

**F. No. 12(7)/2017/DP/NPPA/Div.II / Vol-IV**  
**National Pharmaceutical Pricing Authority**

**Subject: Minutes of the 28<sup>th</sup> meeting of Multidisciplinary Committee of Experts held on 04.03.2021 at 11:00 AM in NPPA**

28<sup>th</sup> meeting of the “Multidisciplinary Committee of Experts” was held on 04.03.2021 under the Convenorship of Sh. N.I. Chowdhury, Adviser (Cost), in NPPA. The following members attended the meeting through video conferencing:-

1. Dr. Rakesh K. Singh, Assoc. Professor, NIPER, Raebareli
2. Shri A. K. Pradhan, Dy. Drugs Controller, CDSCO
3. Dr. Jai Prakash, Sr. Principal Scientific Officer, Indian Pharmacopoeia Commission
4. Dr. Pooja Gupta, Assoc. Prof., Pharmacology, AIIMS, New Delhi

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, Deputy 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 film coated tablet containing Calcium Carbonate IP 1250 mg + Vitamin D3 IP 2000 IU + Methylcobalamin IP 1500 mcg + Calcium L-5-Methyltetrahydrofolate (L-Methylfolate Calcium ) USP 1 mg + Pyridoxal-5-Phosphate 20 mg for M/s Tirupati Medicare Ltd. (manufacturer) and M/s Intas Pharmaceuticals Ltd. (marketer).**

1.1 The Committee deliberated upon the matter in detail and recommended the retail price of each film coated tablet containing Calcium Carbonate IP 1250 mg + Vitamin D3 IP 2000 IU + Methylcobalamin IP 1500 mcg + Calcium L-5-Methyltetrahydrofolate (L- Methylfolate Calcium ) USP 1 mg + Pyridoxal-5-Phosphate 20 mg for M/s Tirupati Medicare Ltd. (manufacturer) and M/s Intas Pharmaceuticals Ltd. (marketer) at Rs. 18.02 per tablet excluding GST as detailed below:

<b>Computation of Retail Price per Tablet</b>	<b>Source/Method</b>	<b>Amount (Rs.)</b>
Composition – Calcium 500mg + L-Methylfolate Calcium 1 mg + Pyridoxal -5 Phosphate 20 mg + Methylcobalamin 1500mcg + Vitamin D3 2000IU		
a. Methylcobalamin 1500 mcg	Retail price (as per June 2020 data)	9.37
b. Calcium 500mg	Ceiling Price	1.72
c. Vitamin D3 2000IU	Retail Price as per Pronab Sen Committee Report	6.73
d. Pyridoxal -5 Phosphate 20 mg	Retail Price as per Pronab Sen Committee Report	0.20
e. L-Methylfolate Calcium 1 mg	Data not available	-

Computation of Retail Price per Tablet	Source/Method	Amount (Rs.)
Worked out Retail Price		18.02
d. Less 20% of the lowest of (a) to (e) as recommended in the Pronab Sen Committee report		0.00
Net Retail Price (a+b-c)		18.02
Company Claimed Price		21.50
Recommended price		18.02

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 Vitamin D3 2000IU tablet

Ceiling Price of Vitamin D3 1000 IU Tablet = Rs. 3.74

Derived Retail price for Vitamin D3 =  $3.74[1 + 0.80\{(20-10)/10\}] = \text{Rs. } 6.73$  per tablet

Derived Retail Price of Pyridoxal -5 Phosphate 20 mg

Ceiling Price of Pyridoxine 10mg Tablet = Rs. 0.11

Derived Retail price for Pyridoxal -5 Phosphate 20 mg =  $0.11[1 + 0.80\{(20-10)/10\}] = \text{Rs. } 0.20$  per tablet

**2. Agenda No. 2 Retail price fixation under Para 5 of DPCO, 2013- Each uncoated bilayered tablet containing Metformin Hydrochloride IP (as sustained release form) 500 mg + Vildagliptin 50 mg for M/s Exemed Pharmaceuticals (manufacturer) and M/s Mankind Pharma Ltd. (marketer).**

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 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 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 500 mg tablet comes to Rs. 6.45 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 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 (i.e. Rs. 0.41) 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 500mg (as sustained release form) for various companies. The Committee also observed that similar decision was also taken by the Authority in its 81<sup>st</sup>, 82<sup>nd</sup> and 83<sup>rd</sup> meeting dated 24.11.2020, 23.12.2020 and 27.01.2021 respectively.

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 500mg (as sustained release) at Rs. 6.86 per tablet excluding GST 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 72<sup>nd</sup> meeting dated 20.01.2020, as specified in 2.2, i.e. Rs. 6.45. The Committee also noted that the applicant company has claimed price of Rs. 6.58 per tablet excluding GST.

2.7 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 Exemed Pharmaceuticals (manufacturer) and M/s Mankind Pharma Ltd. (marketer) at Rs. 6.58 per tablet excluding GST.

**3. Agenda No. 3 - Retail price fixation under Para 5 of DPCO, 2013-Each uncoated bilayered tablet containing Metformin Hydrochloride IP (as sustained release form) 1000 mg + Vildagliptin 50 mg for M/s Exemed Pharmaceuticals (manufacturer) and M/s Mankind Pharma Ltd. (marketer).**

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 72<sup>nd</sup> 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 1(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 1000 mg tablet comes to Rs. 7.10 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 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 (Rs. 0.41) 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 1000mg (as sustained release form) for various companies. The Committee also observed that similar decision was also taken by the Authority in its 81<sup>st</sup>, 82<sup>nd</sup> and 83<sup>rd</sup> meeting dated 24.11.2020, 23.12.2020 and 27.01.2021 respectively.

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 1000mg (as sustained release) at Rs. 7.51 per tablet excluding GST 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. 7.10. The Committee also noted that the applicant company has claimed price of Rs. 7.07 per tablet excluding GST.

