

National Pharmaceutical Pricing Authority

Subject: Minutes of the 14th meeting of Multidisciplinary Committee of Experts held on 04.12.2019 at 12:00 noon in NPPA

14th meeting of the "Multidisciplinary Committee of Experts" was held on 04.12.2019 under the Convenorship of the Sh. Kalyan Nag, Adviser (Cost), in the Conference Room of NPPA. The following members/officers attended the meeting:-

1. Prof. Y. K. Gupta, Advisor (Projects), THSTI
2. Dr.C.D.Tripathi, Head Department of Pharmacology, VMMC & Safdarjung Hospital.
3. Dr. Shashi Bhusan, Sr. Scientific Officer, Indian Pharmacopoeia Commission
4. Dr. Monika Ahuja, Scientist-C, ICMR, New Delhi
5. Shri Jayant Kumar, DDC(I), CDSCO
6. Sh. Prasenjit Das, Assistant Director (Pricing), NPPA
7. Sh. Prakash Hemani, Assistant Director (Pricing), NPPA

Agenda No. 1 - Retail price fixation under Para 5 of DPCO, 2013 - TAFFIC Tablet (Each film coated tablet containing Bictegravir 50mg + Tenofovir Alafenamide 25mg + Emtricitabine IP 200mg for M/s Hetero Labs Limited (Manufacturer) and M/s Hetero Healthcare Limited (marketer)).

The Committee deliberated upon the matter in details and noted the price prevailing of the subject formulation in different countries and observed that the maximum price is in USA. Therefore, the claim of the company regarding offering price at 2.38% of the International Price is not relevant. The Committee further noted that Bictegravir shows similar efficacy as that of Dolutegravir with better adverse events profile and resistance profile. The Committee noted that NPPA fixed the retail price of the film coated tablet containing Dolutegravir Sodium eq. to Dolutegravir 50mg, Emtricitabine IP 200mg and Tenofovir Alafenamide Fumarate eq. to Tenofovir Alafenamide 25mg at Rs. 130.61 per tablet (excluding GST) vide SO. 3032(E) dated 23.08.2019. The Committee observed that there is no substantiable data available for admissibility of differential pricing under Pharmacoeconomics and accordingly, recommended that the same price i.e. Rs. 130.61 per tablet (excluding GST) be given to the film coated tablet containing Bictegravir 50mg + Tenofovir Alafenamide 25mg + Emtricitabine IP 200mg for M/s Hetero Labs Limited (Manufacturer) and M/s Hetero Healthcare Limited (marketer).

Agenda No. 2 Retail price fixation under Para 5 of DPCO, 2013 - Clobazam 7.5mg Tablet for M/s Sun Pharma Laboratories Limited (Manufacturer and marketer).

The Committee deliberated upon the matter in details and recommended the retail price of Clobazam 7.5mg Tablet for M/s Sun Pharma Laboratories Limited (Manufacturer and marketer) at Rs. 7.04 per tablet excluding GST. The details of the calculation is summarised below:

a) The Clobazam 5mg Tablet is scheduled formulation under DPCO, 2013 and the present ceiling price is Rs. 5.03 per tablet as per notification SO 1485(E) dated 29.03.2019.

b) The calculation of retail price of Clobazam 7.50mg Tablet is done as per the formula recommended by Pronab Sen Committee as provided below:

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

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 injectibles.

c) Accordingly, the retail price of Clobazam 7.50mg Tablet is calculated as
 $= 5.03[1+0.80\{7.5-5\}/5] = \text{Rs. } 7.04$ per tablet (excluding GST)

Agenda no. 3 Retail price fixation under Para 5 of DPCO, 2013 - Clobazam 2.5mg Tablet for M/s Sun Pharma Laboratories Limited (Manufacturer and marketer).

