

**Subject: Minutes of the 26<sup>th</sup> meeting of Multidisciplinary Committee of Experts held on 18.01.2021 at 11:00 AM in NPPA**

26th meeting of the “Multidisciplinary Committee of Experts” was held on 18.01.2021 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. Rajni Kaul, Scientist G and Head, Pharmacology, ICMR, New Delhi
3. Dr. Jai Prakash, Sr. Principal Scientific Officer, Indian Pharmacopoeia Commission
4. Dr. Rakesh K. Singh, Assoc. Professor, NIPER, Raebareli
5. Dr. Pooja Gupta, Assoc. Prof., Pharmacology, AIIMS, New Delhi
6. Shri A. K. Pradhan, Dy. Drugs Controller, CDSCO

The following officers of NPPA attended and presented the cases to the Committee

1. Sh. S. S. Ojha, Jt. Director (Pricing), NPPA
2. Sh. Prasenjit Das, Assistant Director (Pricing), NPPA
3. Sh. Prakash Hemani, Assistant Director (Pricing), NPPA

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

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

1.2 The Committee also noted that the minutes of 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 I(ii) in public interest.

1.3 The Committee observed that based on the methodology decided by the Authority in its 72nd meeting dated 20.01.2020, as specified in 1.2 above, the retail price of Vildagliptin 50 mg + Metformin 500 mg tablet comes to Rs. 6.45 per tablet excluding GST.

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

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

1.5. The Committee also observed that the Authority in its 80th meeting dated 26.10.2020 approved the recommended methodology, as mentioned in para 1.4 above, towards fixation of retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 500mg (as sustained release form) for various companies. The Committee also observed that similar decision was also taken by the Authority in its 81<sup>st</sup> and 82<sup>nd</sup> meeting dated 24.11.2020 and 23.12.2020 respectively.

1.6 The Committee deliberated upon the matter in detail and decided to derive the retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 500mg (as sustained release) by adding the maximum of the difference in presently applicable notified ceiling price of Metformin IR & CR

500mg and 1000 mg tablet i.e. Rs. 0.41, as mentioned in para 1.1 above, with the retail price calculated based on the methodology decided by the Authority in its 72nd meeting dated 20.01.2020, as specified in 1.2, i.e. Rs. 6.45 and recommend the same.

1.7 Accordingly, the Committee recommended the retail price of each uncoated bilayered tablet containing Vildagliptin 50 mg + Metformin Hydrochloride 500 mg (Sustained Release) for M/s Torrent Pharmaceuticals Limited (marketer) and M/s Exemed Pharmaceuticals (manufacturer) at Rs. 6.86 per tablet excluding GST.

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

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

2.2 The Committee also noted that the minutes of 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 I(ii) in public interest.

2.3 The Committee observed that based on the methodology decided by the Authority in its 72nd meeting dated 20.01.2020, as specified in 2.2 above, the retail price of Vildagliptin 50 mg + Metformin 1000 mg tablet comes to Rs. 7.10 per tablet excluding GST.

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

“..... to derive the retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 1000mg (as sustained release form) by adding the maximum of the difference (Rs. 0.41) in presently applicable notified ceiling price of Metformin IR & CR 500mg and 1000 mg tablet, with the retail price calculated based on the methodology decided by the Authority in its 72nd meeting dated 20.01.2020.”

2.5. The Committee also observed that the Authority in its 80th meeting dated 26.10.2020 approved the recommended methodology, as mentioned in para 2.4 above, towards fixation of retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 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> and 82<sup>nd</sup> meeting dated 24.11.2020 and 23.12.2020 respectively.

2.6 The Committee deliberated upon the matter in detail and decided to derive the retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 1000mg (as sustained release) by adding the maximum of the difference in presently applicable notified ceiling price of Metformin IR & CR 500mg and 1000 mg tablet i.e. Rs. 0.41, as mentioned in para 2.1 above, with the retail price calculated based on the methodology decided by the Authority in its 72nd meeting dated 20.01.2020, as specified in 2.2, i.e. Rs. 7.10 and recommend the same.

