

National Pharmaceutical Pricing Authority**Subject: Minutes of the 24th meeting of Multidisciplinary Committee of Experts held on 11.11.2020 at 12:00 noon in NPPA**

24th meeting of the “Multidisciplinary Committee of Experts” was held on 11.11.2020 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. Rajni Kaul, Scientist G and Head, Pharmacology, ICMR, New Delhi
3. Dr. Rakesh K. Singh, Assoc. Professor, NIPER, Raebareli
4. Dr. Pooja Gupta, Assoc. Prof., Pharmacology, AIIMS, New Delhi
5. Dr. Gaurav Pratap Singh, Sr. Scientific Officer, Indian Pharmacopoeia Commission
6. Shri A. K. Pradhan, Dy. Drugs Controller, CDSCO

Dr. Arti Kapil, Professor, Department of Microbiology, All India Institute of Medical Sciences (AIIMS), New Delhi was also present in 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
3. Sh. Prakash Hemani, Assistant Director (Pricing), NPPA

I. Agenda No. I - Retail price fixation under Para 5 of DPCO, 2013 - Povidone-Iodine Gargle 0.5% w/v containing povidone iodine IP 0.5% w/v (available iodine 0.06% w/v) for M/s Mankind Pharma Ltd. (marketer) and M/s Windlas Biotech Pvt. Ltd. (manufacturer).

I.I The Committee deliberated upon the matter in detail and recommended the retail price of Povidone-Iodine Gargle 0.5% w/v containing povidone iodine IP 0.5% w/v (available iodine 0.06% w/v) for M/s Mankind Pharma Ltd. (marketer) and M/s Windlas Biotech Pvt. Ltd. (manufacturer) at Rs. 0.79 per ml excluding GST as detailed below:

Computation of Retail Price per tablet	Source/Method	Rs.
Composition – Each ml solution contains: Povidone-Iodine 0.5% w/v (Available Iodine 0.06% w/v)		
Net Retail Price		Rs. 0.79 per ml
Company Claimed Price		Rs. 0.95 per ml

Computation of Retail Price per tablet	Source/Method	Rs.
Recommended price		Rs. 0.79 per ml

Derived retail price as per recommendation of Pronab Sen committee:

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

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.

Calculation of price of Povidone-Iodine Gargle 0.5% w/v

Price Calculated as per Para 4 of DPCO, Povidone-Iodine Gargle 2% w/v = Rs. 1.66 per ml

Therefore, derived Retail price for Povidone-Iodine Gargle 0.5% w/v = $1.66[1 + 0.70\{(0.5 - 2) / 2\}] = \text{Rs. } 0.79 \text{ per ml}$

2. Agenda No. 2 - Retail price fixation under Para 5 of DPCO, 2013 - Trihexyphenidyl Hydrochloride tablets 1 mg in which each uncoated tablet contains Trihexyphenidyl Hydrochloride IP 1 mg for M/s D.D. Pharmaceuticals Pvt. Ltd. (manufacturer and marketer).

2.1 The Committee deliberated upon the matter in detail and recommended the retail price of Trihexyphenidyl Hydrochloride tablets 1 mg in which each uncoated tablet contains Trihexyphenidyl Hydrochloride IP 1 mg for M/s D.D. Pharmaceuticals Pvt. Ltd. (manufacturer and marketer) at Rs. 0.73 per tablet excluding GST as detailed below:

Computation of Retail Price per tablet	Source/Method	Rs.
Composition – Each uncoated tablet contains: Trihexyphenidyl Hydrochloride IP 1mg		
Net Retail Price		Rs. 0.73
Company Claimed Price		Rs. 1.25
Recommended price		Rs.0.73

Derived retail price as per recommendation of Pronab Sen committee:

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

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.

