

Subject: Minutes of the 25th meeting of Multidisciplinary Committee of Experts held on 16.12.2020 at 11:00 AM in NPPA

25th meeting of the “Multidisciplinary Committee of Experts” was held on 16.12.2020 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. Pooja Gupta, Assoc. Prof., Pharmacology, AIIMS, New Delhi
4. Shri A. K. Pradhan, Dy. Drugs Controller, CDSCO

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

1. Agenda No. 1 - Retail price fixation under Para 5 of DPCO, 2013 – Each uncoated bilayered tablet containing Vildagliptin 50 mg + Metformin Hydrochloride 500 mg (Sustained Release) for M/s Zydus Healthcare Limited (marketer) and M/s Exemed Pharmaceuticals (manufacturer).

1.1 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.

1.2 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.

1.3 The Committee observed that based on the methodology decided by the Authority in its 72nd meeting dated 20.01.2020, as specified in 1.2 above, the retail price of Vildagliptin 50 mg + Metformin 500 mg tablet comes to Rs. 6.17 per tablet excluding GST.

1.4 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.”

1.5. The Committee also observed that the Authority in its 80th meeting dated 26.10.2020 approved the recommended methodology, as mentioned in para 1.4 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.

1.6 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 1.1 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 1.2, i.e. Rs. 6.17 and recommend the same.

1.7 Accordingly, the Committee recommended the retail price of each uncoated bilayered tablet containing Vildagliptin 50 mg + Metformin Hydrochloride 500 mg (Sustained Release) for M/s Zydus Healthcare Limited (marketer) and M/s Exemed Pharmaceuticals (manufacturer) at Rs. 6.58 per tablet excluding GST.

2. Agenda No. 2 - Retail price fixation under Para 5 of DPCO, 2013 – Each uncoated bilayered tablet containing Vildagliptin 50 mg + Metformin Hydrochloride 1000 mg (Sustained Release) for M/s Zydus Healthcare Limited (marketer) and M/s Exemed Pharmaceuticals (manufacturer).

2.1 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.

2.2 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 1(ii) in public interest.

2.3 The Committee observed that based on the methodology decided by the Authority in its 72nd meeting dated 20.01.2020, as specified in 2.2 above, the retail price of Vildagliptin 50 mg + Metformin 1000 mg tablet comes to Rs. 6.66 per tablet excluding GST.

2.4 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.”

2.5. The Committee also observed that the Authority in its 80th meeting dated 26.10.2020 approved the recommended methodology, as mentioned in para 2.4 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.

2.6 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 2.1 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 2.2, i.e. Rs. 6.66 and recommend the same.

3.7 Accordingly, the Committee recommended the retail price of each uncoated bilayered tablet containing Vildagliptin 50 mg + Metformin Hydrochloride 1000 mg (Sustained Release) for M/s Zydus Healthcare Limited (marketer) and M/s Exemed Pharmaceuticals (manufacturer) at Rs. 7.07 per tablet excluding GST.

3. Agenda no. 3 - Retail price fixation under Para 5 of DPCO, 2013 – Each uncoated bilayered tablet containing Vildagliptin 50 mg + Metformin Hydrochloride 500 mg (Sustained Release) for M/s Lupin Limited (marketer) and M/s Exemed Pharmaceuticals (manufacturer).

3.1 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.

3.2 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 Vildigliptin tablets for various companies, in which it was decided as follows:

1. The retail price of the Fixed Dose Combinations (FDCs) of Metformin and Vildigliptin 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.

3.3 The Committee observed that based on the methodology decided by the Authority in its 72nd meeting dated 20.01.2020, as specified in 3.2 above, the retail price of Vildagliptin 50 mg + Metformin 500 mg tablet comes to Rs. 6.17 per tablet excluding GST.

3.4 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.”

3.5. The Committee also observed that the Authority in its 80th meeting dated 26.10.2020 approved the recommended methodology, as mentioned in para 3.4 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.

3.6 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 3.1 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 3.2, i.e. Rs. 6.17 and recommend the same.

3.7 Accordingly, the Committee recommended the retail price of each uncoated bilayered tablet containing Vildagliptin 50 mg + Metformin Hydrochloride 500 mg (Sustained Release) for M/s Lupin Limited (marketer) and M/s Exemed Pharmaceuticals (manufacturer) at Rs. 6.58 per tablet excluding GST.

4. Agenda no. 4 - Retail price fixation under Para 5 of DPCO, 2013 – Each uncoated bilayered tablet containing Vildagliptin 50 mg + Metformin Hydrochloride 1000 mg (Sustained Release) for M/s Lupin Limited (marketer) and M/s Exemed Pharmaceuticals (manufacturer).

4.1 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.