2.7 Accordingly, the Committee recommended the retail price of each uncoated bilayered tablet containing Vildagliptin 50 mg + Metformin Hydrochloride 1000 mg (Sustained Release) for M/s Torrent Pharmaceuticals Limited (marketer) and M/s Exemed Pharmaceuticals (manufacturer) at Rs. 7.51 per tablet excluding GST.

**3. Agenda no. 3 - Retail price fixation under Para 5 of DPCO, 2013 – Each uncoated bilayered tablet containing Vildagliptin 50 mg + Metformin Hydrochloride 500 mg (Sustained Release) for M/s Alkem Laboratories Limited (marketer) and M/s Mascot Health Series Pvt. Ltd (manufacturer).**

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

3.2 The Committee also noted that the minutes of 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 I(ii) in public interest.*

3.3 The Committee observed that based on the methodology decided by the Authority in its 72<sup>nd</sup> meeting dated 20.01.2020, as specified in 3.2 above, the retail

price of Vildagliptin 50 mg + Metformin 500 mg tablet comes to Rs. 6.45 per tablet excluding GST.

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

“..... to derive the retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 500mg (as sustained release form) by adding the maximum of the difference (Rs. 0.41) in presently applicable notified ceiling price of Metformin IR & CR 500mg and 1000 mg tablet, with the retail price calculated based on the methodology decided by the Authority in its 72nd meeting dated 20.01.2020.”

3.5. The Committee also observed that the Authority in its 80th meeting dated 26.10.2020 approved the recommended methodology, as mentioned in para 3.4 above, towards fixation of retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 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> and 82<sup>nd</sup> meeting dated 24.11.2020 and 23.12.2020 respectively.

3.6 The Committee deliberated upon the matter in detail and decided to derive the retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 500mg (as sustained release) by adding the maximum of the difference in presently applicable notified ceiling price of Metformin IR & CR 500mg and 1000 mg tablet i.e. Rs. 0.41, as mentioned in para 3.1 above, with the retail price calculated based on the methodology decided by the Authority in its 72nd meeting dated 20.01.2020, as specified in 3.2, i.e. Rs. 6.45 and recommend the same.

3.7 Accordingly, the Committee recommended the retail price of each uncoated bilayered tablet containing Vildagliptin 50 mg + Metformin Hydrochloride 500 mg (Sustained Release) for M/s Alkem Laboratories Limited (marketer) and M/s Mascot Health Series Pvt. Ltd (manufacturer) at Rs. 6.86 per tablet excluding GST.

**4. Agenda no. 4 - Retail price fixation under Para 5 of DPCO, 2013 – Each uncoated bilayered tablet containing Vildagliptin 50 mg + Metformin Hydrochloride 1000 mg (Sustained Release) for M/s Alkem Laboratories Limited (marketer) and M/s Mascot Health Series Pvt. Ltd (manufacturer).**

4.1 The Committee noted that separate ceiling price has been fixed for Metformin Immediate release tablet and Metformin Controlled release tablet. The Committee further noted that as per notification SO.1213(E) dated 25.03.2020, the present

ceiling price of Metformin 500 mg controlled release (CR) tablet is Rs. 0.41 more than Metformin 500 mg immediate release (IR) tablet. Similarly, the ceiling price of Metformin 1000 mg controlled release tablet is Rs. 0.05 more than Metformin 1000 mg Immediate release tablet.

4.2 The Committee also noted that the minutes of 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.*

4.3 The Committee observed that based on the methodology decided by the Authority in its 72<sup>nd</sup> meeting dated 20.01.2020, as specified in 4.2 above, the retail price of Vildagliptin 50 mg + Metformin 1000 mg tablet comes to Rs. 7.10 per tablet excluding GST.

4.4 The Committee further observed that in its 22<sup>nd</sup> 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.”

4.5. The Committee also observed that the Authority in its 80th meeting dated 26.10.2020 approved the recommended methodology, as mentioned in para 4.4 above, towards fixation of retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 1000mg (as sustained release form) for various companies. The Committee also observed that similar decision was also taken by the Authority in its 81<sup>st</sup> and 82<sup>nd</sup> meeting dated 24.11.2020 and 23.12.2020 respectively.