The Committee deliberated upon the matter in details and recommended the retail price of Clobazam 2.5 mg Tablet for M/s Sun Pharma Laboratories Limited (Manufacturer and marketer) at Rs. 3.02 per tablet excluding GST. The details of the calculation is summerised below:

a) The Clobazam 5mg Tablet is scheduled formulation under DPCO, 2013 and the present ceiling price is Rs. 5.03 per tablet as per notification SO 1485(E) dated 29.03.2019.

b) The calculation of retail price of Clobazam 2.50mg Tablet is done as per the formula recommended by Pronab Sen Committee as provided below:

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

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 injectibles.

c) Accordingly, the retail price of Clobazam 2.50mg Tablet is calculated as
 $= 5.03[1+0.80\{2.5-5\}/5] = \text{Rs. } 3.02$ per tablet (excluding GST)

Agenda no. 4 Retail price fixation under Para 5 of DPCO, 2013 - Ranitidine, Dicyclomine Hydrochloride & Simethicone Tablet (each film coated tablet containing Ranitidine Hydrochloride IP eq. to Ranitidine 150mg, Dicyclomine Hydrochloride IP 10mg, Simethicone IP 20mg) for M/s Mankind Pharma Limited (marketer) and M/s Windlas Biotech Private Limited (Manufacturer).

The Committee deliberated the matter in details. The Committee was informed by the representative of DCGI (one of the Committee members) that the subject formulation is approved for manufacturing and marketing in India. Accordingly, the Committee recommended the retail price of Ranitidine, Dicyclomine Hydrochloride & Simethicone Tablet (each film coated tablet containing Ranitidine Hydrochloride IP eq. to Ranitidine 150mg, Dicyclomine Hydrochloride IP 10mg, Simethicone IP 20mg) for M/s Mankind Pharma Limited (marketer) and M/s Windlas Biotech Private Limited (Manufacturer) at Rs. 4.86 per tablet excluding GST as detailed below:

| Computation of Retail Price per Tablet | Source/Method | Price (Rs.) |
|--|----------------|-------------|
| Composition – Ranitidine 150mg + Dicyclomine Hydrochloride 10mg + Simethicone 20mg | | |
| a. Ranitidine 150mg + Dicyclomine Hydrochloride 10mg Tablet | As per Para 4 | 2.18 |
| b. Simethicone 20mg Tablet | As per para 4* | 3.12 |
| Worked out Retail Price | | 5.30 |
| c. Less 20% of the lowest of (a) and (b) similar to formula recommended in the Pronab Sen Committee report | | 0.44 |
| Net Retail Price (a+b-c) | | 4.86 |
| Company Claimed Price | | 5.00 |
| Recommended price | | 4.86 |

* The Price of Simethicone 20mg Tablet have been worked out as below
Retail Price of Simethicone 25mg Tablet (Sheet enclosed) Rs. 3.72
As per report of Pronab Sen Committee the price of other strengths is to be decided as per formula provided below:

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

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 injectibles.

Price as per above referred formula is $3.72[1 + 0.80\{(20-25)/25\}] = \text{Rs. } 3.12$ per tablet

Agenda no. 5 Retail price fixation under Para 5 of DPCO, 2013 - Amoxicillin, Cloxacillin and Lactic Acid Bacillus Capsules (Each hard gelatin capsule containing Amoxicillin Trihydrate IP eq. to Amoxicillin 250mg, Cloxacillin Sodium IP eq. to Cloxacillin 250mg, Lactic Acid Bacillus 2 billion spores) for M/s Skymap Pharmaceuticals Private Limited (marketer and Manufacturer).

The Committee deliberated the matter in details and decided to deferred the same till the next meeting due to clarification needed with respect to the fixation of retail price.

Agenda no. 6 Overcharging cases in respect of the the formulation "Cloxacillin based formulations Klox Injection 500mg, Baxin Inj 1gm (1000 mg), Baxin Inj 500mg, Baxin Inj 250mg, Baxin Kid Tab" reg.

The Committee directed NPPA to place in the next meeting after detailed examination.

