Human Coagulation Factor II 175-412 IU, Human Coagulation Factor VII 40-260 IU, Human Coagulation Factor IX 250 IU, Human Coagulation Factor X 150-530 IU, Protein C 230-450 IU, Protein S 220-440 IU, Heparin 15-30 IU, Total protein not more than 52g/l for M/s Intas Pharmaceuticals Ltd. (manufacturer and marketer) at Rs. 19819.49 per vial excluding GST as detailed below:

Computation of Retail Price per vial	Source/Method	Price excluding GST (Rs.)
Worked out Retail price for Human Prothrombin Complex I.P. 500 IU. = 30491.52 per vial	Calculation as para 4 of DPCO 2013 (January 2020)	Rs. 30491.52 per vial
Retail price for Human Prothrombin Complex I.P. 250 IU applying the formula of Pronab Sen Committee Report*	$30491.52[1+0.70\{(250-500)/500\}]$	Rs. 19819.49 per vial
Company claimed Price		Rs. 20000.00 per vial
Recommended price		Rs. 19819.49 per vial

* 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 injectables

2. Agenda No. 2 - Retail price fixation under Para 5 of DPCO, 2013 - Betadine Alcoholic Handrub in which each 100 ml contains Povidone Iodine IP 1.0g (Available Iodine 0.1 g) and 2-Propanol IP 50 mg for M/s Win Medicare Pvt. Ltd (marketer) and M/s G.S. Pharmbutor Pvt. Ltd (manufacturer/ importer).

2.1 The Committee deliberated upon the matter in detail and recommended the retail price of Betadine Alcoholic Handrub in which each 100 ml contains Povidone Iodine IP 1.0g (Available Iodine 0.1 g) and 2-Propanol IP 50 mg for M/s Win Medicare Pvt. Ltd (marketer) and M/s G.S. Pharmbutor Pvt. Ltd (manufacturer/ importer). at Rs. 92.00 per 200 ml pack excluding GST as detailed below:

Computation of Retail Price per ml	Source/Method	Rs.
Composition – Each 100 ml containing Povidone Iodine IP 1.0g (Available Iodine 0.1 g)+ 2-Propanol IP 50 mg		
a. Povidone Iodine *	Retail Price as per Pronab Sen Committee Report	0.17 per ml
b. 2-Propanol IP Solution	Ceiling Price of Ethyl Alcohol 50% (Data of Isopropyl Alcohol not available)	0.34 per ml
Worked out Retail Price		0.51 per ml
c. Less 30% of the lowest of (a) and (b) similar to formula recommended in the Pronab Sen Committee report		0.05 per ml
Net Retail Price (a+b-c)		0.46 per ml
Retail price for 200ml pack		Rs. 92.00
Company Claimed Price for 200ml pack		Rs. 245.53
Recommended price		Rs. 92.00

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 injectables.

Calculation of price of Povidone Iodine IP 1.0g solution

Ceiling Price for Povidone Iodine 5% = Rs. 0.39 per ml

Derived Retail price for Povidone Iodine Solution = $0.39[1 + 0.70\{(1-5)/5\}] = \text{Rs. } 0.17 \text{ per ml}$

Calculation of price for 2-Propanol IP solution

Ceiling Price of Ethyl Alcohol (denatured) 70% = Rs. 0.42 per ml

Derived Retail price for Ethyl Alcohol 50% = $0.42[1 + 0.70\{(50-70)/70\}] = \text{Rs. } 0.34 \text{ per ml.}$

3. Agenda no. 3 - Retail price fixation under Para 5 of DPCO, 2013 - Valera M 500 Tablet in which each film coated bilayer tablet contains Evogliptin Tartrate eq. to Evogliptin 5 mg and Metformin Hydrochloride IP 500 mg (as sustained release form) for M/s Alkem Laboratories Ltd. (marketer) and M/s Alkem Healthscience (manufacturer/ importer).

3.1 The Committee deliberated upon the matter in detail and recommended the retail price of Valera M 500 Tablet in which each film coated bilayer tablet contains Evogliptin Tartrate eq. to Evogliptin 5 mg and Metformin Hydrochloride IP 500 mg (as sustained release form) for M/s Alkem Laboratories Ltd. (marketer) and M/s Alkem Healthscience (manufacturer/ importer) at Rs. 17.11 per tablet excluding GST as detailed below:

Computation of Retail Price per Tablet	Source/Method	Rs.
Composition – Evogliptin 5mg + Metformin HCL 500mg Tablet		
a. Evogliptin 5mg *	Retail Price calculated as per Para 4 (December 19 data)	15.58
b. Metformin HCL 500mg (As sustained release)	Notified Ceiling Price	1.91
Worked out Retail Price		17.49
c. Less 20% of the lowest of (a) and (b) similar to formula recommended in the Pronab Sen Committee report		0.38
Net Retail Price (a+b-c)		17.11
Company Claimed Price		19.94
Recommended price		17.11

