

National Pharmaceutical Pricing Authority

Subject: Minutes of the 36th meeting of Multidisciplinary Committee of Experts held on 11.10.2021 at 2:30 PM in NPPA

36th meeting of the "Multidisciplinary Committee of Experts" was held on 11.10.2021 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, GoI & Ex-HoD, Pharmacology & Dean (Academics), AIIMS, New Delhi
2. Shri A. K. Pradhan, Jt. Drugs Controller, CDSCO
3. Dr. Jai Prakash, Sr. Principal Scientific Officer, Indian Pharmacopoeia Commission

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

1. Ms. Rashmi Tahiliani, Jt. Director (Pricing), NPPA
2. Sh. Prasenjit Das, Deputy Director (Pricing), NPPA
3. Sh. Mahaveer Saini, Deputy Director (Pricing), NPPA

1. Agenda No. 1 - Retail price fixation under Para 5 of DPCO, 2013- Each film coated tablet containing Metoprolol Tartrate IP 25 mg + Ivabradine Hydrochloride eq. to Ivabradine 5 mg for M/s Ajanta Pharma Ltd. (manufacturer and marketer)

1.1 The Committee observed the reply of M/s Ajanta Pharma Ltd and noted that M/s Ajanta Pharma Ltd had manufactured/ marketed the formulation "tablet containing Metoprolol Tartrate IP 25 mg + Ivabradine Hydrochloride eq. to Ivabradine 5 mg" without obtaining prior price approval which is in contravention to the provisions of DPCO 2013. The Committee further noted from the Pharmatrac Database that M/s Ajanta Pharma Ltd had launched the formulation since November 2017.

1.2 The Committee deliberated upon the matter in detail and recommend the retail price based on the data available for the month of April 2017 i.e. six month prior to the launch of the formulation by M/s Ajanta Pharma Ltd. Accordingly, the Committee recommended the retail price of each film coated tablet containing Metoprolol Tartrate IP 25 mg + Ivabradine Hydrochloride eq. to Ivabradine 5 mg for M/s Ajanta Pharma Ltd. (manufacturer and marketer) at Rs. 15.46 per tablet excluding GST as detailed below:

Computation of Retail Price per Tablet	Source/Method	Amount (Rs.)
Composition – Each film coated tablet containing Metoprolol Tartrate IP 25 mg + Ivabradine Hydrochloride eq. to Ivabradine 5 mg		
a. Metoprolol Tartrate IP 25 mg	Ceiling Price (as per notification)	2.94

	no.1039(E) dated 01 st April, 2017	
b. Ivabradine Hydrochloride eq. to Ivabradine 5 mg	Retail price (as per April, 2017 data)	14.18
Worked out Retail Price		17.12
c. Less 20% of the lowest of (a) and (b) as recommended in the Pronab Sen Committee report		0.59
Net Retail Price (a+b-c)		16.53
Company Claimed Price		15.46
Recommended price		15.46

2. Agenda No. 2 - Retail price fixation under Para 5 of DPCO, 2013- Each film coated tablet containing Metoprolol Tartrate IP 50 mg + Ivabradine Hydrochloride eq. to Ivabradine 5 mg for M/s Ajanta Pharma Ltd. (manufacturer and marketer).

2.1 The Committee observed the reply of M/s Ajanta Pharma Ltd and noted that M/s Ajanta Pharma Ltd had manufactured/ marketed the formulation "tablet containing Metoprolol Tartrate IP 50 mg + Ivabradine Hydrochloride eq. to Ivabradine 5 mg" without obtaining prior price approval which is in contravention the provisions of DPCO 2013. The Committee further noted from the Pharmatrac Database that M/s Ajanta Pharma Ltd had launched the formulation since November 2017.

2.2 The Committee deliberated upon the matter in detail and recommended the retail price based on the data available for the month of April 2017 i.e. six month prior to the launch of the formulation by M/s Ajanta Pharma Ltd. Accordingly, the Committee recommended the retail price of each film coated tablet containing Metoprolol Tartrate IP 50 mg + Ivabradine Hydrochloride eq. to Ivabradine 5 mg for M/s Ajanta Pharma Ltd. (manufacturer and marketer) at Rs. 17.74 per tablet excluding GST as detailed below:

Computation of Retail Price per Tablet	Source/Method	Amount (Rs)
Composition – Each film coated tablet containing Metoprolol Tartrate IP 50 mg + Ivabradine Hydrochloride eq. to Ivabradine 5 mg		
a. Metoprolol Tartrate IP 50 mg	Ceiling Price (as per notification no.1039(E) dated 01 st April, 2017	4.45
b. Ivabradine Hydrochloride eq. to Ivabradine 5 mg	Retail price (as per April, 2017 data)	14.18
Worked out Retail Price		18.63

c. Less 20% of the lowest of (a) and (b) as recommended in the Pronab Sen Committee report	0.89
Net Retail Price (a+b-c)	17.74
Company Claimed Price	17.81
Recommended price	17.74

3. Agenda No. 3 – Retail price fixation under Para 5 of DPCO, 2013- Each ml solution containing Cyclosporine IP 0.9 mg in 0.25 ml pack for M/s Sun Pharmaceutical Industries Ltd. (manufacturer and marketer)

3.1 The Committee deliberated upon the matter in detail and recommended the retail price of each ml solution containing Cyclosporine IP 0.9 mg per ml in 0.25 ml pack for M/s Sun Pharmaceutical Industries Ltd. (manufacturer and marketer) at Rs. 35.57 per 0.25 ml pack excluding GST as detailed below:

a. Calculation of retail Price of Cyclosporine IP 0.05% w/v drops based on Pharmatrac data for the month of February 2021 = Rs. 91.20 per ml

b. Derived Retail price for Cyclosporine IP 0.9 mg/ ml based on the recommendation of Pronab Sen Committee Report with respect to calculated retail price of Cyclosporine IP 0.05% w/v drops

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

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

$$= 91.20[1 + 0.70\{(0.9 - 0.5) / 0.5\}] = \text{Rs. } 142.272 \text{ per ml}$$

c. Therefore, the retail price of Cyclosporine solution 0.9 mg/ml in 0.25 ml pack = Rs. 142.272 x 0.25 = Rs. 35.57 (excluding GST)

4. Agenda no. 4 - Clarification on Clotrimazole 1% mouth paint as Scheduled formulation

4.1 The Committee deliberated upon the matter in detail and decided that Clotrimazole 1% mouth paint is a scheduled formulation based on explanation I of DPCO 2013.

The meeting ended with a vote of thanks to all.

Rashmi
12/10/2021
(Rashmi Tahiliani)
Jt. Director (Pricing)

Copy to:
All members of the Committee.