4.6 The Committee deliberated upon the matter in detail and decided to derive the retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 1000mg (as sustained release) by adding the maximum of the difference in presently applicable notified ceiling price of Metformin IR & CR 500mg and 1000 mg tablet i.e. Rs. 0.41, as mentioned in para 4.1 above, with the retail price calculated based on the methodology decided by the Authority in its 72nd meeting dated 20.01.2020, as specified in 4.2, i.e. Rs. 7.10 and recommend the same.

4.7 Accordingly, the Committee recommended the retail price of each uncoated bilayered tablet containing Vildagliptin 50 mg + Metformin Hydrochloride 1000 mg (Sustained Release) for M/s Alkem Laboratories Limited (marketer) and M/s Mascot Health Series Pvt. Ltd (manufacturer) at Rs. 7.51 per tablet excluding GST.

## **5. Agenda no. 5 – Application for extension of ceiling price for I.V. Fluids with packaging in Non-glass with special feature.**

5.1 The Committee deliberated upon the matter in detail and noted that two companies namely, M/s Puniska Healthcare Pvt. Ltd and M/s Realcade Lifescience Pvt. Ltd had applied for separate ceiling price for IV fluids with packaging in non-glass with special features in line with S.O. 1215(E) dated 25.03.2020 [M/s Puniska Healthcare Pvt. Ltd applied for product mentioned in Sl. No. 5,6,7 and 8 of S.O. 1215(E) dated 25.03.2020] . Both the companies namely, M/s Puniska Healthcare Pvt. Ltd and M/s Realcade Lifescience Pvt. Ltd made demonstration before the members. The Committee observed that the non-glass packages of I.V. fluids of M/s Puniska Healthcare Pvt. Ltd and M/s Realcade Lifescience 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. Accordingly, the Committee recommended to extend the ceiling prices and the formulations mentioned in SO. 1215(E) dated 25.03.2020 to M/s Puniska Healthcare Pvt. Ltd [for M/s Puniska Healthcare Pvt. Ltd, product mentioned in Sl. No. 5,6,7 and 8 of S.O. 1215(E) dated 25.03.2020] and M/s Realcade Lifescience Pvt. Ltd for I.V. fluids in packages in non-glass with special features.



## **6. Agenda no. 6 – Application for extension of ceiling price for Ringer Lactate Injection in packaging with special feature.**

6.1 The Committee deliberated upon the matter in detail and noted that one company namely, M/s Realcade Lifescience Pvt. Ltd had applied for separate ceiling price for ringer lactate injection in packages with special features in line with S.O. 1216(E) dated 25.03.2020. M/s Realcade Lifescience Pvt. Ltd made demonstration before the members. The Committee observed that the packages of ringer lactate injection of M/s Realcade Lifescience 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. Accordingly, the Committee recommended to extend the ceiling prices and the formulations mentioned in SO. 1216(E) dated 25.03.2020 to M/s Realcade Lifescience Pvt. Ltd for ringer lactate injection for packages with special features.

## **7. Agenda no. 7 - Retail price fixation under Para 5 of DPCO, 2013 - Each film coated tablet containing Azathioprine IP 75 mg for M/s RPG Life Sciences Ltd. (manufacturer and marketers).**

7.1 The Committee deliberated upon the matter in detail and recommended the retail price of each film coated tablet containing Azathioprine Tablets IP 75 mg for M/s RPG Life Sciences Ltd. (manufacturer and marketers) at Rs. 14.17 per tablet excluding GST as detailed below:

Derived retail price as per recommendation of Pronab Sen Committee :

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

Where : P(s) = Price ceiling of the strength s,  
P\* = price ceiling for reference strength s\*  
s = strength in terms of API content  
s\* = reference strength  
a= 0.8 for tablet / capsule and 0.7 for injectibles.

Working of Retail Price of Azathioprine 75 mg Tablet

Ceiling Price for Azathioprine 50 mg Tablet= 10.12 per tablet

Derived Retail price for Azathioprine 75 mg Tablet =  $10.12[1+0.80\{75-50\}/50]$  = Rs. 14.17 per tablet

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

8.1 The Committee noted the data submitted by M/s Intervet India (P) Ltd for 33 ml pack and the submission that the company's 100 ml pack is not yet being marketed/ sold in India.