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

**4. Agenda no. 4 - Retail price fixation under Para 5 of DPCO, 2013 - Each film coated tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended release form) 1000 mg for M/s Exemed Pharmaceuticals (manufacturer) and M/s Zydus Healthcare Ltd. (marketer).**

4.1 The Committee noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug. The Committee further noted that the Authority in its 82nd meeting dated 23.12.2020 approved the retail price of Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 1000 mg tablet as per the methodology described below:

*“(i) The Authority noted that the applications have been received for retail price fixation of Fixed Dose Combinations (FDCs) of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet. The Authority further noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug.*

*(ii) The Authority recalled the decision taken in its 72nd meeting dated 20.01.2020 regarding retail price fixation of Fixed Dose Combinations (FDCs) of Metformin and Vildagliptin tablets in which it emphasized that the 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 of FDCs of Metformin and Vildagliptin tablet by adding 16% retailer margin to the average Price to Retailer (PTR) based on Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Metformin and Vildagliptin tablets to give the benefits of patent expiry of the drug Vildagliptin to consumers.*

*(iii) The Authority deliberated upon the matter in detail and decided to fix the retail price of FDC of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablets in line with the decision taken in the 72nd meeting 20.01.2020 regarding retail price fixation of FDC of Metformin and Vildagliptin tablets. (iv) Accordingly, the Authority approved retail price fixation of FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet 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 FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet in public interest so as to extend the benefit of price reduction due to patent expiry to the consumers.”*

4.2 The Committee deliberated upon the matter in detail and decided to derive the retail price of each film coated tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended release form) 1000 mg at Rs. 11.81 per tablet excluding GST, in line with the decisions taken by the Authority in its 82nd meeting dated 23.12.2020, by taking data as per Form-V submitted by the companies to which the retail price for the Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 1000 mg tablet was earlier approved. The Committee also noted that the applicant company has claimed price of Rs. 55.57 per tablet excluding GST.

4.3 Accordingly, the Committee recommended the retail price of each film coated tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended

release form) 1000 mg for M/s Exemed Pharmaceuticals (manufacturer) and M/s Zydus Healthcare Ltd. (marketer) at Rs. 11.81 per tablet excluding GST.

**5. Agenda no. 5 - Retail price fixation under Para 5 of DPCO, 2013 - Each film coated tablet containing Dapagliflozin 10 mg +Metformin Hydrochloride IP (in extended release form) 500 mg for M/s Exemed Pharmaceuticals (manufacturer) and M/s Zydus Healthcare Ltd. (marketer).**

5.1 The Committee noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug. The Committee further noted that the Authority in its 82nd meeting dated 23.12.2020 approved the retail price of Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 500 mg tablet as per the methodology described below:

*“(i) The Authority noted that the applications have been received for retail price fixation of Fixed Dose Combinations (FDCs) of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet. The Authority further noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug.*

*(ii) The Authority recalled the decision taken in its 72nd meeting dated 20.01.2020 regarding retail price fixation of Fixed Dose Combinations (FDCs) of Metformin and Vildagliptin tablets in which it emphasized that the 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 of FDCs of Metformin and Vildagliptin tablet by adding 16% retailer margin to the average Price to Retailer (PTR) based on Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Metformin and Vildagliptin tablets to give the benefits of patent expiry of the drug Vildagliptin to consumers.*

*(iii) The Authority deliberated upon the matter in detail and decided to fix the retail price of FDC of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablets in line with the decision taken in the 72nd meeting 20.01.2020 regarding retail price fixation of FDC of Metformin and Vildagliptin tablets. (iv) Accordingly, the Authority approved retail price fixation of FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet 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 FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet in public interest so as to extend the benefit of price reduction due to patent expiry to the consumers.”*

5.2 The Committee deliberated upon the matter in detail and decided to derive the retail price of each film coated tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended release form) 500 mg at Rs. 10.22 per tablet, in line with the decisions taken by the Authority in its 82nd meeting dated 23.12.2020, by taking data as per Form-V submitted by the companies to which the retail price for the Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 500 mg tablet was earlier approved. The Committee also noted that the applicant company has claimed price of Rs. 53.57 per tablet excluding GST.

5.3 Accordingly, the Committee recommended the retail price of each film coated tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended release form) 500 mg for M/s Exemed Pharmaceuticals (manufacturer) and M/s Zydus Healthcare Ltd. (marketer) at Rs. 10.22 per tablet excluding GST.

**6. Agenda no. 6 Retail price fixation under Para 5 of DPCO, 2013- Each film coated bilayered tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5 mg + Metformin Hydrochloride IP 500 mg (as an extended release form) for M/s. Alkem Healthscience (manufacturer) and M/s Alkem Laboratories Ltd. (marketers).**

6.1 The Committee noted the minutes of 72<sup>nd</sup> 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 1(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 72<sup>nd</sup> 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 M/s Torrent Pharmaceuticals Ltd and the companies have launched the formulation and has submitted the Form-V data. The retail price of Dapagliflozin 5mg + Metformin 500mg tablet has also been fixed earlier for M/s Torrent Pharmaceuticals Ltd, however, the company has not launched the product.

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. 5.21 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	10.22
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)		8.69

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. 8.69per tablet

Derived Retail price of Dapagliflozin 10mg Tablet =  $8.69 [1 + 0.80\{(5-10)/10\}] = \text{Rs. } 5.21$  per tablet.

6.5 The Committee further deliberated upon the matter in detail and recommended the retail price of each film coated bilayered tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5 mg + Metformin Hydrochloride IP 500 mg (as an extended release form) for M/s. Alkem Healthscience (manufacturer) and M/s Alkem Laboratories Ltd. (marketers) at Rs. 6.74 per tablet excluding GST as detailed below::

<b>Computation of Retail Price per dose</b>	<b>Source/Method</b>	<b>Amount (Rs.)</b>
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	5.21
b. Metformin Hydrochloride IP (in extended release form) 500 mg	Ceiling Price	1.91
Total		7.12
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)		6.74
Company Claimed Price		42.70
Recommended price		6.74

**7. Agenda no. 7 Retail price fixation under Para 5 of DPCO, 2013- Each film coated bilayered tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5 mg + Metformin Hydrochloride IP 1000 mg (as an extended release form) for M/s. Alkem Healthscience (manufacturer) and M/s Alkem Laboratories Ltd. (marketers).**

7.1 The Committee noted the minutes of 72<sup>nd</sup> 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 1(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 M/s Torrent Pharmaceuticals Ltd and the companies have launched the formulation and has submitted the Form-V data. The retail price of Dapagliflozin 5mg + Metformin 1000mg tablet has also been fixed earlier for M/s Torrent Pharmaceuticals Ltd, however, the company has not launched the product.

