

**Subject: Minutes of the 22nd meeting of Multidisciplinary Committee of Experts held on 07.10.2020 at 11:00 AM in NPPA**

22<sup>nd</sup> meeting of the “Multidisciplinary Committee of Experts” was held on 07.10.2020 under the Convenorship of Sh. N.I. Chowdhury, Adviser (Cost), in NPPA. The following members attended the meeting through video conferencing:-

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

Dr. Manjari Tripathi, Professor Neurology, AIIMS, New Delhi attended the meeting as special invitee.

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 - Amoxicillin and Potassium Clavulanate Oral Suspension IP in which each 5 ml of the reconstituted suspension containing Amoxicillin Trihydrate (759.04 mg) eq. to Amoxicillin Free Acid 652.78 mg and Potassium Clavulanate (61.48 mg) eq. to Clavulanic Acid 50.41 mg (Brand Name: Augmentin ES) for M/s GlaxoSmithKline Pharmaceuticals Ltd (marketer) and M/s Glaxo Wellcome Production (manufacturer/ importer).**

I.I The Committee noted that M/s GlaxoSmithKline Pharmaceuticals Ltd has applied for retail price fixation of Fixed Dose Combination (FDC) Amoxicillin and Potassium Clavulanate Oral Suspension in which each 5 ml of the reconstituted suspension containing Amoxicillin Trihydrate (759.04 mg) eq. to Amoxicillin Free Acid 652.78 mg and Potassium Clavulanate (61.48 mg) eq. to Clavulanic Acid 50.41 mg. The Committee also noted that FDC of this medicine in other strength is a scheduled formulation under DPCO 2013 and its ceiling price is notified. The Committee also observed the presentation made by M/s GlaxoSmithKline Pharmaceuticals Ltd. The Committee deliberated upon the matter in detail and directed that therapeutic rationale together with study report/ published journal for changing the strength of the FDC be obtained from M/s GlaxoSmithKline Pharmaceuticals Ltd.

**2. Agenda No. 2 - Retail price fixation under Para 5 of DPCO, 2013 - Betadine Alcoholic Handrub in which each 100 ml containing Povidone Iodine IP 1.0g (Available Iodine 0.1 g) and 2-Propanol IP 50 g for M/s Win Medicare Pvt. Ltd (marketer) and M/s G.S. Pharmbutor Pvt. Ltd (manufacturer/ importer).**

2.1 The Committee noted that based on the recommended retail price of Betadine Alcoholic Handrub in which each 100 ml containing Povidone Iodine IP 1.0g (Available Iodine 0.1 g) and 2-Propanol IP 50 g at Rs. 92.00 per 200 ml pack excluding GST, M/s Win Medicare Pvt. Ltd made a representation that the price of Ethyl Alcohol (denatured) was considered in the calculation. However, the price of 2-Propanol (Isopropyl Alcohol) is more compared to Ethyl Alcohol (denatured). The Committee also examined the documentary evidence submitted by the company. The Committee decided to defer the agenda and to discuss the matter in the next meeting.

**3. Agenda no. 3 - Retail price fixation of Recombinant Rabies G Protein Vaccine in which each vial of 0.5 ml containing rRabies G Protein 50.00 µg, Disodium Hydrogen Phosphate Anhydrous 0.87 mg, Monobasic Sodium Phosphate Monohydrate BP 0.88 mg, Sodium Chloride IP 8.76 mg, Tergitol NP9 0.1 µl under Para 11(3) of DPCO, 2013 for M/s Cadila Pharmaceuticals Ltd. ( manufacturer and marketer).**

3.1 The Committee noted that M/s Cadila Pharmaceuticals Ltd applied for retail price fixation of Recombinant Rabies G Protein Vaccine in which each vial of 0.5 ml containing rRabies G Protein 50.00 µg, Disodium Hydrogen Phosphate Anhydrous 0.87 mg, Monobasic Sodium Phosphate Monohydrate BP 0.88 mg, Sodium Chloride IP 8.76 mg, Tergitol NP9 0.1 µl under para 11(3) of DPCO 2013.