Agenda no. 7 Retail price fixation under Para 5 of DPCO, 2013 - Dareit R (Darunavir 600 mg + Ritonavir 100 mg tablet) for M/s Aurobindo Pharma Ltd (marketer) and M/s Emcure Pharmaceuticals Ltd (manufacturer/ importer).

The Committee deliberated the matter in details and observed that NPPA in its 60th Authority meeting dated 29.10.2018 approved the retail price of Darunavir 600 mg + Ritonavir 100 mg tablet at Rs. 172.52 per tablet (excluding GST) for M/s Emcure Pharmaceuticals Ltd. The Committee also observed that the NPPA in its 66th meeting held on 24.04.2019 approved the retail price of Darunavir 600 mg + Ritonavir 100 mg tablet for M/s Hetero Labs Ltd (manufacturer)/ M/s Hetero healthcare Ltd (marketer) at Rs. 160.71 per tablet (excluding GST). Accordingly, the Committee recommended the retail price of Dareit R (Darunavir 600 mg + Ritonavir 100 mg tablet) for M/s Aurobindo Pharma Ltd (marketer) and M/s Emcure Pharmaceuticals Ltd (manufacturer/ importer) at Rs. 160.71 per tablet (excluding GST) being the latest price approved by the Authority.

Agenda no. 8 Retail price fixation under Para 5 of DPCO, 2013 - Taxim 2g (Cefotaxim 2 gm injection) Injection for M/s Alkem Laboratories Limited (marketer and Manufacturer)

The Committee deliberated upon the matter in details and recommended the retail price of each Taxim 2g Injection (Cefotaxime 2 gm injection) for M/s Alkem Laboratories Limited (marketer and Manufacturer) at Rs. 57.10 per pack excluding GST as enumerated below:

a) The Cefotaxim 1 gm injection is scheduled formulation under DPCO, 2013 and the present ceiling price is Rs. 33.59 per pack as per notification SO 1485(E) dated 29.03.2019.

b) The calculation of retail price of Taxim 2g (Cefotaxim 2 gm injection) is done as per the formula recommended by Pronab Sen Committee as provided below:

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

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 injectibles.

c) Accordingly, the retail price of **Taxim 2g (Cefotaxim 2 gm injection)** is calculated as
= 33.59[1+0.70{2-1}/1}] = Rs. 57.10 per pack (excluding GST)

Agenda no. 9 Application of M/s Glenmark Pharmaceuticals Ltd for separate price of “Budesonite+ Formeterol MDI Digital Inhalation under the brand “Digihaler”.

1. The Committee deliberated upon the representation of M/s Glenmark Pharmaceuticals Ltd in which the company has sought for differential pricing of “Budesonite+ Formeterol MDI Digital Inhalation because the inhalation has digital counting mechanisms for the puffs and have benefits including dosage compliance etc. The Committee is in favour of promoting incremental innovation since it will increase the therapeutic outcome. The Committee noted that on being asked, the M/s Glenmark Pharmaceuticals Ltd vide its letter dated 08.03.2017 submitted the clinical data, study report to substantiate the incremental innovations. The Committee observed that although the various reports/studies are showing increase in therapeutic outcome but the result is not supported by higher level of evidence due to absence of clinical trials in a well designed form and diverse population.

2. Accordingly, the Committee recommended that in case the incremental innovation is not supported by published journal, well designed study, adequate trial, conclusive clinical data then an incremental price increase of 15% be allowed. In case, the incremental innovation is supported by published journal, well designed study, adequate trial, conclusive clinical data then an incremental price increase of 20% be allowed.