4. Agenda no. 4 - Retail price fixation under Para 5 of DPCO, 2013 - Amoxicillin and Potassium Clavulanate Oral Suspension IP in which Each 5 ml of the reconstituted suspension contains Amoxicillin Trihydrate (759.04 mg) eq. to Amoxicillin Free Acid 652.78 mg and Potassium Clavulanate (61.48 mg) eq. to Clavulanic Acid 50.41 mg (Brand name: Augmentin ES) for M/s GlaxoSmithKline Pharmaceuticals Ltd. (marketer/ importer)

4.1 The Committee deliberated upon the matter in detail and recommended the retail price of Amoxicillin and Potassium Clavulanate Oral Suspension IP in which Each 5 ml of the reconstituted suspension contains Amoxicillin Trihydrate (759.04 mg) eq. to Amoxicillin Free Acid 652.78 mg and Potassium Clavulanate (61.48 mg) eq. to Clavulanic Acid 50.41 mg (Brand name: Augmentin ES) for M/s GlaxoSmithKline Pharmaceuticals Ltd. (marketer/ importer) at Rs. 181.50 per 50 ml pack excluding GST as detailed below:

Computation of Retail Price per ml	Source/Method	Rs.
Composition – Each 5ml containing Amoxicillin Trihydrate eq. to Amoxicillin Free Acid 652.78mg + Potassium Clavulanate eq. to		

Clavulanic Acid 50.41mg		
a. Amoxicillin 652.78mg *	Retail Price as per Pronab Sen Committee Report	2.85 per ml
b. Clavulanic Acid 50.41mg	Derived retail price	1.12 per ml
Worked out Retail Price		3.97 per ml
c. Less 30% of the lowest of (a) and (b) similar to formula recommended in the Pronab Sen Committee report		0.34 per ml
Net Retail Price (a+b-c)		3.63 per ml
Retail price for 50ml pack		Rs. 181.50
Company Claimed Price for 50ml pack		Rs. 400.00
Recommended price		Rs. 181.50

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 injectables.

Calculation of price of Amoxicillin 652.78 mg suspension

Ceiling Price for Amoxicillin 250mg/5ml Oral liquid = Rs. 1.34 per ml

Derived Retail price for Amoxicillin 652.78mg/5ml Suspension = $1.34[1 + 0.70\{(652.78 - 250) / 250\}] =$
Rs. 2.85 per ml

Calculation of price for Clavulanic Acid 50.41mg suspension

Ceiling Price of Amoxycillin 200mg + Clavulanic Acid 28.50mg / 5ml dry syrup = Rs. 1.80 per ml

Less: Price of Amoxycillin 200mg / 5ml (Rs. 1.34/250*200) = Rs. 1.07 per ml

Price of Clavulanic Acid 28.50mg / 5ml dry syrup (Rs. 1.80-Rs. 1.07) = Rs. 0.73 per ml

Derived Retail price for Clavulanic Acid 50.41mg dry syrup = $0.73[1 + 0.70\{(50.41 - 28.50) / 28.50\}] =$ Rs. 1.12 per ml

5. Agenda no. 5 - Application for extension of ceiling price for Ringer lactate injection in packaging with special feature.

5.1 The Committee deliberated upon the matter in detail and noted that 2 companies namely, M/s Axa Parenterals Ltd and M/s Rusoma Laboratories Pvt. 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 two companies made demonstration before the members. The Committee observed that the packages of ringer lactate injection of the two companies namely, M/s Axa Parenterals Ltd and M/s Rusoma Laboratories Pvt. 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 two companies namely, M/s Axa Parenterals Ltd and M/s Rusoma Laboratories Pvt. Ltd for ringer lactate injection for packages with special features.

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 one company namely, M/s Rusoma Laboratories Pvt. Ltd had 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. M/s Rusoma Laboratories Pvt. Ltd made demonstration before the members. The Committee observed that the non-glass packages of I.V. fluids of M/s Rusoma Laboratories Pvt. 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 M/s Rusoma Laboratories Pvt. Ltd for I.V. fluids in packages in non-glass with special features.

7. Agenda no. 7 - Application for upward price revision of Mannitol Injection 20% under para 19 of DPCO 2013 by Rusoma Laboratories Ltd

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

8. Agenda no. 8 - Ceiling Price fixation of Tetanus + Diphtheria (TD) Vaccine

8.1 The Committee deliberated upon the matter in detail and noted that as per explanation 3 of amended schedule-I of DPCO 2013, all available strength of TD vaccine be considered as scheduled formulations and recommended that separate ceiling price of TD vaccine for different strength may be fixed.

The meeting ended with a vote of thanks to all.

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

Copy to:
All members of the Committee.