3.2 The Committee further noted that the claim of the company that the Recombinant Rabies G Protein Vaccine would require 3 doses as against the present vaccines available which requires 5 doses. The Committee also noted that Rabies vaccine is a scheduled formulation under DPCO 2013.

3.3 The Committee deliberated upon the matter in detail and observed that the formulation is innovative formulation for which incremental price be allowed under para 11(3) of DPCO 2013. Accordingly, the Committee decided to recommend the retail price of Recombinant Rabies G Protein Vaccine in which each vial of 0.5 ml containing rRabies G Protein 50.00 µg, Disodium Hydrogen Phosphate Anhydrous 0.87 mg, Monobasic Sodium Phosphate Monohydrate BP 0.88 mg, Sodium Chloride IP 8.76 mg, Tergitol NP9 0.1 µl under Para 11(3) of DPCO, 2013 for M/s Cadila Pharmaceuticals Ltd. ( manufacturer and marketer) at Rs. 681.44 per vial excluding GST as detailed below:

| S. No. | Particulars                                      | Number of Doses | Rate / Unit (Rs.)                               | Total (Rs.) |
|--------|--|-----------------|---|-------------|
| A      | Ceiling Price of 5 doses of Rabies Vaccine       | 5               | 340.72<br>(As per SO. 1213(E) dated 25.03.2020) | 1703.60     |
| B      | Incremental Innovation Cost (at 20% of A)        |                 |   | 340.72      |
| C      | Total (C)  |                 |   | 2044.32     |
| D      | Retail Price per dose for 3 dose vaccine (C / 3) |                 |   | 681.44      |

#### **4. Agenda no. 4 - Application for extension of ceiling price for I.V. Fluids with packaging in Non-glass with special feature.**

4.1 The Committee deliberated upon the matter in detail and noted that one company namely, M/s R.K. Laboratories 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 R.K. Laboratories Pvt. Ltd made demonstration before the members. The Committee observed that the non-glass packages of I.V. fluids of M/s R.K. Laboratories 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 R.K. Laboratories Pvt. Ltd for I.V. fluids in packages in non-glass with special features.

4.2 The Committee also noted the deliberation made in its 20th meeting held on 17.07.2020 in which M/s Eurolife Healthcare Pvt. Ltd made a demonstration before the Committee regarding the packages in non-glass of IV fluid having special features like (i) Self Collapsibility and self-seal ability, (ii) not having air-vent and (iii) having no chance of contamination during manufacture / infusion / admixing levels based on which the Committee sought information from M/s Eurolife Healthcare Pvt. Ltd regarding the availability of licence for manufacturing of IV fluids with packaging in non-glass having special features. The Joint Inspection Report of Central Drugs Standard Control Organisation and FDA, Aurangabad submitted by M/s Eurolife Healthcare Pvt. Ltd was placed before the Committee. The Committee deliberated upon the matter in detail. Accordingly, the Committee recommended to extend the ceiling prices and the formulations mentioned in SO. 1215(E) dated 25.03.2020 to M/s Eurolife Healthcare Pvt. Ltd for I.V. fluids in packages in non-glass with special features.

#### **5. Agenda no. 5 - Application for extension of ceiling price for Ringer lactate injection in packaging with special feature.**

5.1 The Committee deliberated upon the matter in detail and noted that one company namely, M/s R.K. Laboratories Pvt. Ltd have 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 R.K. Laboratories Pvt. Ltd made demonstration before the members. The Committee observed that the packages of ringer lactate injection of M/s R.K. Laboratories 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 R.K. Laboratories Pvt. Ltd for ringer lactate injection for packages with special features.