3. In this case, M/s Glenmark Pharmaceuticals Ltd has sought incremental price increase of three formulations namely, Budesonide 100mcg+Formoterol 6 mcg 120MDI Inhalation, Budesonide 200mcg+Formoterol 6 mcg 120MDI Inhalation and Budesonide 400mcg+Formoterol 6 mcg 120MDI Inhalation. Since the claim of M/s Glenmark Pharmaceuticals Ltd of incremental innovation is not supported by published journal, well designed study, adequate trial, conclusive clinical data, the Committee opined that 15% price increase may be allowed to the company for its incremental innovation. Accordingly, the Committee recommended the additional price for the digital dose counter brand “Digihaler” of Rs. 44.70 (excluding GST) on the ceiling price of the MDI Digital Inhalation (Inhalation having digital dose counter) as calculated below:

| Formulation | Present Ceiling Price as per SO. 1485(E) dtd 29.03.2019 | Total ceiling price of 120MDI (ex. GST) (Rs) |
|--|---|--|
| Budesonide 100mcg+Formoterol 6 mcg 120MDI Inhalation | 1.85 | 222.00 |
| Budesonide 200mcg+Formoterol 6 mcg 120MDI Inhalation | 2.62 | 314.40 |
| Budesonide 400mcg+Formoterol 6 mcg 120MDI Inhalation | 2.98 | 357.60 |
| TOTAL | | 894.00 |
| Average (Rs. 894.00/3) | | 298.00 |
| Additional price for the incremental innovation (Rs. 298.00 X 15%) | | 44.70 |

4. The Committee also recommended that the additional price of Rs. 44.70 (excluding GST) on the applicable ceiling price of the MDI Digital Inhalation (Inhalation having digital dose counter) brand “Digihaler” would remain fixed irrespective of the change in ceiling price of the Inhalation.

Agenda no. 10 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

1. The Committee deliberated upon the representation of M/s Cipla Ltd for separate/ special price of “Synchrobreathe inhaler device” and noted the documents/ journal/ study report submitted by the company. The Committee noted the demonstration made by M/s Cipla Ltd in respect of its product “Synchrobreathe inhaler device”.

2. In this case, M/s Cipla Ltd has sought incremental price increase of two formulations namely, Budesonide 200mcg+Formoterol 6 mcg 120MDI Inhalation and Budesonide 400mcg+Formoterol 6 mcg 120MDI Inhalation. Since the claim of M/s Cipla Ltd of incremental innovation is supported by published journal, well designed study, adequate trial, conclusive clinical data, the Committee opined that 20% price increase may be allowed to the company for its “Synchrobreathe inhaler device”. Accordingly, the Committee recommended the additional price of Rs. 67.20 (excluding GST) on the ceiling price of the Inhalation having Synchrobreathe inhaler device as calculated below:

| Formulation | Present Ceiling Price as per SO. 1485(E) dtd 29.03.2019 | Total ceiling price of 120MDI (ex. GST) (Rs) |
|--|---|--|
| Budesonide 200mcg+Formoterol 6 mcg 120MDI Inhalation | 2.62 | 314.40 |
| Budesonide 400mcg+Formoterol 6 mcg 120MDI Inhalation | 2.98 | 357.60 |
| TOTAL | | 672.00 |
| Average (Rs. 672.00/2) | | 336.00 |
| Additional price for the incremental innovation (Rs. 336.00 X 20%) | | 67.20 |

3. The Committee also recommended that the additional price of Rs. 67.20 (excluding GST) on the applicable ceiling price of the Inhalation Synchrobreathe inhaler device would remain fixed irrespective of the change in ceiling price of the Inhalation.

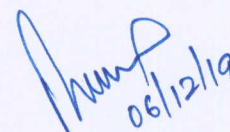
Agenda no. 11 Retail price fixation under Para 5 of DPCO, 2013 - Rabies Human Monoclonal Antibody (rDNA) Inj. 1.25ml injection for M/s Serum Institute of India Private Limited (Manufacturer and Marketer)

The agenda was deferred due to paucity of time.

Agenda no. 12 Retail price fixation under Para 5 of DPCO, 2013 – Paclitaxel protein bound particles for injection 100 mg for M/s Intas Pharmaceuticals Ltd (marketer) and M/s SPAL Pvt. Ltd (manufacturer/ importer)

The agenda was deferred due to paucity of time.

The meeting ended with a vote of thanks to the Convener.


06/12/19

(Prakash Hemani)
Asstt. Director (Pricing)

Copy to:
All members of the Committee.