Calculation of price of Trihexyphenidyl Hydrochloride IP 1 mg

Ceiling Price for Trihexyphenidyl Hydrochloride IP 2 mg = Rs. 1.21 per tablet

Therefore, derived Retail price for Trihexyphenidyl Hydrochloride IP 1mg = $1.21[1+0.80\{1-2\}/2]$ = Rs. 0.73 per tablet

3. Agenda no. 3 - Retail price fixation under Para 5 of DPCO, 2013 – Azelnidipine and Telmisartan tablet in which each film coated bilayered tablet contains Azelnidipine IP 8 mg and Telmisartan IP 40 mg tablets for M/s Torrent Pharmaceuticals Ltd. (marketer) and M/s Synokem Pharmaceuticals Ltd. (manufacturer/ importer)

3.1 The Committee deliberated upon the matter in detail and recommended the retail price of Azelnidipine and Telmisartan tablet in which each film coated bilayered tablet contains Azelnidipine IP 8 mg and Telmisartan IP 40 mg tablets for M/s Torrent Pharmaceuticals Ltd. (marketer) and M/s Synokem Pharmaceuticals Ltd. (manufacturer/ importer) at Rs. 12.45 per tablet excluding GST as detailed below:

Computation of Retail Price per Tablet	Source/Method	Rs.
Composition – Each film coated bi-layered tablet contains Azelnidipine IP 8 mg+ Telmisartan IP 40 mg		
a. Azelnidipine IP 8 mg *	Retail Price calculated as per Para 4 (August 2020 data)	7.67
b. Telmisartan IP 40 mg	Notified Ceiling Price	6.57
Worked out Retail Price		14.24
c. Less 20% of the lowest of (a) and (b) similar to formula recommended in the Pronab Sen Committee report		1.31
Net Retail Price (a+b-c)		12.93
Company Claimed Price		12.45
Recommended price		Rs. 12.45

The data for the Azelnidipine 8 mg Tablet is not available for the month of March, 2020 (i.e. six months prior to date of application). It has been noted that the data for the formulation Azelnidipine IP 8 mg the month of August, 2020 is available. Accordingly, the data for the month of August, 2020 was used in the calculation of retail price.

4. Agenda no. 4 - Retail price fixation under Para 5 of DPCO, 2013 – Azelnidipine and Telmisartan tablet in which each film coated bilayered tablet contains Azelnidipine IP 8 mg and Telmisartan IP 80 mg tablets for M/s Torrent Pharmaceuticals Ltd. (marketer) and M/s Synokem Pharmaceuticals Ltd. (manufacturer/ importer)

4.1 The Committee deliberated upon the matter in detail and recommended the retail price of Azelnidipine and Telmisartan tablet in which each film coated bilayered tablet contains Azelnidipine IP 8 mg and Telmisartan IP 80 mg tablets for M/s Torrent Pharmaceuticals Ltd. (marketer) and M/s Synokem Pharmaceuticals Ltd. (manufacturer/ importer) at Rs. 14.20 per tablet excluding GST as detailed below:

Computation of Retail Price per Tablet	Source/Method	Rs.
Composition – Each film coated bi-layered tablet contains Azelnidipine IP 8 mg+ Telmisartan IP 80 mg		
a. Azelnidipine IP 8 mg *	Retail Price calculated as per Para 4 (August 2020 data)	7.67
b. Telmisartan IP 80 mg	Notified Ceiling Price	10.02
Worked out Retail Price		17.69
c. Less 20% of the lowest of (a) and (b) similar to formula recommended in the Pronab Sen Committee report		1.53
Net Retail Price (a+b-c)		16.16
Company Claimed Price		14.20
Recommended price		Rs. 14.20

The data for the Azelnidipine 8 mg Tablet is not available for the month of March, 2020 (i.e. six months prior to date of application). It has been noted that the data for the formulation Azelnidipine IP 8 mg the month of August, 2020 is available. Accordingly, the data for the month of August, 2020 was used in the calculation of retail price.

5. Agenda no. 5 – Retail price fixation under Para 5 of DPCO, 2013 – Each uncoated bilayered tablet containing Vildagliptin 50 mg and Metformin Hydrochloride IP 500mg (as sustained release) for M/s Eris Lifesciences Ltd. (marketer) and M/s Exemed Pharmaceuticals (manufacturer).