#### **6. Agenda no. 6 - Retail price fixation under Para 5 of DPCO, 2013 – Each film coated bilayered tablet containing Azelnidipine 8 mg + Telmisartan 80 mg**

**tablets for M/s Glenmark Pharmaceuticals Ltd. (marketer) and M/s Synkem Pharmaceuticals Ltd. (manufacturer/ importer).**

6.1 The Committee deliberated upon the matter in detail and recommended the retail price of each film coated bilayered tablet containing Azelnidipine 8 mg + Telmisartan 80 mg tablets for M/s Glenmark Pharmaceuticals Ltd. (marketer) and M/s Synkem Pharmaceuticals Ltd. (manufacturer/ importer) at Rs. 16.16 per tablet excluding GST as detailed below:

| Computation of Retail Price per Tablet   | Source/Method  | Rs.   |
|--|--|-------|
| Composition – Each film coated bi-layered tablet contains Azelnidipine IP 8 mg+ Telmisartan IP 80 mg       |  |       |
| a. Azelnidipine IP 8 mg *  | Retail Price calculated as per Para 4 (August 2020 data) | 7.67  |
| b. Telmisartan IP 80 mg  | Notified Ceiling Price                                   | 10.02 |
| Worked out Retail Price  |  | 17.69 |
| c. Less 20% of the lowest of (a) and (b) similar to formula recommended in the Pronab Sen Committee report |  | 1.53  |
| Net Retail Price (a+b-c)   |  | 16.16 |
| Company Claimed Price  |  | 17.85 |
| Recommended price  |  | 16.16 |

**7. Agenda no. 7 - Retail price fixation under Para 5 of DPCO, 2013 – Each film coated bilayered tablet containing Azelnidipine 8 mg + Telmisartan 40 mg tablets for M/s Glenmark Pharmaceuticals Ltd. (marketer) and M/s Synkem Pharmaceuticals Ltd. (manufacturer/ importer).**

7.1 The Committee deliberated upon the matter in detail and recommended the retail price of each film coated bilayered tablet containing Azelnidipine 8 mg + Telmisartan 40 mg tablets for M/s Glenmark Pharmaceuticals Ltd. (marketer) and M/s Synkem Pharmaceuticals Ltd. (manufacturer/ importer) at Rs. 12.93 per tablet excluding GST as detailed below:

| Computation of Retail Price per Tablet   | Source/Method  | Rs.   |
|--|--|-------|
| Composition – Each film coated bi-layered tablet contains Azelnidipine IP 8 mg+ Telmisartan IP 40 mg |  |       |
| a. Azelnidipine IP 8 mg *  | Retail Price calculated as per Para 4 (August 2020 data) | 7.67  |
| b. Telmisartan IP 40 mg  | Notified Ceiling Price                                   | 6.57  |
| Worked out Retail Price  |  | 14.24 |
| c. Less 20% of the lowest of (a) and (b) similar to formula recommended in the Pronab Sen Committee  |  | 1.31  |

|                          |  |       |
|--------------------------|--|-------|
| report                   |  |       |
| Net Retail Price (a+b-c) |  | 12.93 |
| Company Claimed Price    |  | 14.28 |
| Recommended price        |  | 12.93 |

**8. Agenda no. 8 - Sub: Retail price fixation under Para 5 of DPCO, 2013 – Each film coated tablet containing Alogliptin 12.5 mg + Metformin Hydrochloride 500 mg tablet for M/s Indoco Remedies Ltd. (manufacturer and marketer).**

8.1 The Committee deliberated upon the matter in detail and recommended the retail price of each film coated tablet containing Alogliptin 12.5 mg + Metformin Hydrochloride 500 mg tablet for M/s Indoco Remedies Ltd. (manufacturer and marketer) at Rs. 7.82 per tablet excluding GST as detailed below:

| Computation of Retail Price per Tablet   | Source/Method   | Rs.   |
|--|---|-------|
| Composition – Alogliptin Benzoate 17 mg eq. to Alogliptin 12.5 mg Metformin Hydrochloride IP 500 mg        |   |       |
| a. Alogliptin 12.5 mg *  | Retail Price calculated as per Para 4 (February, 2020 data)   | 6.62  |
| b. Metformin HCL 500mg   | Notified Ceiling Price (S.O. dated 1213 (E) dated 25.03.2020) | 1.50  |
| Worked out Retail Price  |   | 8.12  |
| c. Less 20% of the lowest of (a) and (b) similar to formula recommended in the Pronab Sen Committee report |   | 0.30  |
| Net Retail Price (a+b-c)   |   | 7.82  |
| Company Claimed Price  |   | 10.00 |
| Recommended price  |   | 7.82  |

