

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

Subject: Minutes of the 29th meeting of Multidisciplinary Committee of Experts held on 12.04.2021 at 02:30 PM in NPPA

29th meeting of the "Multidisciplinary Committee of Experts" was held on 12.04.2021 under the Convenorship of Sh. N.I. Chowdhury, Adviser (Cost), in NPPA. The following members attended the meeting through video conferencing:-

1. Prof. Y. K. Gupta, Principal Scientific Advisor (Projects), THSTI-DBT, Gol & Ex-HoD, Pharmacology & Dean (Academics), AIIMS, New Delhi
2. Dr. Rakesh K. Singh, Assoc. Professor, NIPER, Raebareli
3. Shri A. K. Pradhan, Dy. Drugs Controller, CDSCO
4. Dr. Jai Prakash, Sr. Principal Scientific Officer, Indian Pharmacopoeia Commission
5. 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

1. Agenda No. 1 - 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)

1.1 The Committee deliberated upon the matter in detail and also noted the reply received from the Office of the Central Drugs Standard Control Organisation (CDSCO). Accordingly, the Committee decided to place the same in the next meeting for further deliberation on the matter.

2. Agenda No. 2 - Retail price fixation under Para 5 of DPCO, 2013 - Each film coated tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5 mg + Metformin Hydrochloride IP (in extended release form) 1000 mg for M/s Exemed Pharmaceuticals (manufacturer) and M/s Wockhardt Ltd. (marketer).

2.1 The Committee noted 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.

2.2 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.

2.3 The Committee observed that the retail price of Dapagliflozin 10mg + Metformin 500mg tablet and Dapagliflozin 10mg + Metformin 1000mg tablet have been fixed earlier for various companies and some of them have launched the formulation and submitted the Form-V data. The retail price of Dapagliflozin 5mg + Metformin 1000mg tablet has also been fixed earlier for some companies. However, the companies have not launched the product.

2.4 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 and 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. 5.11 per tablet excluding GST as detailed below:

S.No.	Particulars	Price (Rs.)	Price (Rs.)
A	Based on price recommended for Dapagliflozin 10mg + Metformin (ER) 500mg		
	Derived retail price	9.98	
	Less : 80% of Ceiling price of Metformin (CR) 500mg tablet i.e Rs. 1.92 per tablet excluding GST	1.54	
	Derived Retail price for Dapagliflozin 10mg Tablet (A-B)		8.44

B	Based on price recommended for Dapagliflozin 10mg + Metformin (ER) 1000mg	11.53	
	Less : 80% of Ceiling price of Metformin (CR) 1000mg tablet i.e Rs. 3.66 per tablet excluding GST	2.93	8.60
	Derived price of Dapagloflozin 10mg tablet [Average of (A) and (B)]		8.52

Derived Retail Price for Dapagliflozin 5mg Tablet.

Derived Retail Price of Dapagliflozin 10mg Tablet = Rs. 8.52 per tablet

Derived Retail price of Dapagliflozin 5 mg Tablet = $8.52[1+0.80\{5-10\}/10]$ = Rs. 5.11 per tablet.

2.5 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 Exemed Pharmaceuticals (manufacturer) and M/s Wockhardt Ltd. (marketer) at Rs. 8.04 per tablet excluding GST as detailed below:

Computation of Retail Price per dose	Source/Method	Amount (Rs.)
Composition – Dapagliflozin 5 mg + Metformin Hydrochloride IP (in extended release form) 1000 mg		
a. Dapagliflozin 5mg	Worked out Retail price	5.11
b. Metformin Hydrochloride IP (in extended release form) 1000 mg	Ceiling Price	3.66
Total		8.77
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)		8.04
Company Claimed Price		11.00
Recommended price		8.04

3. Agenda No. 3 – Retail price fixation under Para 5 of DPCO, 2013 - Each film coated tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended release form) 500 mg for M/s Exemed Pharmaceuticals (manufacturer) and M/s Wockhardt Ltd. (marketer).

3.1 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.”

3.2 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. 9.98 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. 15.00 per tablet.

3.3 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 Wockhardt Ltd. (marketer) at Rs. 9.98 per tablet excluding GST.

4. Agenda no. 4 - Retail price fixation under Para 5 of DPCO, 2013 - Each film coated tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended release form) 1000 mg for M/s Exemed Pharmaceuticals (manufacturer) and M/s Wockhardt 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. 11.53 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. 15.50 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 Wockhardt Ltd. (marketer) at Rs. 11.53 per tablet excluding GST.