4.2 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 Vildigliptin tablets for various companies, in which it was decided as follows:

1. The retail price of the Fixed Dose Combinations (FDCs) of Metformin and Vildigliptin 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.

4.3 The Committee observed that based on the methodology decided by the Authority in its 72nd meeting dated 20.01.2020, as specified in 4.2 above, the retail price of Vildagliptin 50 mg + Metformin 1000 mg tablet comes to Rs. 6.66 per tablet excluding GST.

4.4 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.”

4.5. The Committee also observed that the Authority in its 80th meeting dated 26.10.2020 approved the recommended methodology, as mentioned in para 4.4 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.

4.6 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 4.1 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 4.2, i.e. Rs. 6.66 and recommend the same.

4.7 Accordingly, the Committee recommended the retail price of each uncoated bilayered tablet containing Vildagliptin 50 mg + Metformin Hydrochloride 1000 mg (Sustained Release) for M/s Lupin Limited (marketer) and M/s Exemed Pharmaceuticals (manufacturer) at Rs. 7.07 per tablet excluding GST.

5. Agenda no. 5 – Retail price fixation under Para 5 of DPCO, 2013 Metronidazole and Dextrose Injection in 500 ml bottle in which each 100 ml contains Metronidazole IP 0.2 gm and Dextrose IP (as anhydrous) 5.0 gm for M/s Aculife Healthcare Pvt. Ltd. (manufacturer and marketer)

5.1 The Committee deliberated upon the matter in detail and recommended the retail price of Metronidazole and Dextrose Injection in 500 ml bottle in which each 100 ml contains Metronidazole IP 0.2 gm and Dextrose IP (as anhydrous) 5.0 gm for M/s Aculife Healthcare Pvt. Ltd. (manufacturer and marketer) at Rs. 79.29 per 500 ml pack excluding GST as detailed below:

Computation of Retail Price per dose	Source/Method	Amount (Rs.) 500ml/pack
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Computation of Retail Price per dose	Source/Method	Amount (Rs.) 500ml/pack
Composition – Metronidazole IP 0.2gm + Dextrose IP (Anhydrous) 5.0gm water for Injection		
a. Metronidazole 0.2gm	Worked out Retail price	58.00
b. Dextrose 5gm	Ceiling Price of Glucose 5% Injection (500ml non-glass pack)	30.42
Total		88.42
c. Less 30% of the lowest of (a) to (b) as recommended in the Pronab Sen Committee report		9.13
Net Retail Price (a+b-c)		79.29
Company Claimed Price		100
Recommended price		79.29

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.

Derived Retail Price for Metronidazole 0.2gm/ 100ml Inj.

Ceiling Price of Metronidazole 500mg/100ml = Rs. 0.20per ml

Derived Retail price of Metronidazole 200mg/100ml = $0.20[1 + 0.70\{200 - 500\}/500]$ = Rs. 0.116 per ml i.e. Rs. 58 for 500ml pack.

6. Agenda no. 6 – Retail price fixation under Para 5 of DPCO, 2013 – Each film coated tablet containing Dapagliflozin 5 mg + Metformin Hydrochloride IP (in extended release form) 500 mg for M/s Torrent Pharmaceuticals Limited (manufacturer & marketer).

6.1 The Committee 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:

I. 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.

6.2 The Committee further noted that the Patent of Dapagliflozin was expired on 02.10.2020 making it an off-patent drug. Accordingly, to give benefits to the consumers, the Committee recommended that the price be fixed on the basis of decision taken in 72nd Authority meeting dated 20.01.2020 w.r.t. the formulation Vildagliptin + Metformin tablets.

6.3 The Committee observed that the retail price of Dapagliflozin 10mg + Metformin 500mg tablet has been fixed earlier for M/s Micro Labs Limited and the company has launched the formulation and has submitted the Form-V data. However, no retail price of the formulation Dapagliflozin 5 mg + Metformin Hydrochloride IP (in extended release form) 500 mg tablet has been approved earlier.

6.4 The Committee deliberated upon the matter in detail and recommended to derive the price of Dapagliflozin 5 mg tablet based on the Form-V data submitted by the company for the formulation Dapagliflozin 10mg + Metformin 500mg tablet in line with the recommendations of the Pronab Sen Committee. Accordingly, the derived price of Dapagliflozin 5 mg tablet came to Rs. 5.44 per tablet excluding GST as detailed below:

S.No.	Particulars	Price	Price (Rs.)
A	Derived retail price of Dapagliflozin 10mg + Metformin (ER) 500mg tablet based on the data submitted by the company as per Form-V.	Retail Price	10.60
B	Less : 80% of Ceiling price of Metformin (ER) 500mg	Ceiling Price 1.91*80%	1.53

C	Derived Retail price for Dapagliflozin 10mg Tablet (A-B)		9.07
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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.