5.1 The Committee noted that separate ceiling price has been fixed for Metformin Immediate release tablet and Metformin Controlled release tablet. The Committee further noted that as per notification SO.1213(E) dated 25.03.2020, the present ceiling price of Metformin 500 mg controlled release (CR) tablet is Rs. 0.41 more than Metformin 500 mg

immediate release (IR) tablet. Similarly, the ceiling price of Metformin 1000 mg controlled release tablet is Rs. 0.05 more than Metformin 1000 mg Immediate release tablet.

5.2 The Committee also noted that the minutes of 72nd Authority meeting held on 20.01.2020 relating to retail price fixation of Fixed Dose Combinations (FDCs) of Metformin and Vildagliptin tablets for various companies, in which it was decided as follows:

1. The retail price of the Fixed Dose Combinations (FDCs) of Metformin and Vildagliptin tablets were proposed to be calculated as per two options, as follows:

(i) Under para 5 of DPCO 2013 by taking the data of six month prior to the date of application

(ii) By adding 16% retailer margin to the average Price To Retailer (PTR) based on the Form-V data submitted by the companies for whom retail prices were earlier approved for these subject FDCs.

2. The Authority observed that the subject formulations are off-patent items and any fixation of retail prices on the basis of para 5 of DPCO 2013 by taking six month prior data (when the patent was in force) would result in extending the price of patented products to off-patent products. Hence, the benefit of price reduction due to patent expiry would not be made available to the public.

3. The Authority also observed that in its earlier meetings on 30.10.2019 and 09.12.2019, it had approved the fixation of the retail prices of the subject FDCs for various companies under para 5 of DPCO 2013 by taking six month prior data. The companies have since submitted the launch prices. These prices are much lower prices than those approved by the Authority earlier.

4. The Authority deliberated upon the matter in detail and emphasized that benefit of price reduction in case of formulations becoming off-patent ought to be passed on to the consumers in public interest and decided to fix the retail price as per the Price To Retailer (PTR) based on Form-V data submitted by the companies for whom retail prices were earlier approved for these subject FDCs.

5. Accordingly, the Authority decided to fix the retail price of the subject FDCs for the companies as per option I(ii) in public interest.

5.3 The Committee observed that based on the methodology decided by the Authority in its 72nd meeting dated 20.01.2020, as specified in 5.2 above, the retail price of Vildagliptin 50 mg + Metformin 500 mg tablet comes to Rs. 6.17 per tablet excluding GST.

5.4 The Committee further observed that in its 22nd meeting dated 07.10.2020, it recommended the retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 500mg (as sustained release form) for various manufacturing/ marketing companies based on the following methodology:

“..... to derive the retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 500mg (as sustained release form) by adding the maximum of the difference in presently applicable notified ceiling price of Metformin IR & CR 500mg and 1000 mg tablet, with the retail price calculated based on the methodology decided by the Authority in its 72nd meeting dated 20.01.2020.”

5.5. The Committee also observed that the Authority in its 80th meeting dated 26.10.2020 approved the recommended methodology, as mentioned in para 5.4 above, towards fixation of retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 500mg (as sustained release form) for various companies.

5.6 The Committee deliberated upon the matter in detail and decided to derive the retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 500mg (as sustained release) by adding the maximum of the difference in presently applicable notified ceiling price of Metformin IR & CR 500mg and 1000 mg tablet i.e. Rs. 0.41, as mentioned in para 5.1 above, with the retail price calculated based on the methodology decided by the Authority in its 72nd meeting dated 20.01.2020, as specified in 5.2, i.e. Rs. 6.17 and recommend the same.

5.7 Accordingly, the Committee recommended the retail price of each uncoated bilayered tablet containing Vildagliptin 50 mg and Metformin Hydrochloride IP 500mg (as sustained release) for M/s Eris Lifesciences Ltd. (marketer) and M/s Exemed Pharmaceuticals (manufacturer) at Rs. 6.58 per tablet excluding GST.

