

National Pharmaceutical Pricing Authority

Subject: Minutes of the 39th meeting of the Multidisciplinary Committee of Experts held on 25.02.2022 at 11:00 AM.

39th meeting of the "Multidisciplinary Committee of Experts" was held on 25.02.2022 at 11:00 A.M. under the convenorship of Shri Manmohan Sachdeva, Advisor (Cost), through video-conferencing. The following members attended the meeting through video conferencing:-

1. Shri A. K. Pradhan, Jt. Drugs Controller, CDSCO
2. Dr. J. J. Cherian, Scientist-D, ICMR
3. Prof. Y. K. Gupta, Principal Scientific Advisor (projects), THSTI-DBT, GoI& Ex-HoD, Pharmacology & Dean (Academics), AIIMS, New Delhi – Co-opted member
4. Dr. Pooja Gupta, Associate Professor, Department of Pharmacology, AIIMS-New Delhi,
5. Shri Gaurav Pratap Singh, Sr. Scientific Officer, Indian Pharmacopoea Commission –Co-opted member nominated by Dr. Jai Prakash, Sr. Principal Scientific officer, Indian Pharmacopoea Commission

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

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

1. Agenda No. 1 - Retail price fixation under Para 5 of DPCO, 2013-Each vial contains Total Protein 50g/L + Immunoglobulin M 6g/L + Immunoglobulin A 6g/L + Immunoglobulin G 38g/L + Glucose Monohydrate (as stabilizer) 27.5 g/L + Sodium Chloride 4.56 g/L + Water for injection, Distribution of Ig G subclass is approx. 62% IgG1, 27% IgG2, 1%lg G3, 10% Ig G4 for M/s Intas Pharmaceuticals Ltd. (manufacturer and marketer)

1.1 The Committee noted the additional representation made by M/s Intas Pharmaceuticals Ltd vide letter dated 16.02.2022 and the presentation made by M/s Intas Pharmaceuticals Ltd with respect to the subject formulation. The Committee also noted that the Human Normal Immunoglobulin Solution for Infusion 5 % is a scheduled formulation under DPCO 2013 and the present applicable ceiling price is Rs. 154.65 per ml excluding GST. The Committee observed that the subject formulation is an incremental innovation and have advantage without any increased side effect over normal human immunoglobulin 5 % infusion. The Committee deliberated upon the matter in detail and decided that an additional 15% increase over the present applicable ceiling price of Normal Human Immunoglobulin 5% infusion be allowed to the subject formulation of M/s Intas Pharmaceuticals Ltd for incremental innovation.

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1.2 Accordingly, the Committee recommended the retail price of each vial of Human Normal Immunoglobulin 5% solution (Ig M enriched) which contains Total Protein 50g/L + Immunoglobulin M 6g/L + Immunoglobulin A 6g/L + Immunoglobulin G 38g/L + Glucose Monohydrate (as stabilizer) 27.5 g/L + Sodium Chloride 4.56 g/L + Water for injection, Distribution of Ig G subclass is approx. 62% IgG1, 27% IgG2, 1% IgG3, 10% IgG4 for M/s Intas Pharmaceuticals Ltd. (manufacturer and marketer) at Rs. 177.85 per ml [Rs. 154.65 per + additional 15% increment] excluding GST.

2. Agenda No. 2 - Retail price fixation under Para 5 of DPCO, 2013- Each uncoated bilayered tablet containing Efonidipine Hydrochloride Ethanolate 20 mg + Telmisartan IP 40 mg for M/s Zuventus Healthcare Ltd. (manufacturer and marketer)

2.1 The Committee deliberated upon the matter in detail and recommended the retail price of each uncoated bilayered tablet containing Efonidipine Hydrochloride Ethanolate 20 mg + Telmisartan IP 40 mg for M/s Zuventus Healthcare Ltd. (manufacturer and marketer) at Rs. 15.67 per tablet excluding GST as detailed below:

Computation of Retail Price per Tablet	Source/Method	Amount (Rs.)
Composition – Each uncoated bilayered tablet containing Efonidipine Hydrochloride Ethanolate 40 mg + Telmisartan IP 40 mg		
a. Efonidipine Hydrochloride Ethanolate 40 mg (Calculated as per Para 4 of DPCO 2013)	Retail price (as per June, 2021 data)	10.38
b. Telmisartan IP 40 mg	Ceiling Price (as per notification no.1330(E) dated 25th March, 2021)	6.61
Worked out Retail Price (a+b)		16.99
c. Less 20% of the lowest of (a) and (b) as recommended in the Pronab Sen Committee report		1.32
Net Retail Price (a+b-c) (per tablet excluding GST)		15.67
Company Claimed Price excluding GST (per tablet)		19.20
Recommended price excluding GST (per tablet)		15.67

3. Agenda No. 3 - Retail price fixation under Para 5 of DPCO, 2013- Each modified release tablet containing Cefixime IP as trihydrate eq. to Anhydrous Cefixime 200 mg (in immediate release form) + Dicloxacillin Sodium IP eq. to Dicloxacillin 500 mg (in modified release form) + Lactic Acid Bacillus 2.5 billion spores (appropriate overages of lactic acid bacillus spores added) for M/s Akums Drugs & Pharmaceuticals Ltd. (manufacturer) and M/s Abbott Healthcare Pvt. Ltd. (marketer)

3.1 The Committee deliberated upon the matter in detail and recommended the retail price of each modified release tablet containing Cefixime IP as trihydrate eq. to Anhydrous Cefixime 200 mg (in immediate release form) + Dicloxacillin Sodium IP eq.

