

**National Pharmaceutical Pricing Authority**

**Subject: Minutes of the 35<sup>th</sup> meeting of Multidisciplinary Committee of Experts held on 18.08.2021 at 12.00 noon in NPPA**

35<sup>th</sup> meeting of the "Multidisciplinary Committee of Experts" was held on 18.08.2021 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, Jt. Drugs Controller, CDSCO
4. Dr. Jai Prakash, Sr. Principal Scientific Officer, Indian Pharmacopoeia Commission

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. Mahaveer Saini, Deputy Director (Pricing), NPPA

**1. Agenda No. 1 - 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 (extended release) 1000 mg for M/s Synokem Pharmaceuticals Ltd. (manufacturer) and M/s Aristo Pharmaceuticals Pvt. Ltd. (marketer)**

1.1 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) 500/1000 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.”*

1.2 The Committee also noted that in the similar methodology, the retail price of FDCs of Dapagliflozin 5mg and Metformin Hydrochloride 500mg/ 1000 mg tablet has been fixed for various companies in the 89<sup>th</sup> and 91<sup>st</sup> Authority meeting held on 28.06.2021 and 29.07.2021 respectively. The Committee deliberated upon the matter in detail and decided to derive the retail price of each film coated bilayered tablet containing Dapagliflozin 5 mg + Metformin Hydrochloride IP (in extended release form) 1000 mg at Rs. 7.54 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 5 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. 27.87 per tablet excluding GST.

1.3 Accordingly, the Committee recommended the retail price of each film coated bilayered tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5 mg + Metformin Hydrochloride IP (extended release) 1000 mg for M/s Synkem Pharmaceuticals Ltd. (manufacturer) and M/s Aristo Pharmaceuticals Pvt. Ltd. (marketer) at Rs. 7.54 per tablet excluding GST.

**2. Agenda No. 2 - 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 (extended release) 500 mg for M/s Synkem Pharmaceuticals Ltd. (manufacturer) and M/s Aristo Pharmaceuticals Pvt. Ltd. (marketer)**

2.1 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) 500/1000 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.”*

2.2 The Committee also noted that in the similar methodology, the retail price of FDCs of Dapagliflozin 5mg and Metformin Hydrochloride 500mg/ 1000 mg tablet has been fixed for various companies in the 89<sup>th</sup> and 91<sup>st</sup> Authority meeting held on 28.06.2021 and 29.07.2021 respectively. The Committee deliberated upon the matter in detail and decided to derive the retail price of each film coated bilayered tablet containing Dapagliflozin 5 mg + Metformin Hydrochloride IP (in extended release form) 500 mg at Rs. 6.25 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 5 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. 26.50 per tablet excluding GST.

2.3 Accordingly, the Committee recommended the retail price of each film coated bilayered tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5 mg + Metformin Hydrochloride IP (in extended release form) 500 mg for M/s Synokem Pharmaceuticals Ltd. (manufacturer) and M/s Aristo Pharmaceuticals Pvt. Ltd. (marketer) at Rs. 6.25 per tablet excluding GST.

### **3. Agenda No. 3 – 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 (extended release) 1000 mg for M/s Synokem Pharmaceuticals Ltd. (manufacturer) and M/s Aristo Pharmaceuticals Pvt. 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) 500/1000 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."*

3.2 The Committee deliberated upon the matter in detail and decided to derive the retail price of each film coated bilayered tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended release form) 1000 mg at Rs. 11.17 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) 1000 mg tablet was earlier approved. The Committee also noted that the applicant company has claimed price of Rs. 53.40 per tablet excluding GST.

3.3 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 Synokem Pharmaceuticals Ltd. (manufacturer) and M/s Aristo Pharmaceuticals Pvt. Ltd. (marketer) at Rs. 11.17 per tablet excluding GST.

