

National Pharmaceutical Pricing Authority**Subject: Minutes of the 23rd meeting of Multidisciplinary Committee of Experts held on 20.10.2020 at 11:00 AM in NPPA**

23rd meeting of the “Multidisciplinary Committee of Experts” was held on 20.10.2020 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. Rakesh K. Singh, Assoc. Professor, NIPER, Raebareli
3. Dr. Pooja Gupta, Assoc. Prof., Pharmacology, AIIMS, New Delhi
4. Dr. Robin Mumar, Principal 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

I. Agenda No. 1 - 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 containing 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) and M/s Glaxo Wellcome Production (manufacturer/ importer).

I.I The Committee noted the documents submitted by the company. The Committee also noted that the oral liquid having Fixed Dose Combination (FDC) of Amoxicillin 200 mg and Clavulanic acid 28.5 mg per 5 ml is a scheduled formulation under DPCO 2013 and dry syrup having Fixed Dose Combination (FDC) of Amoxicillin 125 mg and Clavulanic acid 31.5 mg per 5 ml are scheduled formulation under DPCO 2013. The Committee observed that the product Augmentin ES which is an oral suspension have FDC of Amoxicillin and Clavulanic Acid in different proportion than the scheduled formulation. The Committee deliberated upon the matter in detail and is of the view that there is reduction in the ratio of clavulanic acid in the new combination. This innovation should reduce the cost due to lower clavulanic acid needed now. The dose of amoxicillin has however not been reduced in the combination. There is no evidence that demonstrate that this combination has reduced the AMR in clinical practice. Accordingly, the Committee decided that the price as recommended earlier in its 21st meeting dated 28.08.2020, at Rs. 181.50 per 50 ml pack excluding GST for 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), be considered, as detailed below:

Computation of Retail Price per ml	Source/Method	Rs.

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 :

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

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 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

2. Agenda No. 2 - Retail price fixation under Para 5 of DPCO, 2013 - Betadine Alcoholic Handrub in which each 100 ml containing Povidone Iodine IP 1.0g (Available Iodine 0.1 g) and 2-Propanol IP 50 g 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 observed that although the price of 2-Propanol (Isopropyl Alcohol) is substantially higher than Ethyl alcohol (denatured), therapeutic advantages of using 2-Propanol (Isopropyl Alcohol) over Ethyl alcohol (denatured) needs to be established. Accordingly, the Committee decided that the opinion of Dr. Arti Kapil, Professor, Department of Microbiology, All India Institute of Medical Sciences (AIIMS), New Delhi regarding therapeutic advantages of using 2-Propanol (Isopropyl Alcohol) over Ethyl alcohol (denatured), if any, may be obtained. The Committee further directed that the therapeutic advantages of using 2-Propanol (Isopropyl Alcohol) over Ethyl alcohol (denatured) be also obtained from M/s Win Medicare Pvt. Ltd.

3. Agenda no. 3 - Application for grant of separate price/ special price for “Synchrobreathe inhaler device” under the provision of Para 11(3) or para 32(3) of DPCO 2013

3.1 The Committee noted the documents submitted by the company and observed that based on its recommendation in the 14th meeting held on 04.12.2019, the Authority in its 71st meeting dated 09.12.2019 approved the additional price of Rs. 67.20 (excluding GST) of ‘Synchrobreathe inhaler device’ of M/s Cipla Ltd on the applicable ceiling price of the Inhalation having the formulation (a) Budesonide 200mcg+ Formeterol 6mcg per dose Inhaler 120 MDI and (b) Budesonide 400mcg+ Formeterol 6mcg per dose Inhaler 120 MDI. The additional price of Synchrobreathe inhaler device’ at Rs. 67.20 (excluding GST) would remain fixed irrespective of the subsequent change in ceiling price of the Inhalation

3.2 The Committee noted that presently M/s Cipla has applied for separate/ special price for “Synchrobreathe Inhaler Device” for its product Tiotropium inhalation (MDI) 9mcg/dose. The Committee deliberated upon the matter in detail and opined that since the additional price for “Synchrobreathe Inhaler Device” at Rs. 67.20 (excluding GST) had already been approved for M/s Cipla Ltd for (a) Budesonide 200mcg+ Formeterol 6mcg per dose Inhaler 120 MDI and (b) Budesonide 400mcg+ Formeterol 6mcg per dose Inhaler 120 MDI, the same price may be extended for its product Tiotropium inhalation (MDI) 9mcg/dose since the devices are the same. Accordingly, the Committee recommended an additional price of Rs. 67.20 (excluding GST) for “Synchrobreathe inhaler device” on the ceiling price of Tiotropium inhalation (MDI) 9mcg/dose having Inhalation with Synchrobreathe inhaler device.

3.3 The Committee also noted its earlier recommendation in the 14th meeting held on 04.12.2019 and the decision of the Authority in its 71st meeting dated 09.12.2019 that the additional price of Rs. 67.20 (excluding GST) for “Synchrobreathe inhaler device” would remain fixed irrespective of the change in the ceiling price of the Inhalation. The Committee observed that the “Synchrobreathe inhaler device” is the component of Tiotropium inhalation (MDI) 9mcg/dose and Tiotropium inhalation (MDI) 9mcg/dose is a scheduled formulation for which annual price increase as per Wholesale Price Index (WPI) is allowed as per the provisions of DPCO 2013. The Committee deliberated upon the matter in detail and recommended that since “Synchrobreathe inhaler device” is a component of the scheduled formulation Tiotropium inhalation (MDI) 9mcg/dose, Wholesale Price Index

(WPI), as applicable for scheduled formulation, be allowed on the additional price of “Synchrobreathe inhaler device” from the next year.

4. Agenda no. 4 - Ceiling price fixation of Pheniramine Maleate Injection 22.75 mg/ ml in 33 ml and 100 ml pack.

4.1 The Committee noted that the formulation Pheniramine Maleate Injection 22.75 mg/ ml is a scheduled formulation under DPCO 2013 and the ceiling price of Pheniramine Maleate Injection 22.75 mg/ ml in 2 ml and 10 ml pack has been notified. The Committee also noted regarding the fixation ceiling price of Pheniramine Maleate Injection 22.75 mg/ ml in 33 ml and 100 ml pack for which no data is available. The Committee deliberated upon the matter in detail and directed that draft ceiling price of Pheniramine Maleate Injection 22.75 mg/ ml for 33 ml and 100 ml pack be worked out based on the notified price of Pheniramine Maleate Injection 22.75 mg/ ml in 2ml and 10ml pack in line with the price regulation formula mentioned in Pronab Sen Committee and place before the Committee in its next meeting.

The meeting ended with a vote of thanks to all.

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

Copy to:
All members of the Committee.