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

5.1 The Committee noted 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.*

5.2 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.

5.3 The Committee observed that the retail price of Dapagliflozin 10mg + Metformin 500mg tablet and Dapagliflozin 10mg + Metformin 1000mg tablet have been fixed earlier for various companies and some of them have launched the formulation and submitted the Form-V data. The retail price of Dapagliflozin 5mg + Metformin 500mg tablet has also been fixed earlier for some companies. However, the companies have not launched the product.

5.4 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 and 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. 5.11 per tablet excluding GST as detailed below:

S.No.	Particulars	Price (Rs.)	Price (Rs.)
A	Based on price recommended for Dapagliflozin 10mg + Metformin (ER) 500mg		
	Derived retail price	9.98	
	Less : 80% of Ceiling price of Metformin (CR) 500mg tablet i.e Rs. 1.92 per tablet excluding GST	1.54	
	Derived Retail price for Dapagliflozin 10mg Tablet (A-B)		8.44
B	Based on price recommended for Dapagliflozin 10mg + Metformin (ER) 1000mg	11.53	
	Less : 80% of Ceiling price of Metformin (CR) 1000mg tablet i.e Rs. 3.66 per tablet excluding GST	2.93	8.60
	Derived price of Dapagloflozin 10mg tablet [Average of (A) and (B)]		8.52

Derived Retail Price for Dapagliflozin 5mg Tablet.

Derived Retail Price of Dapagliflozin 10mg Tablet = Rs. 8.52 per tablet

Derived Retail price of Dapagliflozin 5 mg Tablet = $8.52[1+0.80\{5-10\}/10]$ = Rs. 5.11 per tablet.

5.5 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 MSN Laboratories Pvt. Ltd. (manufacturer) and M/s Alembic Pharmaceuticals Ltd. (marketer) at Rs. 6.65 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	Worked out Retail price	5.11
b. Metformin Hydrochloride IP (in extended release form) 500 mg	Ceiling Price	1.92
Total		7.03
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)		6.65
Company Claimed Price		13.39
Recommended price		6.65

6. Agenda no. 6 - Retail price fixation under Para 5 of DPCO, 2013 - Each film coated tablet containing Dapagliflozin 5 mg +Metformin Hydrochloride IP/USP (in extended release form) 1000 mg for M/s MSN Laboratories Pvt. Ltd. (manufacturer) and M/s Alembic Pharmaceuticals Ltd. (marketer).

6.1 The Committee noted 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.

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

6.3 The Committee observed that the retail price of Dapagliflozin 10mg + Metformin 500mg tablet and Dapagliflozin 10mg + Metformin 1000mg tablet have been fixed earlier for various companies and some of them have launched the formulation and submitted the Form-V data. The retail price of Dapagliflozin 5mg + Metformin 1000mg tablet has also been fixed earlier for some companies. However, the companies have 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 and 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. 5.11 per tablet excluding GST as detailed below:

S.No.	Particulars	Price (Rs.)	Price (Rs.)
A	Based on price recommended for Dapagliflozin 10mg + Metformin (ER) 500mg		
	Derived retail price	9.98	
	Less : 80% of Ceiling price of Metformin (CR) 500mg tablet i.e Rs. 1.92 per tablet excluding GST	1.54	
	Derived Retail price for Dapagliflozin 10mg Tablet (A-B)		8.44
B	Based on price recommended for Dapagliflozin 10mg + Metformin (ER) 1000mg	11.53	
	Less : 80% of Ceiling price of Metformin (CR) 1000mg tablet i.e Rs. 3.66 per tablet excluding GST	2.93	8.60
	Derived price of Dapagloflozin 10mg tablet [Average of (A) and (B)]		8.52

Derived Retail Price for Dapagliflozin 5mg Tablet.

Derived Retail Price of Dapagliflozin 10mg Tablet = Rs. 8.52 per tablet

Derived Retail price of Dapagliflozin 5 mg Tablet = $8.52[1+0.80\{5-10\}/10]$ = Rs. 5.11 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 1000 mg (as an extended release form) for M/s MSN Laboratories Pvt. Ltd. (manufacturer) and M/s Alembic Pharmaceuticals Ltd. (marketer) at Rs. 8.04 per tablet excluding GST as detailed below:

Computation of Retail Price per dose	Source/Method	Amount (Rs.)
Composition – Dapagliflozin 5 mg + Metformin Hydrochloride IP (in extended release form) 1000 mg		
a. Dapagliflozin 5mg	Worked out Retail price	5.11
b. Metformin Hydrochloride IP (in extended release form) 1000 mg	Ceiling Price	3.66
Total		8.77
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)		8.04
Company Claimed Price		16.07
Recommended price		8.04

7. Agenda no. 7 - Retail price fixation under Para 5 of DPCO, 2013 - Each film coated tablet containing Dapagliflozin 10 mg +Metformin Hydrochloride IP/USP (in extended release form) 500 mg for M/s MSN Laboratories Pvt. Ltd. (manufacturer) and M/s Alembic Pharmaceuticals Ltd. (marketer).