6. Agenda no. 6 – Retail price fixation under Para 5 of DPCO, 2013 – Each uncoated bilayered tablet containing Vildagliptin 50 mg and Metformin Hydrochloride IP 1000mg (as sustained release) for M/s Eris Lifesciences Ltd. (marketer) and M/s Exemed Pharmaceuticals (manufacturer).

6.1 The Committee noted that separate ceiling price has been fixed for Metformin Immediate release tablet and Metformin Controlled release tablet. The Committee further noted that as per notification SO.1213(E) dated 25.03.2020, the present ceiling price of Metformin 500 mg controlled release (CR) tablet is Rs. 0.41 more than Metformin 500 mg immediate release (IR) tablet. Similarly, the ceiling price of Metformin 1000 mg controlled release tablet is Rs. 0.05 more than Metformin 1000 mg Immediate release tablet.

6.2 The Committee also noted that the minutes of 72nd Authority meeting held on 20.01.2020 relating to retail price fixation of Fixed Dose Combinations (FDCs) of Metformin and Vildiglipitin tablets for various companies, in which it was decided as follows:

1. The retail price of the Fixed Dose Combinations (FDCs) of Metformin and Vildiglipitin tablets were proposed to be calculated as per two options, as follows:

(i) Under para 5 of DPCO 2013 by taking the data of six month prior to the date of application

(ii) By adding 16% retailer margin to the average Price To Retailer (PTR) based on the Form-V data submitted by the companies for whom retail prices were earlier approved for these subject FDCs.

2. The Authority observed that the subject formulations are off-patent items and any fixation of retail prices on the basis of para 5 of DPCO 2013 by taking six month prior data (when the patent was in force) would result in extending the price of patented products to off-patent

products. Hence, the benefit of price reduction due to patent expiry would not be made available to the public.

3. The Authority also observed that in its earlier meetings on 30.10.2019 and 09.12.2019, it had approved the fixation of the retail prices of the subject FDCs for various companies under para 5 of DPCO 2013 by taking six month prior data. The companies have since submitted the launch prices. These prices are much lower prices than those approved by the Authority earlier.

4. The Authority deliberated upon the matter in detail and emphasized that benefit of price reduction in case of formulations becoming off-patent ought to be passed on to the consumers in public interest and decided to fix the retail price as per the Price To Retailer (PTR) based on Form-V data submitted by the companies for whom retail prices were earlier approved for these subject FDCs.

5. Accordingly, the Authority decided to fix the retail price of the subject FDCs for the companies as per option I(ii) in public interest.

6.3 The Committee observed that based on the methodology decided by the Authority in its 72nd meeting dated 20.01.2020, as specified in 6.2 above, the retail price of Vildagliptin 50 mg + Metformin 1000 mg tablet comes to Rs. 6.66 per tablet excluding GST.

6.4 The Committee further observed that in its 22nd meeting dated 07.10.2020, it recommended the retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 1000mg (as sustained release form) for various manufacturing/ marketing companies based on the following methodology:

“..... to derive the retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 1000mg (as sustained release form) by adding the maximum of the difference in presently applicable notified ceiling price of Metformin IR & CR 500mg and 1000 mg tablet, with the retail price calculated based on the methodology decided by the Authority in its 72nd meeting dated 20.01.2020.”

6.5. The Committee also observed that the Authority in its 80th meeting dated 26.10.2020 approved the recommended methodology, as mentioned in para 5.4 above, towards fixation of retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 1000mg (as sustained release form) for various companies.

6.6 The Committee deliberated upon the matter in detail and decided to derive the retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 1000mg (as sustained release) by adding the maximum of the difference in presently applicable notified ceiling price of Metformin IR & CR 500mg and 1000 mg tablet i.e. Rs. 0.41, as mentioned in para 6.1 above, with the retail price calculated based on the methodology decided by the Authority in its 72nd meeting dated 20.01.2020, as specified in 6.2, i.e. Rs. 6.66 and recommend the same.