**4. Agenda no. 4 - 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 (extended release) 500 mg for M/s Synokem Pharmaceuticals Ltd. (manufacturer) and M/s Aristo Pharmaceuticals Pvt. 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) 500/1000 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/USP (in extended release form) 500 mg at Rs. 9.65 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. 51.52 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/USP 500 mg (extended release) for M/s Synokem Pharmaceuticals Ltd. (manufacturer) and M/s Aristo Pharmaceuticals Pvt. Ltd. (marketer) at Rs. 9.65 per tablet excluding GST.

**5. Agenda no. 5 - 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 Aristo Pharmaceuticals Pvt. Ltd. (marketer)**

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

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

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

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

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

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

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

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

*5. Accordingly, the Authority decided to fix the retail price of the subject FDCs for the companies as per option 1(ii) in public interest.*

5.3 The Committee observed that based on the methodology decided by the Authority in its 72nd meeting dated 20.01.2020, as specified in 5.2 above, the retail price of Vildagliptin 50 mg + Metformin 500 mg tablet comes to Rs. 6.45 per tablet excluding GST.

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

*“..... to derive the retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 500mg (as sustained release form) by adding the maximum of the difference (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.”*

5.5 The Committee also observed that the Authority in its 80th meeting dated 26.10.2020 approved the recommended methodology, as mentioned in para 5.4 above, towards fixation of retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 500mg (as sustained release form) for various companies. The Committee also observed that similar decision was also taken by the Authority in its 81<sup>st</sup>, 82<sup>nd</sup>, 83<sup>rd</sup> and 86<sup>th</sup> meeting dated 24.11.2020, 23.12.2020, 27.01.2021 and 28.04.2021 respectively.

5.6 The Committee deliberated upon the matter in detail and decided to derive the retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 500mg (as sustained release) 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 5.1 above, with the retail price calculated based on the methodology decided by the Authority in its 72nd meeting dated 20.01.2020, as specified in 5.2, i.e. Rs. 6.45. The Committee also noted that the applicant company has claimed price of Rs. 11.61 per tablet excluding GST.

5.7 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 Aristo Pharmaceuticals Pvt. Ltd. (marketer) at Rs. 6.86 per tablet excluding GST.

**6. Agenda no. 6 - Retail price fixation under Para 5 of DPCO, 2013 - Each uncoated bilayered tablet containing Vildagliptin 50 mg +Metformin HCL IP (as sustained release form) 1000 mg for M/s Mascot Health Series Pvt. Ltd. (manufacturer) and M/s Aristo Pharmaceuticals Pvt. Ltd. (marketer)**

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

6.2 The Committee also noted that the minutes of 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.*

6.3. The Committee observed that based on the methodology decided by the Authority in its 72nd meeting dated 20.01.2020, as specified in 6.2 above, the retail price of Vildagliptin 50 mg + Metformin 1000 mg tablet comes to Rs. 7.10 per tablet excluding GST.

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

*"..... to derive the retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 1000mg (as sustained release form) by adding the maximum of the difference (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."*

6.5. The Committee also observed that the Authority in its 80th meeting dated 26.10.2020 approved the recommended methodology, as mentioned in para 6.4 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>, 83<sup>rd</sup> and 86<sup>th</sup> meeting dated 24.11.2020, 23.12.2020, 27.01.2021 and 28.04.2021 respectively.

6.6. The Committee deliberated upon the matter in detail and decided to derive the retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 1000mg (as sustained release) 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 6.1 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 6.2, i.e. Rs. 7.10. The Committee also noted that the applicant company has claimed price of Rs. 12.80 per tablet excluding GST.

6.7. 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 Aristo Pharmaceuticals Pvt. Ltd. (marketer) at Rs. 7.51 per tablet excluding GST.