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. 5.21 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	10.22
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)		8.69

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. 8.69per tablet

Derived Retail price of Dapagliflozin 10mg Tablet =  $8.69 [1+0.80\{5-10\}/10]$  = Rs. 5.21 per tablet.

7.5 The Committee further deliberated upon the matter in detail and recommended the retail price of each film coated bilayered tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5 mg + Metformin Hydrochloride IP 1000 mg (as an extended release form) for M/s. Alkem Healthscience (manufacturer) and M/s Alkem Laboratories Ltd. (marketers) at Rs. 8.12 per tablet excluding GST as detailed below::

<b>Computation of Retail Price per dose</b>	<b>Source/Method</b>	<b>Amount (Rs.)</b>
Composition – Dapagliflozin 5 mg + Metformin Hydrochloride IP (in extended release form) 1000 mg		
a. Dapagliflozin 5mg (as per para 7.4 above)	Worked out Retail price	5.21
b. Metformin Hydrochloride IP (in extended release form) 1000 mg	Ceiling Price	3.64
Total		8.85
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)		8.12
Company Claimed Price		45.00
Recommended price		8.12

**8. Agenda no. 8 Retail price fixation under Para 5 of DPCO, 2013 - Each film coated bilayered tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended release form) 500 mg for M/s Alkem Healthscience (manufacturer) and M/s Alkem Laboratories Ltd. (marketer).**

8.1 The Committee noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug. The Committee further noted that the Authority in its 82nd meeting dated 23.12.2020 approved the retail price of Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 500 mg tablet as per the methodology described below:

*“(i) The Authority noted that the applications have been received for retail price fixation of Fixed Dose Combinations (FDCs) of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet. The Authority further noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug.*

*(ii) The Authority recalled the decision taken in its 72nd meeting dated 20.01.2020 regarding retail price fixation of Fixed Dose Combinations (FDCs) of Metformin and Vildagliptin tablets in which it emphasized that the 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 of FDCs of Metformin and Vildagliptin tablet by adding 16% retailer margin to the average Price to Retailer (PTR) based on*

*Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Metformin and Vildagliptin tablets to give the benefits of patent expiry of the drug Vildagliptin to consumers.*

*(iii) The Authority deliberated upon the matter in detail and decided to fix the retail price of FDC of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablets in line with the decision taken in the 72nd meeting 20.01.2020 regarding retail price fixation of FDC of Metformin and Vildagliptin tablets. (iv) Accordingly, the Authority approved retail price fixation of FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet 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 FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet in public interest so as to extend the benefit of price reduction due to patent expiry to the consumers.”*

8.2 The Committee deliberated upon the matter in detail and decided to derive the retail price of each film coated tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended release form) 500 mg at Rs. 10.22 per tablet, in line with the decisions taken by the Authority in its 82nd meeting dated 23.12.2020, by taking data as per Form-V submitted by the companies to which the retail price for the Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 500 mg tablet was earlier approved. The Committee also noted that the applicant company has claimed price of Rs. 46.70 per tablet excluding GST.

8.3 Accordingly, the Committee recommended the retail price of each film coated bilayered tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended release form) 500 mg for M/s Alkem Healthscience (manufacturer) and M/s Alkem Laboratories Ltd. (marketer) at Rs. 10.22 per tablet excluding GST.

**9. Agenda no. 9 Retail price fixation under Para 5 of DPCO, 2013 - Each film coated bilayered tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10 mg +Metformin Hydrochloride IP (in extended release form) 1000 mg for M/s Alkem Healthscience (manufacturer) and M/s Alkem Laboratories Ltd. (marketer).**

9.1 The Committee noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug. The Committee further noted that the Authority in its 82nd meeting dated 23.12.2020 approved the retail price of Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 1000 mg tablet as per the methodology described below:

*“(i) The Authority noted that the applications have been received for retail price fixation of Fixed Dose Combinations (FDCs) of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet. The Authority further noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug.*

*(ii) The Authority recalled the decision taken in its 72nd meeting dated 20.01.2020 regarding retail price fixation of Fixed Dose Combinations (FDCs) of Metformin and Vildagliptin tablets in which it emphasized that*

*the 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 of FDCs of Metformin and Vildagliptin tablet by adding 16% retailer margin to the average Price to Retailer (PTR) based on Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Metformin and Vildagliptin tablets to give the benefits of patent expiry of the drug Vildagliptin to consumers.*

*(iii) The Authority deliberated upon the matter in detail and decided to fix the retail price of FDC of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablets in line with the decision taken in the 72nd meeting 20.01.2020 regarding retail price fixation of FDC of Metformin and Vildagliptin tablets. (iv) Accordingly, the Authority approved retail price fixation of FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet 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 FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet in public interest so as to extend the benefit of price reduction due to patent expiry to the consumers.”*

9.2 The Committee deliberated upon the matter in detail and decided to derive the retail price of each film coated tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended release form) 1000 mg at Rs. 11.81 per tablet excluding GST, in line with the decisions taken by the Authority in its 82nd meeting dated 23.12.2020, by taking data as per Form-V submitted by the companies to which the retail price for the Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 1000 mg tablet was earlier approved. The Committee also noted that the applicant company has claimed price of Rs. 48.70 per tablet excluding GST.

9.3 Accordingly, the Committee recommended the retail price of each film coated bilayered tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended release form) 1000 mg for M/s Alkem Healthscience (manufacturer) and M/s Alkem Laboratories Ltd. (marketer). (marketer) at Rs. 11.81 per tablet excluding GST.

**10. Agenda no. 10 Retail price fixation under Para 5 of DPCO, 2013- Each film coated tablet containing Metformin Hydrochloride IP 500 mg + Vildagliptin 50 mg for M/s Pure & Cure Healthcare Pvt. Ltd. (manufacturer) and M/s Blue Cross Laboratories Pvt. Ltd. (marketer).**

10.1 The Committee noted the minutes of 72<sup>nd</sup> 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 1(ii) in public interest.*

10.2 The Committee observed that based on the methodology decided by the Authority in its 72nd meeting dated 20.01.2020, as specified in 10.1 above, the retail price of Vildagliptin 50 mg + Metformin 500 mg tablet comes to Rs. 6.45 per tablet excluding GST. The Committee also noted that the company claimed retail price at Rs. 5.90 per tablet excluding GST.