6.7 Accordingly, the Committee recommended the retail price of each uncoated bilayered tablet containing Vildagliptin 50 mg and Metformin Hydrochloride IP 1000mg (as sustained release) for M/s Eris Lifesciences Ltd. (marketer) and M/s Exemed Pharmaceuticals (manufacturer) at Rs. 7.07 per tablet excluding GST.

7. Agenda no. 7 Retail price fixation under Para 5 of DPCO, 2013 - Betadine Alcoholic Handrub for M/s Win Medicare Pvt. Ltd (marketer) and M/s G.S. Pharmbutor Pvt. Ltd (manufacturer/ importer).

7.1 The Committee noted the observations of Dr. Arti Kapil, Professor, Department of Microbiology, All India Institute of Medical Sciences (AIIMS), New Delhi as detailed below:

“The efficacy of ethyl alcohol and Isopropyl alcohol is similar when used as hand rub or skin disinfectant. As per the international guidelines and recommendations on Hand hygiene by CDC (<https://www.cdc.gov/infectioncontrol/guidelines/disinfection/>) and WHO (www.who.int/infection-prevention/publication/handhygiene/). Therefore there is no justification or advantage of using one over the other”.

7.2 Dr. Arti Kapil also reiterated that the matter has also been discussed with other experts in infection control and Microbiology at AIIMS who are in agreement with the view mentioned above.

7.3 The Committee deliberated upon the matter in detail and noted that there is no/negligible therapeutic efficacy in the usage of Isopropyl alcohol over ethyl alcohol. Accordingly, the Committee reiterated its decision taken in the 21st meeting dated 28.08.2020 and decided to recommend the the retail price of Betadine Alcoholic Handrub in which each 100 ml contains Povidone Iodine IP 1.0g (Available Iodine 0.1 g) and 2-Propanol IP 50 mg for M/s Win Medicare Pvt. Ltd (marketer) and M/s G.S. Pharmbutor Pvt. Ltd (manufacturer/ importer). at Rs. 92.00 per 200 ml pack excluding GST as detailed below:

Computation of Retail Price per ml	Source/Method	Rs.
Composition – Each 100 ml containing Povidone Iodine IP 1.0g (Available Iodine 0.1 g)+ 2-Propanol IP 50 mg		
a. Povidone Iodine *	Retail Price as per Pronab Sen Committee Report	0.17 per ml
b. 2-Propanol IP Solution	Ceiling Price of Ethyl Alcohol 50% (Data of Isopropyl Alcohol not available)	0.34 per ml
Worked out Retail Price		0.51 per ml
c. Less 30% of the lowest of (a) and (b) similar to formula recommended		0.05 per ml

Computation of Retail Price per ml	Source/Method	Rs.
in the Pronab Sen Committee report		
Net Retail Price (a+b-c)		0.46 per ml
Retail price for 200ml pack		Rs. 92.00
Company Claimed Price for 200ml pack		Rs. 245.53
Recommended price		Rs. 92.00

Derived retail price as per recommendation of Pronab Sen committee :

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

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 injectables.

Calculation of price of Povidone Iodine IP 1.0g solution

Ceiling Price for Povidone Iodine 5% = Rs. 0.39 per ml

Derived Retail price for Povidone Iodine Solution = $0.39[1 + 0.70\{(1-5)/5\}] = \text{Rs. } 0.17$ per ml

Calculation of price for 2-Propanaol IP solution

Ceiling Price of Ethyl Alcohol (denatured) 70% = Rs. 0.42 per ml

Derived Retail price for Ethyl Alcohol 50% = $0.42[1 + 0.70\{(50-70)/70\}] = \text{Rs. } 0.34$ per ml.

8. Agenda no. 8 Ceiling price fixation of Pheniramine Maleate Injection 22.75 mg/ ml in 33 ml and 100 ml pack.

8.1 The Committee deliberated upon the matter in detail and observed that some further analysis is required in the matter. Accordingly, the Committee decided to defer the same.

The meeting ended with a vote of thanks to all.

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

Copy to:
All members of the Committee.