#### **7. Agenda no. 7 - Application filed by M/s Cipla Ltd for grant of separate price / special price for 'Ciphaler Inhaler Device' under the provisions of para 11(3) of DPCO 2013**

7.1 The Committee noted the document submitted by M/s Cipla Ltd in connection with the application for grant of separate price / special price for 'Ciphaler Inhaler Device' under the provisions of para 11(3) of DPCO 2013. The Committee also observed the presentation given by M/s Cipla Ltd specifying the technical and other details for the product 'Ciphaler Inhaler Device'. The Committee deliberated upon the matter in detail and observed that the claim of M/s Cipla Ltd regarding the efficacy of the product is yet to be validated and the report as submitted by M/s Cipla Ltd is not based on the product of M/s Cipla Ltd. Accordingly, the Committee decided to reject the application of M/s Cipla Ltd for grant of separate price / special price for 'Ciphaler Inhaler Device' under the provisions of Para 11(3) of DPCO 2013.

#### **8. Agenda no. 8- Application by M/s Otsuka Pharmaceuticals India Pvt. Ltd. for separate price under Para 11(3) of DPCO 2013 with respect to Metronidazole Injection IP (0.5% w/v) 100ml in Non-glass pack having Special features**

8.1 The Committee noted the application filed by M/s Otsuka Pharmaceuticals Pvt. Ltd for separate price under Para 11(3) of DPCO 2013 with respect to Metronidazole Injection IP (0.5% w/v) in 100ml Non-glass pack having Special features. The Committee also noted that Metronidazole Injection 500mg/ml is a scheduled formulation and its ceiling price is fixed. The present applicable ceiling price is Rs. 0.20 per ml excluding GST. The Committee observed that the formulation Metronidazole Injection IP (0.5% w/v) 100ml is same as Metronidazole Injection 500mg/ml and is a scheduled formulation. The Committee also noted the demonstration given by M/s Otsuka Pharmaceuticals Pvt. Ltd and observed that the

- that the non-glass pack of Metronidazole Injection IP (0.5% w/v) 100ml of M/s Otsuka Pharmaceuticals Pvt. Ltd have special features as (i) Self Collapsibility and self-seal ability, (ii) not having air-vent and (iii) having no chance of contamination during manufacture / infusion / admixing levels.

8.2 The Committee deliberated upon the matter in detail and recommended that an increase of 15% over and above the ceiling present applicable ceiling price be allowed to M/s Otsuka Pharmaceuticals Pvt. Ltd for the product Metronidazole Injection IP (0.5% w/v) 100ml in non-glass having special features. Accordingly, the Committee recommended the ceiling price of Rs. 0.23 per ml excluding GST for the formulation 'Metronidazole Injection IP (0.5% w/v) 100ml in non glass having special features' for 100 ml pack for M/s Otsuka Pharmaceuticals Pvt. Ltd. The Committee also recommended that Wholesale Price Index (WPI), as applicable for scheduled formulation, on the ceiling price of Rs. 0.23 per ml excluding GST for the formulation 'Metronidazole Injection IP (0.5% w/v) in non-glass having special features' for 100 ml pack for M/s Otsuka Pharmaceuticals Pvt. Ltd.

**9. Agenda no. 9 - Application by M/s Otsuka Pharmaceuticals India Pvt. Ltd for separate price under Para 11(3) of DPCO 2013 with respect Mannitol Injection 20% in Non-glass pack having Special features.**

9.1 The Committee noted the application filed by M/s Otsuka Pharmaceuticals Pvt. Ltd for separate price under Para 11(3) of DPCO 2013 with respect to Mannitol Injection 20% in 100ml Non-glass pack having Special features. The Committee also noted that Mannitol Injection 20% is a scheduled formulation and its ceiling price is fixed. The present applicable ceiling price is Rs. 0.30 per ml excluding GST. The Committee also noted the demonstration given by M/s Otsuka Pharmaceuticals Pvt. Ltd and observed that the that the non-glass pack of Mannitol Injection 20% in 100ml pack of M/s Otsuka Pharmaceuticals Pvt. Ltd have special features as (i) Self Collapsibility and self-seal ability, (ii) not having air-vent and (iii) having no chance of contamination during manufacture / infusion / admixing levels.