Derived Retail Price for Dapagliflozin 5mg Tablet.

Derived Retail Price of Dapagliflozin 10mg Tablet = Rs. 9.07per tablet

Derived Retail price of Dapagliflozin 10mg Tablet = $9.07[1 + 0.80\{(5-10)/10\}] = \text{Rs. } 5.44$ per tablet.

6.5 The Committee further deliberated upon the matter in detail and recommended the retail price of each film coated tablet containing Dapagliflozin 5 mg + Metformin Hydrochloride IP (in extended release form) 500 mg for M/s Torrent Pharmaceuticals Limited (manufacturer & marketer) at Rs. 6.97 per tablet excluding GST as detailed below:

Computation of Retail Price per dose	Source/Method	Amount (Rs.)
Composition – Dapagliflozin 5 mg + Metformin Hydrochloride IP (in extended release form) 500 mg		
a. Dapagliflozin 5mg (as per para 6.4 above)	Worked out Retail price	5.44
b. Metformin Hydrochloride IP (in extended release form) 500 mg	Ceiling Price	1.91
Total		7.35
c. Less 20% of the lowest of (a) to (b) as recommended in the Pronab Sen Committee report		0.38
Net Retail Price (a+b-c)		6.97
Company Claimed Price		34.00
Recommended price		6.97

7. Agenda no. 7 Retail price fixation under Para 5 of DPCO, 2013 – Each film coated tablet containing Dapagliflozin 5 mg + Metformin Hydrochloride IP (in extended release form) 1000 mg for M/s Torrent Pharmaceuticals Limited (manufacturer & marketer).

7.1 The Committee 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.

7.2 The Committee further noted that the Patent of Dapagliflozin was expired on 02.10.2020 making it an off-patent drug. Accordingly, to give benefits to the consumers, the Committee recommended that the price be fixed on the basis of decision taken in 72nd Authority meeting dated 20.01.2020 w.r.t. the formulation Vildagliptin + Metformin tablets.

7.3 The Committee observed that the retail price of Dapagliflozin 10mg + Metformin 500mg tablet has been fixed earlier for M/s Micro Labs Limited and the company has launched the formulation and has submitted the Form-V data. However, no retail price of the formulation Dapagliflozin 5 mg + Metformin Hydrochloride IP (in extended release form) 1000 mg tablet has been approved earlier.

7.4 The Committee deliberated upon the matter in detail and recommended to derive the price of Dapagliflozin 5 mg tablet based on the Form-V data submitted by the company for the formulation Dapagliflozin 10mg + Metformin 500mg tablet in line with the recommendations of the Pronab Sen Committee. Accordingly, the derived price of Dapagliflozin 5 mg tablet came to Rs. 5.44 per tablet excluding GST as detailed below:

S.No.	Particulars	Price	Price (Rs.)
A	Derived retail price of Dapagliflozin 10mg + Metformin (ER) 500mg tablet based on the data submitted by the company as per Form-V.	Retail Price	10.60
B	Less : 80% of Ceiling price of Metformin (ER) 500mg	Ceiling Price 1.91*80%	1.53
C	Derived Retail price for Dapagliflozin 10mg Tablet (A-B)		9.07

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.

Derived Retail Price for Dapagliflozin 5mg Tablet.

Derived Retail Price of Dapagliflozin 10mg Tablet = Rs. 9.07per tablet

Derived Retail price of Dapagliflozin 10mg Tablet = $9.07[1 + 0.80\{(5-10)/10\}] = \text{Rs. } 5.44$ per tablet.

7.5 The Committee further deliberated upon the matter in detail and recommended the retail price of each film coated tablet containing Dapagliflozin 5 mg + Metformin Hydrochloride IP (in extended release form) 1000 mg for M/s Torrent Pharmaceuticals Limited (manufacturer & marketer) at Rs. 8.35 per tablet excluding GST as detailed below:

Computation of Retail Price per dose	Source/Method	Amount (Rs.)
Composition – Dapagliflozin 5 mg + Metformin Hydrochloride IP (in extended release form) 1000 mg		
a. Dapagliflozin 5mg	Worked out Retail price	5.44
b. Metformin Hydrochloride IP (in extended release form) 1000 mg	Ceiling Price	3.64
Total		9.08
c. Less 20% of the lowest of (a) to (b) as recommended in the Pronab Sen Committee report		0.73
Net Retail Price (a+b-c)		8.35
Company Claimed Price		34.00
Recommended price		8.35

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 noted that the data is yet to be received from the company. Accordingly, the Committee decided that the company be directed to give the data at an early date.

The meeting ended with a vote of thanks to all.

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

Copy to:
All members of the Committee.