8.2 The Committee deliberated upon the matter in detail and recommended the ceiling price of Pheniramine Maleate Injection 22.75 mg/ ml in 33 ml pack at Rs. 0.66 per ml excluding GST which has been derived based on the data of the company for the month of July 2020.

8.3 The Committee further recommended the ceiling price of Pheniramine Maleate Injection 22.75 mg/ ml in 100 ml pack at Rs. 0.53 per ml excluding GST as detailed below:

Calculated ceiling price of Pheniramine 22.75 mg/ ml for 33 ml pack based on July 2020 data : Rs. 0.66 per ml excluding GST

Therefore, the ceiling price for 33 ml pack is Rs. 21.78.

Derived retail price as per recommendation of pronab sen committee:

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

Where :  
P(s) = Price ceiling of the strength s  
P\* = price ceiling for reference strength s\*  
s = strength in terms of API content  
s\* = reference strength  
a = 0.8 for tablet / capsule and 0.7 for injectibles.

The ceiling price of 100 ml pack is as follows:

$$= 21.78 [1 + 0.7 \{(100 - 33) / 33\}] = \text{Rs. } 52.71 \text{ for 100 ml pack i.e. Rs. } 0.53 \text{ per ml (for 100 ml pack)}$$

8.4 The Committee also directed that the recommendation of ceiling price of Pheniramine Maleate Injection 22.75 mg/ ml in 33ml and 100 ml pack is subject to confirmation of the availability of manufacturing/ marketing license from the company/ DCGI regarding the pack size of 33ml and 100 ml.

## **9. Agenda no. 9 - Retail price fixation for companies in respect of formulations to which exemption granted under para 32 of DPCO 2013 has been expired**

9.1 The Committee noted that the exemption granted under Para 32(iii) of DPCO 2013 to M/s Torrent Pharmaceuticals Ltd for (a) Fixed Dose Combination (FDC) of Prasugrel Hydrochloride 10 mg (as film coated) plus Aspirin 75 mg (as enteric coated) vide S.O. 2110(E) dated 21.08.2014 and (b) Olanzapine Pamoate Prolong Release Powder for suspension for IM Injection (Olanzapine Pamoate Monohydrate eq to Olanzapine 210mg/ vial, 300 mg/vial and 405 mg/vial) vide S.O. 856(E) dated 25.03.2015 has been expired. Similarly, the exemption granted under Para 32(iii) of DPCO 2013 to M/s Wockhardt Ltd for (a) Insulin Human Injection, 200IU/ml (b) Isophane Insulin Human Suspension 200IU/ml and (c) 70% Isophene Insulin Human Suspension and 30% Insulin Human Injection 200IU/ml vide SO. 3131(E) dated 20.11.2015 has been expired.

9.2 The Committee further noted that for the formulation “Fixed Dose Combination (FDC) of Prasugrel Hydrochloride 10 mg (as film coated) plus Aspirin 75 mg (as enteric coated)” M/s Torrent Pharmaceuticals Ltd is an existing manufacturer/ marketer and need to have price approval for marketing/ manufacturing of the formulation after the expiry of the exemption granted under para 32(iii) of DPCO 2013. Similarly, for the formulations (a) Insulin Human Injection, 200IU/ml (b) Isophane Insulin Human Suspension 200IU/ml and (c) 70% Isophene Insulin Human Suspension and 30% Insulin Human Injection 200IU/ml, M/s Wockhardt Ltd is an existing manufacturer/ marketer and need to have price approval for marketing/ manufacturing of the formulation after the expiry of the exemption granted under para 32(iii) of DPCO 2013. However, both these companies did not seek any price approval.

9.3 The Committee deliberated upon the matter in detail and directed that explanation may be sought from the companies for the non-compliance. The Committee further directed that reply received from the company may be examined and placed in its meeting.

The meeting ended with a vote of thanks to all.

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

Copy to:  
All members of the Committee.