7.1 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.”

7.2 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. 9.98 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. 17.86 per tablet excluding GST.

7.3 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 Alembic Pharmaceuticals Ltd. (marketer) at Rs. 9.98 per tablet excluding GST.

8. Agenda no. 8- Retail price fixation under Para 5 of DPCO, 2013 - Each film coated tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP/USP (in extended release form) 1000 mg for M/s MSN Laboratories Pvt. Ltd. (manufacturer) and M/s Alembic Pharmaceuticals 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) 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."

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) 1000 mg at Rs. 11.53 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. 22.32 per tablet excluding GST.

8.3 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 Alembic Pharmaceuticals Ltd. (marketer) at Rs. 11.53 per tablet excluding GST.

9. Agenda no. 9 - Retail price fixation under Para 5 of DPCO, 2013 - Each film coated tablet containing Dapagliflozin 5 mg +Metformin Hydrochloride IP/USP (in extended release form) 500 mg for M/s MSN Laboratories Pvt. Ltd. (manufacturer and marketer)

9.1 The Committee noted 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.

9.2 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.

9.3 The Committee observed that the retail price of Dapagliflozin 10mg + Metformin 500mg tablet and Dapagliflozin 10mg + Metformin 1000mg tablet have been fixed earlier for various companies and some of them have launched the formulation and submitted the Form-V data. The retail price of Dapagliflozin 5mg + Metformin 500mg tablet has also been fixed earlier for some companies. However, the companies have not launched the product.

9.4 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 and 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. 5.11 per tablet excluding GST as detailed below:



S.No.	Particulars	Price (Rs.)	Price (Rs.)
A	Based on price recommended for Dapagliflozin 10mg + Metformin (ER) 500mg		
	Derived retail price	9.98	
	Less : 80% of Ceiling price of Metformin (CR) 500mg tablet i.e Rs. 1.92 per tablet excluding GST	1.54	
	Derived Retail price for Dapagliflozin 10mg Tablet (A-B)		8.44
B	Based on price recommended for Dapagliflozin 10mg + Metformin (ER) 1000mg	11.53	
	Less : 80% of Ceiling price of Metformin (CR) 1000mg tablet i.e Rs. 3.66 per tablet excluding GST	2.93	8.60
	Derived price of Dapagloflozin 10mg tablet [Average of (A) and (B)]		8.52

Derived Retail Price for Dapagliflozin 5mg Tablet.

Derived Retail Price of Dapagliflozin 10mg Tablet = Rs. 8.52 per tablet

Derived Retail price of Dapagliflozin 5 mg Tablet = $8.52[1+0.80\{5-10\}/10]$ = Rs. 5.11 per tablet.

9.5 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 MSN Laboratories Pvt. Ltd. (manufacturer and marketer) at Rs. 6.65 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	Worked out Retail price	5.11
b. Metformin Hydrochloride IP (in extended release form) 500 mg	Ceiling Price	1.92
Total		7.03
c. Less 20% of the lowest of (a) to (b) as recommended in the Pronab Sen Committee report		0.38

Computation of Retail Price per dose	Source/Method	Amount (Rs.)
Net Retail Price (a+b-c)		6.65
Company Claimed Price		6.88
Recommended price		6.65

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

10.1 The Committee noted 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.*

10.2 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.

10.3 The Committee observed that the retail price of Dapagliflozin 10mg + Metformin 500mg tablet and Dapagliflozin 10mg + Metformin 1000mg tablet have been fixed earlier for various companies and some of them have launched the formulation and submitted the Form-V data. The retail price of Dapagliflozin 5mg + Metformin 1000mg tablet has also been fixed earlier for some companies. However, the companies have not launched the product.