10.3 The Committee deliberated upon the matter in detail and decided to recommend the retail price of each film coated tablet containing Metformin Hydrochloride IP 500 mg + Vildagliptin 50 mg for M/s Pure & Cure Healthcare Pvt. Ltd. (manufacturer) and M/s Blue Cross Laboratories Pvt. Ltd. (marketer) at 5.90 per tablet excluding GST.

## **11. Agenda no. 11 Retail price fixation under Para 5 of DPCO, 2013- Each film coated tablet containing Metformin Hydrochloride IP 1000 mg + Vildagliptin 50 mg for M/s Pure & Cure Healthcare Pvt. Ltd. (manufacturer) and M/s Blue Cross Laboratories Pvt. Ltd. (marketer).**

11.1 The Committee noted the minutes of 72<sup>nd</sup> 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.

11.2 The Committee observed that based on the methodology decided by the Authority in its 72nd meeting dated 20.01.2020, as specified in 11.1 above, the retail price of Vildagliptin 50 mg + Metformin 1000 mg tablet comes to Rs. 7.10 per tablet excluding GST. The Committee also noted that the company claimed retail price at Rs. 6.90 per tablet excluding GST.

11.3 The Committee deliberated upon the matter in detail and decided to recommend the retail price of each film coated tablet containing Metformin Hydrochloride IP 1000 mg + Vildagliptin 50 mg for M/s Pure & Cure Healthcare Pvt. Ltd. (manufacturer) and M/s Blue Cross Laboratories Pvt. Ltd. (marketer) at 6.90 per tablet excluding GST.

## **12. Agenda no. 12 Retail price fixation under Para 5 of DPCO, 2013 - Each film coated tablet containing Dapagliflozin 10 mg +Metformin Hydrochloride IP (in extended release form) 1000 mg for M/s MSN Laboratories Pvt. Ltd. (manufacturer) and M/s USV Pvt. Ltd. (marketer)**

12.1 The Committee noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug. The Committee further noted that the Authority in its 82nd meeting dated 23.12.2020 approved the retail price of Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 1000 mg tablet as per the methodology described below:

*“(i) The Authority noted that the applications have been received for retail price fixation of Fixed Dose Combinations (FDCs) of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet. The Authority further noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug.*

*(ii) The Authority recalled the decision taken in its 72nd meeting dated 20.01.2020 regarding retail price fixation of Fixed Dose Combinations (FDCs) of Metformin and Vildagliptin tablets in which it emphasized that the 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 of FDCs of Metformin and Vildagliptin tablet by adding 16% retailer margin to the average Price to Retailer (PTR) based on Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Metformin and Vildagliptin tablets to give the benefits of patent expiry of the drug Vildagliptin to consumers.*

*(iii) The Authority deliberated upon the matter in detail and decided to fix the retail price of FDC of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablets in line with the decision taken in the 72nd meeting 20.01.2020 regarding retail price fixation of FDC of Metformin and Vildagliptin tablets. (iv) Accordingly, the Authority approved retail price fixation of FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet 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 FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet in public interest so as to extend the benefit of price reduction due to patent expiry to the consumers.”*

12.2 The Committee deliberated upon the matter in detail and decided to derive the retail price of each film coated tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended release form) 1000 mg at Rs. 11.81 per tablet excluding GST, in line with the decisions taken by the Authority in its 82nd meeting dated 23.12.2020, by taking data as per Form-V submitted by the companies to which the retail price for the Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 1000 mg tablet was earlier approved. The Committee also noted that the applicant company has claimed price of Rs. 19.50 per tablet excluding GST.

12.3 Accordingly, the Committee recommended the retail price of each film coated tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended release form) 1000 mg for M/s MSN Laboratories Pvt. Ltd. (manufacturer) and M/s USV Pvt. Ltd. (marketer) at Rs. 11.81 per tablet excluding GST.

**13. Agenda no. 13 Retail price fixation under Para 5 of DPCO, 2013 - Each film coated tablet containing Dapagliflozin 10 mg +Metformin Hydrochloride IP (in extended release form) 500 mg for M/s MSN Laboratories Pvt. Ltd. (manufacturer) and M/s USV Pvt. Ltd. (marketer)**

13.1 The Committee noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug. The Committee further noted that the Authority in its 82nd meeting dated 23.12.2020 approved the retail price of Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 500 mg tablet as per the methodology described below:

*“(i) The Authority noted that the applications have been received for retail price fixation of Fixed Dose Combinations (FDCs) of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet. The Authority further noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug.*

*(ii) The Authority recalled the decision taken in its 72nd meeting dated 20.01.2020 regarding retail price fixation of Fixed Dose Combinations*

*(FDCs) of Metformin and Vildagliptin tablets in which it emphasized that the 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 of FDCs of Metformin and Vildagliptin tablet by adding 16% retailer margin to the average Price to Retailer (PTR) based on Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Metformin and Vildagliptin tablets to give the benefits of patent expiry of the drug Vildagliptin to consumers.*

*(iii) The Authority deliberated upon the matter in detail and decided to fix the retail price of FDC of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablets in line with the decision taken in the 72nd meeting 20.01.2020 regarding retail price fixation of FDC of Metformin and Vildagliptin tablets. (iv) Accordingly, the Authority approved retail price fixation of FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet 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 FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet in public interest so as to extend the benefit of price reduction due to patent expiry to the consumers.”*

13.2 The Committee deliberated upon the matter in detail and decided to derive the retail price of each film coated tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended release form) 500 mg at Rs. 10.22 per tablet, in line with the decisions taken by the Authority in its 82nd meeting dated 23.12.2020, by taking data as per Form-V submitted by the companies to which the retail price for the Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 500 mg tablet was earlier approved. The Committee also noted that the applicant company has claimed price of Rs. 19.00 per tablet excluding GST.