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to Dicloxacillin 500 mg (in modified release form)+ Lactic Acid Bacillus 2.5 billion spores (appropriate overages of lactic acid bacillus spores added) for M/s Akums Drugs & Pharmaceuticals Ltd. (manufacturer) and M/s Abbott Healthcare Pvt. Ltd. (marketer) at Rs. 18.24 per tablet excluding GST as detailed below:

Sl. No.	Company	Unit	PTR	Calculation (Rs)
1	M/s Mankind Pharma Ltd (as per Form-V data submitted by the company) (for the formulation tablet containing Cefixime 200mg + Dicloxacillin 500mg)	10 tablets	127.86	12.79
2	Add: Retailer margin @16% (16% of sl. No. 1)			2.05
3	Calculated Price of (tablet containing Cefixime 200mg + Dicloxacillin 500mg) based on submitted Form-V by the companies (excluding GST) (sl. No. 1+ sl. No. 2)			14.84 (Retail price per tablet ex. GST)
4	Price of Lacto acid bacillus 2.5 billion spores [Note 1]			4.25
5	Worked out Retail Price (3+4)			19.09
6	Less:- 20% of the lowest of (3) and (4) as recommended in the Pronab Sen Committee report			0.85
7	Net Retail Price (5-6) (per tablet excluding GST)			18.24
9.	Retail price claimed (per tablet excluding GST)			Rs.19.99 per tablet excluding GST
10.	Recommended retail price (per tablet excluding GST)			18.24

Note 1. As per SO. 2458(E) dated 24.09.2009, it was decided that "for each 10 million spores or part thereof of Lactic Acid Bacillus Rs. 0.017 shall be added/ subtracted. Accordingly, for 2.5 billion spore of Lactic Acid Bacillus it comes to Rs. 4.25 [2.5 billion = 2500 million i.e Rs. 0.017/10 X 2500]

Note 2. In the notification no. 2458(E) dated 24.09.2009, it was mentioned that for each 10 million spores of Lactic acid bacillus Rs. 0.017 to be added. Accordingly, it is assumed that the retail margin has already been included.

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4. Agenda no. 4 - Retail price fixation under Para 5 of DPCO, 2013- Each hard gelatin PR capsule containing Tacrolimus IP 3 mg for M/s Cadila Healthcare Ltd. (manufacturer and marketer).

4.1 The Committee noted the application of M/s Cadila Healthcare Ltd for retail price fixation of Tacrolimus Prolonged Release capsules 3 mg and the representation made by M/s Cadila Healthcare Ltd vide e-mail dated 28.01.2022. The Committee deliberated upon the matter in detail and decided that the clarification be obtained from Central Drugs Standard Control Organisation (CDSCO) regarding the approval status of the drugs in line with the 'New Drugs and Clinical Trial Rules, 2019'. Accordingly, the matter would be further deliberated upon in the next meeting of the Multidisciplinary Committee of Experts based on inputs provided by Central Drugs Standard Control Organisation (CDSCO).

5. Agenda no. 5 - Fixation of Ceiling Price of Clotrimazole 1% mouth paint under DPCO 2013 (NLEM 2015)

5.1 The Committee noted the issue relating to ceiling price fixation of Clotrimazole 1% mouth paint under DPCO 2013 and the representation received from M/s Zydus Healthcare Ltd vide e-mail dated 14.02.2022. The Committee also noted that Clotrimazole 1% drops, cream and mouth paint are for local application and as such there is no significant difference. Further, M/s Zydus Healthcare Ltd has not submitted any published literature on significant difference in Pharmacokinetics (PK) or Pharmacodynamics (PD) of Clotrimazole 1% mouth paint viz-a-vis other scheduled formulation i.e Clotrimazole 1% cream or drops that leads to different outcomes. The Committee deliberated upon matter in detail and reiterated its earlier stand taken in its 36th meeting held on 11.10.2021 that Clotrimazole 1% mouth paint is a scheduled formulation based on Explanation I of DPCO 2013.

5.2 The Committee further decided that clarification be obtained from Central Drugs Standard Control Organisation (CDSCO) regarding the approval status of the formulation Clotrimazole 1% mouth paint. The matter would be further deliberated upon in the next meeting of the Multidisciplinary Committee of Experts based on inputs provided by Central Drugs Standard Control Organisation (CDSCO).

The meeting ended with a vote of thanks to all.

Rashmi
2/3/2022
(Rashmi Tahiliani)
Jt. Director (Pricing)

Copy to:
All members of the Committee.