**9. Agenda no. 9 - Sub: Retail price fixation under Para 5 of DPCO, 2013 – Each film coated tablet containing Alogliptin 12.5 mg + Metformin Hydrochloride 1000 mg tablet for M/s Indoco Remedies Ltd. (manufacturer and marketer).**

9.1 The Committee deliberated upon the matter in detail and recommended the retail price of each film coated tablet containing Alogliptin 12.5 mg + Metformin Hydrochloride 1000 mg tablet for M/s Indoco Remedies Ltd. (manufacturer and marketer) at Rs. 9.49 per tablet excluding GST as detailed below:

| Computation of Retail Price per Tablet | Source/Method | Rs. |
|--|---------------|-----|
|--|---------------|-----|

|  |  |       |
|--|--|-------|
| Composition – Alogliptin Benzoate 17 mg eq. to Alogliptin 12.5 mg Metformin Hydrochloride IP 1000 mg       |  |       |
| a. Alogliptin 12.5 mg *  | Retail Price calculated as per Para 4 (February, 2020 data)  | 6.62  |
| b. Metformin HCL 1000mg  | Notified Ceiling Price (S.O. dated 1213 (E) dated 25.03.2020 | 3.59  |
| Worked out Retail Price  |  | 10.21 |
| c. Less 20% of the lowest of (a) and (b) similar to formula recommended in the Pronab Sen Committee report |  | 0.72  |
| Net Retail Price (a+b-c)   |  | 9.49  |
| Company Claimed Price  |  | 11.00 |
| Recommended price  |  | 9.49  |

**10. Agenda no. 10 Retail price fixation under Para 5 of DPCO, 2013 – Each film coated tablet containing Calcium Carbonate IP 1250 mg eq to Elemental calcium 500 mg, Vitamin D3 IP 2000 IU, Mecobalamin IP (Methylcobalamin) 1500 mcg, L- Methylfolate Calcium 1 mg, Pyridoxal-5-Phosphate 20 mg for M/s Cipla Ltd. (marketer) and M/s Akums Drugs & Pharmaceuticals Ltd. (manufacturer/ importer).**

10.1 The Committee deliberated upon the matter in detail and recommended the retail price of each film coated tablet containing Calcium Carbonate IP 1250 mg eq to Elemental calcium 500 mg, Vitamin D3 IP 2000 IU, Mecobalamin IP (Methylcobalamin) 1500 mcg, L- Methylfolate Calcium 1 mg, Pyridoxal-5-Phosphate 20 mg for M/s Cipla Ltd. (marketer) and M/s Akums Drugs & Pharmaceuticals Ltd. (manufacturer/ importer) at Rs. 17.78 per tablet excluding GST as detailed below:

| Computation of Retail Price per Tablet   | Source/Method                                   | Amount (Rs.) |
|--|---|--------------|
| Composition – Calcium 500mg + L-Methylfolate Calcium 1 mg + Pyridoxal -5 Phosphate 20 mg + Methylcobalamin 1500mcg + Vitamin D3 2000IU |   |              |
| a. Methylcobalamin 1500 mcg  | Retail price (as per January 2020 data)         | 9.13         |
| b. Calcium 500mg   | Ceiling Price                                   | 1.72         |
| c. Vitamin D3 2000IU   | Retail Price as per Pronab Sen Committee Report | 6.73         |
| d. Pyridoxal -5 Phosphate 20 mg  | Retail Price as                                 | 0.20         |