13.3 Accordingly, the Committee recommended the retail price of each film coated tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended release form) 500 mg for M/s MSN Laboratories Pvt. Ltd. (manufacturer) and M/s USV Pvt. Ltd. at Rs. 10.22 per tablet excluding GST.

**14. Agenda no. 14 Retail price fixation under Para 5 of DPCO, 2013- Each film coated tablet containing Dapagliflozin 5 mg + Metformin Hydrochloride IP 500 mg (as an extended release ) for M/s. MSN Laboratories Pvt. Ltd. (manufacturer) and M/s Intas Pharmaceuticals Ltd. (marketers)**

14.1 The Committee noted the minutes of 72<sup>nd</sup> 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 1(ii) in public interest.*

14.2 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.

14.3 The Committee observed that the retail price of Dapagliflozin 10mg + Metformin 500mg tablet has been fixed earlier for M/s Micro Labs Limited and M/s Torrent Pharmaceuticals Ltd and the companies have launched the formulation and has submitted the Form-V data. The retail price of Dapagliflozin 5mg + Metformin 500mg tablet has also been fixed earlier for M/s Torrent Pharmaceuticals Ltd, however, the company has not launched the product.

14.4 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. 5.21 per tablet excluding GST as detailed below:

<b>S.No.</b>	<b>Particulars</b>	<b>Price</b>	<b>Price (Rs.)</b>
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	10.22

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)		8.69

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. 8.69 per tablet

Derived Retail price of Dapagliflozin 10mg Tablet =  $8.69 [1 + 0.80\{(5-10)/10\}] = \text{Rs. } 5.21$  per tablet.

14.5 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 500 mg (as an extended release ) for M/s. MSN Laboratories Pvt. Ltd. (manufacturer) and M/s Intas Pharmaceuticals Ltd. (marketers) at Rs. 6.74 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 14.4 above)	Worked out Retail price	5.21
b. Metformin Hydrochloride IP (in extended release form) 500 mg	Ceiling Price	1.91
Total		7.12
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)		6.74
Company Claimed Price		10.90
Recommended price		6.74

**15. Agenda no. 15 Retail price fixation under Para 5 of DPCO, 2013- Each film coated tablet containing Dapagliflozin 5 mg + Metformin Hydrochloride IP 1000 mg (as an extended release form) for M/s MSN Laboratories Pvt. Ltd. (manufacturer) and M/s Intas Pharmaceuticals Ltd. (marketers)**

15.1 The Committee noted the minutes of 72<sup>nd</sup> 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 1(ii) in public interest.*

15.2 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 72<sup>nd</sup> Authority meeting dated 20.01.2020 w.r.t. the formulation Vildagliptin + Metformin tablets.

15.3 The Committee observed that the retail price of Dapagliflozin 10mg + Metformin 500mg tablet has been fixed earlier for M/s Micro Labs Limited and M/s Torrent Pharmaceuticals Ltd and the companies have launched the formulation and has submitted the Form-V data. The retail price of Dapagliflozin 5mg + Metformin 1000mg tablet has also been fixed earlier for M/s Torrent Pharmaceuticals Ltd, however, the company has not launched the product.

15.4 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. 5.21 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	10.22
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)		8.69

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. 8.69per tablet

Derived Retail price of Dapagliflozin 10mg Tablet = 8.69 [1+0.80{5-10}/10}] = Rs. 5.21 per tablet.

15.5 The Committee further deliberated upon the matter in detail and recommended the retail price of each film coated bilayered tablet containing Dapagliflozin 5 mg + Metformin Hydrochloride IP 1000 mg (as an extended release form) for M/s MSN Laboratories Pvt. Ltd. (manufacturer) and M/s Intas Pharmaceuticals Ltd. (marketers) at Rs. 8.12 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 (as per para 15.4 above)	Worked out Retail price	5.21
b. Metformin Hydrochloride IP (in extended release form) 1000 mg	Ceiling Price	3.64
Total		8.85
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)		8.12

Computation of Retail Price per dose	Source Method	Amount (Rs.)
Company Claimed Price		11.90
Recommended price		8.12

**16. Agenda no. 16 Retail price fixation under Para 5 of DPCO, 2013- Each film coated tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP 1000 mg (as an extended release form) for M/s MSN Laboratories Pvt. Ltd. (manufacturer) and M/s Intas Pharmaceuticals Ltd. (marketers)**

16.1 The Committee noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug. The Committee further noted that the Authority in its 82nd meeting dated 23.12.2020 approved the retail price of Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 1000 mg tablet as per the methodology described below:

*“(i) The Authority noted that the applications have been received for retail price fixation of Fixed Dose Combinations (FDCs) of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet. The Authority further noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug.*

*(ii) The Authority recalled the decision taken in its 72nd meeting dated 20.01.2020 regarding retail price fixation of Fixed Dose Combinations (FDCs) of Metformin and Vildagliptin tablets in which it emphasized that the 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 of FDCs of Metformin and Vildagliptin tablet by adding 16% retailer margin to the average Price to Retailer (PTR) based on Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Metformin and Vildagliptin tablets to give the benefits of patent expiry of the drug Vildagliptin to consumers.*

*(iii) The Authority deliberated upon the matter in detail and decided to fix the retail price of FDC of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablets in line with the decision taken in the 72nd meeting 20.01.2020 regarding retail price fixation of FDC of Metformin and Vildagliptin tablets. (iv) Accordingly, the Authority approved retail price fixation of FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet 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 FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet in public interest so as to extend the benefit of price reduction due to patent expiry to the consumers.”*

16.2 The Committee deliberated upon the matter in detail and decided to derive the retail price of each film coated tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended release form) 1000 mg at Rs. 11.81 per tablet excluding GST, in line with the decisions taken by the Authority in its 82nd meeting dated 23.12.2020, by taking data as per Form-V submitted by the companies to which the retail price for the Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 1000 mg tablet was earlier

approved. The Committee also noted that the applicant company has claimed price of Rs. 15.90 per tablet excluding GST.

16.3 Accordingly, the Committee recommended the retail price of each film coated tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP 1000 mg (as an extended release form) for M/s MSN Laboratories Pvt. Ltd. (manufacturer) and M/s Intas Pharmaceuticals Ltd. (marketers) at Rs. 11.81 per tablet excluding GST.

