

National Pharmaceutical Pricing Authority

Subject: Minutes of the 17th meeting of Multidisciplinary Committee of Experts held on 19.03.2020 at 11:00 AM in NPPA

17th meeting of the “Multidisciplinary Committee of Experts” was held on 19.03.2020 under the Convenorship of the Sh. N.I. Chowdhury, Adviser (Cost), in the Conference Room of NPPA. The following members attended the meeting:-

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. Jai Prakash, Sr. Principal Scientific Officer, IPC
5. Dr. Pooja Gupta, Asso. Professor of Pharmacology, AIIMS, New Delhi

Dr. D. Parmar, Asso. Professor, Dr. RML Hospital attended the meeting as special invitee.

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

I. Agenda No. 1 - Retail price fixation under Para 5 of DPCO, 2013 of Atorvastatin Calcium 30 mg tablet for M/s Intas Pharmaceuticals Limited (marketer and Manufacturer)

1.1 The Committee deliberated upon the matter in detail and observed that the company has claimed the retail price at Rs. 17.50 per tablet without GST. The Committee further observed that the formulations Atorvastatin 10 mg, 20 mg and 40 mg tablet are scheduled formulations and there ceiling prices are notified. Accordingly, the Committee decided to arrive the retail price of Atorvastatin 30 mg tablet for M/s Intas Pharmaceuticals Ltd by taking the lowest derived price after applying the principles of drugs pricing as per Pronab Sen Committee report based on the notified ceiling price of Atorvastatin 10 mg, 20 mg or 40 mg tablet.

1.2 The retail price was calculated based on the present applicable notified ceiling prices (SO. 1485(E) dated 29.03.2020) of Atorvastatin 10mg, 20g and 30 mg tablet and it was observed the lowest derived price came to Rs. 13.96 per tablet excluding GST by taking the notified ceiling price of Atorvastatin 10 mg tablet as detailed below:

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

$$= 5.37 [1 + 0.80 \{(30 - 10) / 10\}] = \text{Rs. } 13.96 \text{ per tablet}$$

Where : P(s) = Price ceiling of the strength s (i.e. 30 mg tablet)

P* = price ceiling for reference strength s* (10 mg tablet i.e. Rs. 5.37)

s = strength in terms of API content (30 mg)

s* = reference strength (10 mg)

a = 0.8 for tablet / capsule.

1.3. Accordingly, the Committee recommended the retail price of Atorvastatin 30 mg tablet for M/s Intas Pharmaceuticals Ltd (marketer and Manufacturer) at Rs. 13.96 per tablet excluding GST.

2. Agenda No. 2 Retail price fixation under Para 5 of DPCO, 2013 of Atorvastatin Calcium 60 mg tablet for M/s Intas Pharmaceuticals Limited (marketer and Manufacturer)

2.1 The Committee deliberated upon the matter in detail and observed that the company has claimed the retail price at Rs. 25.00 per tablet without GST. The Committee further observed that the formulations Atorvastatin 10 mg, 20 mg and 40 mg tablet are scheduled formulations and their ceiling prices are notified. Accordingly, the Committee decided to arrive at the retail price of Atorvastatin 60 mg tablet for M/s Intas Pharmaceuticals Ltd by taking the lowest derived price after applying the principles of drug pricing as per Pronab Sen Committee report based on the notified ceiling price of Atorvastatin 10 mg, 20 mg or 40 mg tablet.

2.2 The retail price was calculated based on the present applicable notified ceiling prices (SO. 1485(E) dated 29.03.2020) of Atorvastatin 10mg, 20mg and 30 mg tablet and it was observed that the lowest derived price came to Rs. 13.96 per tablet excluding GST by taking the notified ceiling price of Atorvastatin 40 mg tablet as detailed below:

$$P(s) = P^* \cdot [1 + a \cdot \{(s - s^*) / s^*\}]$$
$$= 18.88 [1 + 0.80 \{(60 - 40) / 40\}] = \text{Rs. } 26.43 \text{ per tablet}$$

Where : $P(s)$ = Price ceiling of the strength s (i.e. 60 mg tablet)
 P^* = price ceiling for reference strength s^* (40 mg tablet i.e. Rs. 18.88)
 s = strength in terms of API content (60 mg)
 s^* = reference strength (40 mg)
 $a = 0.8$ for tablet / capsule.

2.3. Accordingly, the Committee also noted the claimed price at Rs. 25.00 per tablet and recommended the retail price of Atorvastatin 60 mg tablet for M/s Intas Pharmaceuticals Ltd (marketer and Manufacturer) at Rs. 25.00 per tablet excluding GST, being lower than the worked out price.

3. Agenda no. 3 Retail price fixation under Para 5 of DPCO, 2013 of syrup in which each 15 ml containing Ferric Ammonium Citrate IP 160mg, Vitamin B12 IP 5mcg, Folic Acid IP 1 mg, Zinc Sulphate Monohydrate IP 30mg for M/s Zydus Healthcare Ltd (marketer) and M/s Zydus Healthcare Ltd (manufacturer/ importer).

3.1 The Committee observed that M/s Zydus Healthcare Ltd applied for the retail price fixation of syrup in which each 15 ml containing Ferric Ammonium Citrate IP 160mg, Vitamin B12 IP 5mcg, Folic Acid IP 1 mg, Zinc Sulphate Monohydrate IP 30mg. The application also indicated that the syrup is for "medicines effecting the blood." The Committee perused in detail each component's role and observed that Zinc Sulphate Monohydrate IP 30 mg does not seem to have any role related to blood as claimed. Further, vitamin B12 5mcg also does not have any therapeutic role related to the blood as the requirement is 1mg and 2mg for initial treatment and 250mcg subsequently. The Committee also noted that the strength of folic acid is also sub-therapeutic.

3.2 The Committee is also of the opinion that since these components i.e. Zinc Sulphate Monohydrate IP 30mg, Vitamin B12 5mcg and Folic acid 1 mg has no relevance towards "medicines effecting the blood" as claimed by the company, the cost of these components may not be considered for fixation of price and directed that the price is to be worked out on the basis of Ferric Ammonium Citrate 160 mg and placed before the Committee in its next meeting.

3.3 The Committee further directed to obtain the status approval of the formulation and the 'indications mentioned therein' from the Office of DCGI and place before the Committee in its next meeting.

4. Agenda no. 4 Retail price fixation under Para 5 of DPCO, 2013 of various strengths of the injection having the composition 'Docaravimab' and 'Miromavimab' for M/s Cadila Healthcare Ltd (marketer) and M/s Cadila Healthcare Ltd (manufacturer/importer)

4.1 The Committee deliberated upon the matter in detail and noted that further details regarding (i) recommended dosage (ii) advantages in terms of efficacy and safety vis-a-vis other anti-rabies formulation available and (iii) Pharmacoeconomics analysis is required.

4.2 Accordingly, the Committee directed that requisite information/ documents be obtained from M/s Zydus Healthcare Ltd and the company be intimated to make presentation on the matter in the next Committee meeting.

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

Copy to:
All members of the Committee.