10.4 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 and 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. 5.11 per tablet excluding GST as detailed below:

S.No.	Particulars	Price (Rs.)	Price (Rs.)
A	Based on price recommended for Dapagliflozin 10mg + Metformin (ER) 500mg		
	Derived retail price	9.98	
	Less : 80% of Ceiling price of Metformin (CR) 500mg tablet i.e Rs. 1.92 per tablet excluding GST	1.54	
	Derived Retail price for Dapagliflozin 10mg Tablet (A-B)		8.44
B	Based on price recommended for Dapagliflozin 10mg + Metformin (ER) 1000mg	11.53	
	Less : 80% of Ceiling price of Metformin (CR) 1000mg tablet i.e Rs. 3.66 per tablet excluding GST	2.93	8.60
	Derived price of Dapagloflozin 10mg tablet [Average of (A) and (B)]		8.52

Derived Retail Price for Dapagliflozin 5mg Tablet.

Derived Retail Price of Dapagliflozin 10mg Tablet = Rs. 8.52 per tablet

Derived Retail price of Dapagliflozin 5 mg Tablet = $8.52[1+0.80\{5-10\}/10]$ = Rs. 5.11 per tablet.

10.5 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 MSN Laboratories Pvt. Ltd. (manufacturer and marketer) at Rs. 8.04 per tablet excluding GST as detailed below:

Computation of Retail Price per dose	Source/Method	Amount (Rs.)
Composition – Dapagliflozin 5 mg + Metformin Hydrochloride IP (in extended release form) 1000 mg		
a. Dapagliflozin 5mg	Worked out Retail price	5.11
b. Metformin Hydrochloride IP (in extended release form) 1000 mg	Ceiling Price	3.66
Total		8.77
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)		8.04
Company Claimed Price		8.13
Recommended price		8.04

11. Agenda no. 11- Retail price fixation under Para 5 of DPCO, 2013 - Each film coated tablet containing Dapagliflozin 10 mg +Metformin Hydrochloride IP/USP (in extended release form) 500 mg for M/s MSN Laboratories Pvt. Ltd. (manufacturer and marketer)

11.1 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."

11.2 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. 9.98 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. 10.36 per tablet.

11.3 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 marketer) at Rs. 9.98 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/USP (in extended release form) 1000 mg for M/s MSN Laboratories Pvt. Ltd. (manufacturer and 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. 11.53 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. 12.06 per tablet.

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 marketer) at Rs. 11.53 per tablet excluding GST.

13. Agenda no. 13- Retail price fixation under Para 5 of DPCO, 2013- Each uncoated bilayered tablet containing Vildagliptin 50 mg + Metformin HCL IP (as sustained release form) 500 mg for M/s Mascot Health Series Pvt. Ltd. (manufacturer) and M/s Alembic Pharmaceuticals Ltd. (marketer)

13.1 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.

13.2 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.

13.3 The Committee observed that based on the methodology decided by the Authority in its 72nd meeting dated 20.01.2020, as specified in 13.2 above, the retail price of Vildagliptin 50 mg + Metformin 500 mg tablet comes to Rs. 6.45 per tablet excluding GST.

13.4 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."

13.5 The Committee also observed that the Authority in its 80th meeting dated 26.10.2020 approved the recommended methodology, as mentioned in para 13.4 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 81st, 82nd and 83rd meeting dated 24.11.2020, 23.12.2020 and 27.01.2021 respectively.

13.6 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 13.1 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 13.2, i.e. Rs. 6.45. The Committee also noted that the applicant company has claimed price of Rs. 7.50 per tablet.

13.7 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 Mascot Health Series Pvt. Ltd. (manufacturer) and M/s Alembic Pharmaceuticals Ltd. (marketer) at Rs. 6.86 per tablet excluding GST.

14. Agenda no. 14- Retail price fixation under Para 5 of DPCO, 2013- Each uncoated bilayered tablet containing Vildagliptin 50 mg +Metformin HCL IP (as sustained release form) 1000 mg for M/s Mascot Health Series Pvt. Ltd. (manufacturer) and M/s Alembic Pharmaceuticals Ltd. (marketer)

14.1 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.

14.2 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.

14.3. The Committee observed that based on the methodology decided by the Authority in its 72nd meeting dated 20.01.2020, as specified in 14.2 above, the retail price of Vildagliptin 50 mg + Metformin 1000 mg tablet comes to Rs. 7.10 per tablet excluding GST.

14.4. 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.”

14.5. The Committee also observed that the Authority in its 80th meeting dated 26.10.2020 approved the recommended methodology, as mentioned in para 14.4 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 81st, 82nd and 83rd meeting dated 24.11.2020, 23.12.2020 and 27.01.2021 respectively.