**17. Agenda no. 17 Retail price fixation under Para 5 of DPCO, 2013- Each film coated tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP 500 mg (as an extended release form) for M/s MSN Laboratories Pvt. Ltd. (manufacturer) and M/s Intas Pharmaceuticals Ltd. (marketers)**

17.1 The Committee noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug. The Committee further noted that the Authority in its 82nd meeting dated 23.12.2020 approved the retail price of Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 500 mg tablet as per the methodology described below:

*“(i) The Authority noted that the applications have been received for retail price fixation of Fixed Dose Combinations (FDCs) of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet. The Authority further noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug.*

*(ii) The Authority recalled the decision taken in its 72nd meeting dated 20.01.2020 regarding retail price fixation of Fixed Dose Combinations (FDCs) of Metformin and Vildagliptin tablets in which it emphasized that the 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 of FDCs of Metformin and Vildagliptin tablet by adding 16% retailer margin to the average Price to Retailer (PTR) based on Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Metformin and Vildagliptin tablets to give the benefits of patent expiry of the drug Vildagliptin to consumers.*

*(iii) The Authority deliberated upon the matter in detail and decided to fix the retail price of FDC of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablets in line with the decision taken in the 72nd meeting 20.01.2020 regarding retail price fixation of FDC of Metformin and Vildagliptin tablets. (iv) Accordingly, the Authority approved retail price fixation of FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet 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 FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet in public interest so as to extend the benefit of price reduction due to patent expiry to the consumers.”*

17.2 The Committee deliberated upon the matter in detail and decided to derive the retail price of each film coated tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended release form) 500 mg at Rs. 10.22 per tablet, in line with the decisions taken by the Authority in its 82nd meeting dated 23.12.2020, by taking data as per Form-V submitted by the companies to which the retail price for



the Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 500 mg tablet was earlier approved. The Committee also noted that the applicant company has claimed price of Rs. 13.90 per tablet excluding GST.

17.3 Accordingly, the Committee recommended the retail price of each film coated tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended release form) 500 mg for M/s MSN Laboratories Pvt. Ltd. (manufacturer) and M/s Intas Pharmaceuticals Ltd. (marketers) at Rs. 10.22 per tablet excluding GST.

**18. Agenda no. 18 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 Exemed Pharmaceuticals (manufacturer) and M/s Zydus Healthcare Ltd. (marketer)**

18.1 The Committee noted the minutes of 72<sup>nd</sup> 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 1(ii) in public interest.*

18.2 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.

18.3 The Committee observed that the retail price of Dapagliflozin 10mg + Metformin 500mg tablet has been fixed earlier for M/s Micro Labs Limited and M/s Torrent Pharmaceuticals Ltd and the companies have launched the formulation and has submitted the Form-V data. The retail price of Dapagliflozin 5mg + Metformin 1000mg tablet has also been fixed earlier for M/s Torrent Pharmaceuticals Ltd, however, the company has not launched the product.

18.4 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. 5.21 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	10.22
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)		8.69

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. 8.69 per tablet

Derived Retail price of Dapagliflozin 10mg Tablet = 8.69 [1 + 0.80{(5-10)/10}] = Rs. 5.21 per tablet.

18.5 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 Exemed Pharmaceuticals (manufacturer) and M/s Zydus Healthcare Ltd. (marketer) at Rs. 8.12 per tablet excluding GST as detailed below:

<b>Computation of Retail Price per dose</b>	<b>Source Method</b>	<b>Amount (Rs.)</b>
Composition – Dapagliflozin 5 mg + Metformin Hydrochloride IP (in extended release form) 1000 mg		
a. Dapagliflozin 5mg (as per para 18.4 above)	Worked out Retail price	5.21
b. Metformin Hydrochloride IP (in extended release form) 1000 mg	Ceiling Price	3.64
Total		8.85
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)		8.12
Company Claimed Price		31.21
Recommended price		8.12

**19. Agenda no. 19 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 Exemed Pharmaceuticals (manufacturer) and M/s Zydus Healthcare Ltd. (marketer)**

19.1 The Committee noted the minutes of 72<sup>nd</sup> 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 1(ii) in public interest.*

19.2 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.

19.3 The Committee observed that the retail price of Dapagliflozin 10mg + Metformin 500mg tablet has been fixed earlier for M/s Micro Labs Limited and M/s Torrent Pharmaceuticals Ltd and the companies have launched the formulation and has submitted the Form-V data. The retail price of Dapagliflozin 5mg + Metformin 500mg tablet has also been fixed earlier for M/s Torrent Pharmaceuticals Ltd, however, the company has not launched the product.

19.4 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. 5.21 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	10.22
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)		8.69

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. 8.69per tablet

Derived Retail price of Dapagliflozin 10mg Tablet = 8.69  $[1+0.80\{5-10\}/10]$  = Rs. 5.21 per tablet.

19.5 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 Exemed Pharmaceuticals (manufacturer) and M/s Zydus Healthcare Ltd. at Rs. 6.74 per tablet excluding GST as detailed below::

<b>Computation of Retail Price per dose</b>	<b>Source Method</b>	<b>Amount (Rs.)</b>
Composition – Dapagliflozin 5 mg + Metformin Hydrochloride IP (in extended release form) 500 mg		
a. Dapagliflozin 5mg (as per para 19.4 above)	Worked out Retail price	5.21
b. Metformin Hydrochloride IP (in extended release form) 500 mg	Ceiling Price	1.91
Total		7.12
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)		6.74
Company Claimed Price		29.07
Recommended price		6.74

**20. Agenda no. 20 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 MSN Laboratories Pvt. Ltd. (manufacturer) and M/s Eris Lifesciences Ltd. (marketer)**

20.1 The Committee noted the minutes of 72<sup>nd</sup> 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 1(ii) in public interest.*

20.2 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.

20.3 The Committee observed that the retail price of Dapagliflozin 10mg + Metformin 500mg tablet has been fixed earlier for M/s Micro Labs Limited and M/s Torrent Pharmaceuticals Ltd and the companies have launched the formulation and has submitted the Form-V data. The retail price of Dapagliflozin 5mg + Metformin 500mg tablet has also been fixed earlier for M/s Torrent Pharmaceuticals Ltd, however, the company has not launched the product.