9.2 The Committee deliberated upon the matter in detail and recommended that an increase of 15% over and above the ceiling present applicable ceiling price be allowed to M/s Otsuka Pharmaceuticals Pvt. Ltd for the product Mannitol Injection 20% in non-glass having special features for 100 ml pack. Accordingly, the Committee recommended the ceiling price of Rs. 0.345 per ml excluding GST for the formulation 'Mannitol Injection 20% in non-glass having special features' for 100 ml pack' for M/s Otsuka Pharmaceuticals Pvt. Ltd. The Committee also recommended that Wholesale Price Index (WPI), as applicable for scheduled formulation, on the ceiling price of Rs. 0.345 per ml excluding GST for the formulation 'Mannitol Injection 20% in non-glass having special features' for 100 ml pack for M/s Otsuka Pharmaceuticals Pvt. Ltd.

**10. Agenda no. 10- Application by M/s Otsuka Pharmaceuticals India Pvt. Ltd for separate price under Para 11(3) of DPCO 2013 with respect Dextrose Injection (25% w/v) 100 ml in Non-glass pack having Special features.**

10.1 The Committee noted the application filed by M/s Otsuka Pharmaceuticals Pvt. Ltd for separate price under Para 11(3) of DPCO 2013 with respect to Dextrose

Injection (25% w/v) in 100 ml Non-glass pack having Special features. The Committee also noted that Glucose Injection 25% is a scheduled formulation and its ceiling price is fixed. The Committee observed the clarification provided by Central Drugs Standard Control Organisation (CDSCO) vide letter dated 13.08.2021 that Dextrose Injection 25% w/v and Glucose Injection 25% w/v are the same. The present applicable ceiling price of Glucose Injection 25% is Rs. 0.17 per ml excluding GST Accordingly, the Committee concluded that Dextrose Injection 25% is a scheduled formulation. The Committee also noted the demonstration given by M/s Otsuka Pharmaceuticals Pvt. Ltd and observed that the that the non-glass pack of Dextrose Injection 25% in 100ml pack of M/s Otsuka Pharmaceuticals Pvt. Ltd have special features as (i) Self Collapsibility and self-seal ability, (ii) not having air-vent and (iii) having no chance of contamination during manufacture / infusion / admixing levels.


10.2 The Committee deliberated upon the matter in detail and recommended that an increase of 15% over and above the ceiling present applicable ceiling price be allowed to M/s Otsuka Pharmaceuticals Pvt. Ltd for the product Dextrose Injection 25%% in non-glass having special features for 100 ml pack. Accordingly, the Committee recommended the ceiling price of Rs. 0.195 per ml excluding GST for the formulation 'Dextrose Injection 25% in non-glass having special features' for 100 ml pack' for M/s Otsuka Pharmaceuticals Pvt. Ltd. The Committee also recommended that Wholesale Price Index (WPI), as applicable for scheduled formulation, on the ceiling price of Rs. 0.195 per ml excluding GST for the formulation 'Dextrose Injection 25% in non-glass having special features' for 100 ml pack for M/s Otsuka Pharmaceuticals Pvt. Ltd.

**11. Agenda no. 11 - Issues relating to Fixed Dose Combination (FDC) of uncoated dispersible tablet containing Cefixime 200 mg and Lactic Acid Bacillus 60 million spores**

11.1 The Committee noted that Cefixime 200 mg tablet is a scheduled formulation and its ceiling price is fixed. The present applicable ceiling price is Rs. 9.62 per tablet excluding GST. The Committee also noted that various companies are manufacturing/ marketing the Fixed Dose Combination (FDC) tablet containing Cefixime 200 mg and Lactic Acid Bacillus 60 million spores at a price which is much higher.

11.2 The Committee deliberated upon the matter in detail and observed that abnormal higher price due to addition of Lactic acid bacillus with the scheduled formulation Cefixime 200 mg tablet is not in public interest and decided that further examination may be undertaken in this regard.

The meeting ended with a vote of thanks to all.

  
(Prasenjit Das)  
Deputy Director (Pricing)

Copy to:  
All members of the Committee.