14.6. 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 14.1 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 14.2, i.e. Rs. 7.10. The Committee also noted that the applicant company has claimed price of Rs. 8.50 per tablet.

14.7. 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 Mascot Health Series Pvt. Ltd. (manufacturer) and M/s Alembic Pharmaceuticals Ltd. at Rs. 7.51 per tablet excluding GST.

15. Agenda no. 15- Retail price fixation under Para 5 of DPCO, 2013- Each soft gelatin capsule containing Alpha Lipoic Acid USP 200 mcg + Methylcobalamin IP 1500 mcg + Selenium Dioxide Monohydrated USP eq. to Elemental Selenium 55 mcg+ Chromium Picolinate USP 200 mcg + Zinc Sulphate IP 27.5 mg + Myo-Inositol BP 100 mg + Folic Acid IP 1.5 mg for M/s. Akums Drugs & Pharmaceuticals Ltd. (manufacturer) and M/s Intas Pharmaceuticals Ltd. (marketers)

15.1 The Committee deliberated upon the matter in detail and noted the main ingredient in the formulation is Methylcobalamin 1500 mcg and opined that the price of this formulation be fixed under Para 5 of DPCO 2013 on the basis of similar drugs having Methylcobalamin 1500 mcg.

15.2 Accordingly, the Committee recommended the retail price of each soft gelatin capsule containing Alpha Lipoic Acid USP 200 mcg + Methylcobalamin IP 1500 mcg + Selenium Dioxide Monohydrated USP eq. to Elemental Selenium 55 mcg+ Chromium Picolinate USP 200 mcg + Zinc Sulphate IP 27.5 mg + Myo-Inositol BP 100 mg + Folic Acid IP 1.5 mg for M/s. Akums Drugs & Pharmaceuticals Ltd. (manufacturer) and M/s Intas Pharmaceuticals Ltd. (marketers) at Rs. 13.76 per capsule excluding GST.

16. Agenda no. 16- Retail price fixation under Para 5 of DPCO, 2013- Each 5 ml syrup containing Ferric Ammonium Citrate IP 110 mg eq. to Elemental Iron 22.55 mg + Folic Acid IP 1.5 mg + Cyanocobalamin IP 15 mcg for M/s. Biogenetic Drugs Pvt. Ltd. (manufacturer) and M/s Intas Pharmaceuticals Ltd. (marketers)

16.1 The Committee deliberated upon the matter in detail and opined that the price of this formulation be fixed under Para 5 of DPCO 2013 on the basis of data available for syrup having composition of elemental iron 110mg, folic acid 1.5 mg and vitamin B12.

16.2 Accordingly, the Committee recommended the retail price of each 5 ml syrup containing Ferric Ammonium Citrate IP 110 mg eq. to Elemental Iron 22.55 mg + Folic Acid IP 1.5 mg + Cyanocobalamin IP 15 mcg for M/s. Biogenetic Drugs Pvt. Ltd. (manufacturer) and M/s Intas Pharmaceuticals Ltd. (marketers) at Rs. 0.16 per ml excluding GST.

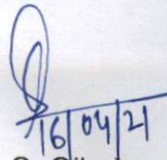
17. Agenda no. 17- Retail price fixation under Para 5 of DPCO, 2013- Each 5 ml syrup containing Ferric Ammonium Citrate IP 110 mg eq. to Elemental Iron 22.55 mg + Folic Acid IP 1.5 mg + Cyanocobalamin IP 15 mcg for M/s. East African (India) Overseas (manufacturer) and M/s Intas Pharmaceuticals Ltd. (marketers)

17.1 The Committee deliberated upon the matter in detail and opined that the price of this formulation be fixed under Para 5 of DPCO 2013 on the basis of data available for syrup having composition of elemental iron 110mg, folic acid 1.5 mg and vitamin B12.

17.2 Accordingly, the Committee recommended the retail price of each 5 ml syrup containing Ferric Ammonium Citrate IP 110 mg eq. to Elemental Iron 22.55 mg + Folic Acid IP 1.5 mg + Cyanocobalamin IP 15 mcg for M/s. East African (India) Overseas (manufacturer) and M/s Intas Pharmaceuticals Ltd. (marketers) at Rs. 0.16 per ml excluding GST.

The meeting ended with a vote of thanks to all.

Copy to:
All members of the Committee.


16/04/21
(S. S. Ojha)
Director (Pricing)