20.4 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. 5.21 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	10.22
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)		8.69

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. 8.69per tablet

Derived Retail price of Dapagliflozin 10mg Tablet = 8.69  $[1+0.80\{5-10\}/10]$  = Rs. 5.21 per tablet.

20.5 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 MSN Laboratories Pvt. Ltd. (manufacturer) and M/s Eris Lifesciences Ltd. (marketer)at Rs. 6.74 per tablet excluding GST as detailed below:

<b>Computation of Retail Price per dose</b>	<b>Source Method</b>	<b>Amount (Rs.)</b>
Composition – Dapagliflozin 5 mg + Metformin Hydrochloride IP (in extended release form) 500 mg		
a. Dapagliflozin 5mg (as per para 20.4 above)	Worked out Retail price	5.21
b. Metformin Hydrochloride IP (in extended release form) 500 mg	Ceiling Price	1.91
Total		7.12
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)		6.74
Company Claimed Price		10.50
Recommended price		6.74

**21. Agenda no. 21 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 MSN Laboratories Pvt. Ltd. (manufacturer) and M/s Eris Lifesciences Ltd. (marketer)**

21.1 The Committee noted the minutes of 72<sup>nd</sup> 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 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 1(ii) in public interest.*

21.2 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.

21.3 The Committee observed that the retail price of Dapagliflozin 10mg + Metformin 500mg tablet has been fixed earlier for M/s Micro Labs Limited and M/s Torrent Pharmaceuticals Ltd and the companies have launched the formulation and has submitted the Form-V data. The retail price of Dapagliflozin 5mg + Metformin 1000mg tablet has also been fixed earlier for M/s Torrent Pharmaceuticals Ltd, however, the company has not launched the product.

21.4 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. 5.21 per tablet excluding GST as detailed below:

<b>S.No.</b>	<b>Particulars</b>	<b>Price</b>	<b>Price (Rs.)</b>
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	10.22
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)		8.69



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. 8.69 per tablet

Derived Retail price of Dapagliflozin 10mg Tablet =  $8.69 [1 + 0.80\{(5-10)/10\}] = \text{Rs. } 5.21$  per tablet.

21.5 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 MSN Laboratories Pvt. Ltd. (manufacturer) and M/s Eris Lifesciences Ltd. at Rs. 8.12 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 (as per para 18.4 above)	Worked out Retail price	5.21
b. Metformin Hydrochloride IP (in extended release form) 1000 mg	Ceiling Price	3.64
Total		8.85
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)		8.12
Company Claimed Price		11.50
Recommended price		8.12

**22. Agenda no. 22 Retail price fixation under Para 5 of DPCO, 2013 - Each film coated tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended release form) 500 mg for M/s MSN Laboratories Pvt. Ltd. (manufacturer) and M/s Eris Lifesciences Ltd. (marketer)**

22.1 The Committee noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug. The Committee further noted that the Authority in its 82nd meeting dated 23.12.2020 approved the retail price of Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 500 mg tablet as per the methodology described below:

*“(i) The Authority noted that the applications have been received for retail price fixation of Fixed Dose Combinations (FDCs) of Dapagliflozin and*

*Metformin Hydrochloride (Extended Release) tablet. The Authority further noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug.*

*(ii) The Authority recalled the decision taken in its 72nd meeting dated 20.01.2020 regarding retail price fixation of Fixed Dose Combinations (FDCs) of Metformin and Vildagliptin tablets in which it emphasized that the 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 of FDCs of Metformin and Vildagliptin tablet by adding 16% retailer margin to the average Price to Retailer (PTR) based on Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Metformin and Vildagliptin tablets to give the benefits of patent expiry of the drug Vildagliptin to consumers.*

*(iii) The Authority deliberated upon the matter in detail and decided to fix the retail price of FDC of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablets in line with the decision taken in the 72nd meeting 20.01.2020 regarding retail price fixation of FDC of Metformin and Vildagliptin tablets. (iv) Accordingly, the Authority approved retail price fixation of FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet 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 FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet in public interest so as to extend the benefit of price reduction due to patent expiry to the consumers.”*

22.2 The Committee deliberated upon the matter in detail and decided to derive the retail price of each film coated tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended release form) 500 mg at Rs. 10.22 per tablet, in line with the decisions taken by the Authority in its 82nd meeting dated 23.12.2020, by taking data as per Form-V submitted by the companies to which the retail price for the Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 500 mg tablet was earlier approved. The Committee also noted that the applicant company has claimed price of Rs. 13.00 per tablet excluding GST.

22.3 Accordingly, the Committee recommended the retail price of each film coated tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended release form) 500 mg for M/s MSN Laboratories Pvt. Ltd. (manufacturer) and M/s Eris Lifesciences Ltd. at Rs. 10.22 per tablet excluding GST.

**23. Agenda no. 23 Retail price fixation under Para 5 of DPCO, 2013 - Each film coated tablet containing Dapagliflozin 10 mg +Metformin Hydrochloride IP (in extended release form) 1000 mg for M/s MSN Laboratories Pvt. Ltd. (manufacturer) and M/s Eris Lifesciences Ltd. (marketer)**

23.1 The Committee noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug. The Committee further noted that the Authority in its 82nd meeting dated 23.12.2020 approved the retail price of Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 1000 mg tablet as per the methodology described below:

*“(i) The Authority noted that the applications have been received for retail price fixation of Fixed Dose Combinations (FDCs) of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet. The Authority further noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug.*

*(ii) The Authority recalled the decision taken in its 72nd meeting dated 20.01.2020 regarding retail price fixation of Fixed Dose Combinations (FDCs) of Metformin and Vildagliptin tablets in which it emphasized that the 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 of FDCs of Metformin and Vildagliptin tablet by adding 16% retailer margin to the average Price to Retailer (PTR) based on Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Metformin and Vildagliptin tablets to give the benefits of patent expiry of the drug Vildagliptin to consumers.*

*(iii) The Authority deliberated upon the matter in detail and decided to fix the retail price of FDC of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablets in line with the decision taken in the 72nd meeting 20.01.2020 regarding retail price fixation of FDC of Metformin and Vildagliptin tablets. (iv) Accordingly, the Authority approved retail price fixation of FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet 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 FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet in public interest so as to extend the benefit of price reduction due to patent expiry to the consumers.”*

23.2 The Committee deliberated upon the matter in detail and decided to derive the retail price of each film coated tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended release form) 1000 mg at Rs. 11.81 per tablet excluding GST, in line with the decisions taken by the Authority in its 82nd meeting dated 23.12.2020, by taking data as per Form-V submitted by the companies to which the retail price for the Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 1000 mg tablet was earlier approved. The Committee also noted that the applicant company has claimed price of Rs. 16.00 per tablet excluding GST.

23.3 Accordingly, the Committee recommended the retail price of each film coated tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended release form) 1000 mg for M/s MSN Laboratories Pvt. Ltd. (manufacturer) and M/s Eris Lifesciences Ltd. (marketer) at Rs. 11.81 per tablet excluding GST.

**24. Agenda no. 24 Retail price fixation under Para 5 of DPCO, 2013- Each hard gelatin capsule containing Atorvastatin Calcium IP eq. to Atorvastatin 40 mg + Aspirin IP 75 mg (as Gastro-resistant Capsule IP) for M/s. USV Pvt. Ltd. (manufacturer and marketers)**

24.1 The Committee deliberated upon the matter in detail and recommended the retail price of each hard gelatin capsule containing Atorvastatin Calcium IP eq. to Atorvastatin 40 mg + Aspirin IP 75 mg (as Gastro-resistant Capsule IP) for M/s. USV

Pvt. Ltd. (manufacturer and marketers) at Rs. 20.22 per capsule excluding GST as detailed below:

<b>Computation of Retail Price per Tablet</b>	<b>Source/Method</b>	<b>Amount (Rs.)</b>
Composition – Each hard gelatin capsule containing Atorvastatin Calcium IP eq. to Atorvastatin 40 mg + Aspirin IP 75 mg (as Gastro-resistant Capsule IP)		
a. Atorvastatin 40 mg tablet	Ceiling Price	19.24
b. Aspirin IP 75 mg (Enteric Coated) tablet	Ceiling Price	1.22
c. Worked out Retail Price		20.46
d. Less:- 20% of the lowest of (a) to (b) as recommended in the Pronab Sen Committee report		0.24
Net Retail Price (c-d)		20.22
Company Claimed Price		25.00
Recommended price		20.22

**25. Agenda no. 25 Retail price fixation under Para 5 of DPCO, 2013- Each uncoated tablet containing Thyroxine sodium IP eq. to anhydrous Thyroxine Sodium 112 mcg for M/s Macleods Pharmaceuticals Ltd. (manufacturer and marketer)**

25.1 The Committee noted application for retail price fixation of each uncoated tablet containing Thyroxine sodium IP eq. to anhydrous Thyroxine Sodium 112 mcg for M/s Macleods Pharmaceuticals Ltd. (manufacturer and marketer). The Committee also noted that the formulation Levothyroxine 112 mcg tablet is a scheduled formulation under DPCO 2013.

25.2 The Committee deliberated upon the matter in detail and observed that there are negligible therapeutic difference between “thyroxine” and “levothyroxine” and both the formulations are used synonymously. Accordingly, the Committee recommended to close the application for retail price fixation of each uncoated tablet containing Thyroxine sodium IP eq. to anhydrous Thyroxine Sodium 112 mcg for M/s Macleods Pharmaceuticals Ltd. (manufacturer and marketer) and direct the company to follow the applicable ceiling price of Levothyroxine 112 mcg tablet.

**26. Agenda no. 26 Retail price fixation under Para 5 of DPCO, 2013 - Each film coated extended release tablet containing Budesonide IP 9 mg for M/s Sun Pharmaceutical Industries Ltd. (manufacturer) and M/s Sun Pharma Laboratories Ltd. (marketer)**

26.1 The Committee deliberated upon the matter in detail and decided that clarification be obtained from the Office of the Central Drugs Standard Control

Organisation (CDSCO) regarding the manufacturers/ marketers to which approval has been granted for the formulation Budesonide IP 9 mg tablet. After receipt of the list, the requisite information be obtained from the concerned manufacturers/ marketers.

26.2 After analysis of the information, the same may be placed before the Multidisciplinary Committee of Experts for further deliberation on the matter.

### **27. Agenda no. 27 - Fixation of Ceiling Price of Povidone Iodine 7.5% Scrub**

27.1 The Committee deliberated upon the matter in detail and recommended that Povidone Iodine Scrub 7.5% be considered as scheduled formulation in accordance with Explanation I of Schedule I of DPCO 2013 and separate ceiling price be fixed for the formulation.

### **28 Agenda no. 28 Retail price fixation under Para 5 of DPCO, 2013- Each uncoated tablet containing Thyroxine sodium IP eq. to anhydrous Thyroxine Sodium 37.5 mcg for M/s Macleods Pharmaceuticals Ltd. (manufacturer and marketer)**

28.1 The Committee noted application for retail price fixation of each uncoated tablet containing Thyroxine sodium IP eq. to anhydrous Thyroxine Sodium 37.5 mcg for M/s Macleods Pharmaceuticals Ltd. (manufacturer and marketer). The Committee also noted that the formulation Levothyroxine 37.5 mcg tablet is a scheduled formulation under DPCO 2013. However, the ceiling price of Levothyroxine 37.5 mcg tablet is not yet fixed.

28.2 The Committee deliberated upon the matter in detail and observed that there negligible therapeutic difference between “thyroxine” and “levothyroxine” and both the formulations are used synonymously. Accordingly, the Committee recommended to close the application for retail price fixation of each uncoated tablet containing Thyroxine sodium IP eq. to anhydrous Thyroxine Sodium 37.5 mcg for M/s Macleods Pharmaceuticals Ltd. (manufacturer and marketer) and direct the company to follow the applicable ceiling price of Levothyroxine 37.5 mcg tablet after the same is notified.

The meeting ended with a vote of thanks to all.

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

Copy to:  
All members of the Committee.