|   |                                 |       |
|---|---------------------------------|-------|
|   | per Pronab Sen Committee Report |       |
| e. L-Methylfolate Calcium 1 mg  | Data not available              | -     |
| Worked out Retail Price   |                                 | 17.78 |
| d. Less 20% of the lowest of (a) to (e) as recommended in the Pronab Sen Committee report |                                 | 0.00  |
| Net Retail Price (a+b-c)  |                                 | 17.78 |
| Company Claimed Price   |                                 | 18.45 |
| Recommended price   |                                 | 17.78 |

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.

Derived Retail Price for Vitamin D3 2000IU tablet

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

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

Derived Retail Price of Pyridoxal -5 Phosphate 20 mg

Ceiling Price of Pyridoxine 10mg Tablet = Rs. 0.11

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

**11. Agenda no. 11 - Retail price fixation under Para 5 of DPCO, 2013 - Each film coated bilayered tablet containing Azelnidipine 8 mg + Telmisartan 40 mg tablets for M/s Emcure Pharmaceuticals Ltd. (marketer) and M/s Synokem Pharmaceuticals Ltd. (manufacturer/ importer)**

11.1 The Committee deliberated upon the matter in detail and recommended the retail price of each film coated bilayered tablet containing Azelnidipine 8 mg + Telmisartan 40 mg tablets for M/s Emcure Pharmaceuticals Ltd. (marketer) and M/s Synokem Pharmaceuticals Ltd. (manufacturer/ importer) at Rs. 12.93 per tablet excluding GST as detailed below:

| Computation of Retail Price per Tablet   | Source/Method   | Rs.  |
|--|---|------|
| Composition – Each film coated bi-layered tablet contains Azelnidipine IP 8 mg+ Telmisartan IP 40 mg |   |      |
| a. Azelnidipine IP 8 mg *  | Retail Price calculated as per Para 4 (August, 2020 data) | 7.67 |

|  |                        |       |
|--|------------------------|-------|
| b. Telmisartan IP 40 mg  | Notified Ceiling Price | 6.57  |
| Worked out Retail Price  |                        | 14.24 |
| c. Less 20% of the lowest of (a) and (b) similar to formula recommended in the Pronab Sen Committee report |                        | 1.31  |
| Net Retail Price (a+b-c)   |                        | 12.93 |
| Company Claimed Price  |                        | 13.20 |
| Recommended price  |                        | 12.93 |

**12. Agenda no. 12 - Retail price fixation under Para 5 of DPCO, 2013 - Each film coated bilayered tablet containing Azelnidipine 8 mg + Telmisartan 80 mg tablets for M/s Emcure Pharmaceuticals Ltd. (marketer) and M/s Synokem Pharmaceuticals Ltd. (manufacturer/ importer)**

12.1 The Committee deliberated upon the matter in detail and recommended the retail price of each film coated bilayered tablet containing Azelnidipine 8 mg + Telmisartan 80 mg tablets for M/s Emcure Pharmaceuticals Ltd. (marketer) and M/s Synokem Pharmaceuticals Ltd. (manufacturer/ importer) at Rs. 14.40 per tablet excluding GST as detailed below:

| Computation of Retail Price per Tablet   | Source/Method   | Rs.   |
|--|---|-------|
| Composition – Each film coated bi-layered tablet contains Azelnidipine IP 8 mg+ Telmisartan IP 80 mg       |   |       |
| a. Azelnidipine IP 8 mg *  | Retail Price calculated as per Para 4 (May 2020 data) | 7.67  |
| b. Telmisartan IP 80 mg  | Notified Ceiling Price                                | 10.02 |
| Worked out Retail Price  |   | 17.69 |
| c. Less 20% of the lowest of (a) and (b) similar to formula recommended in the Pronab Sen Committee report |   | 1.53  |
| Net Retail Price (a+b-c)   |   | 16.16 |
| Company Claimed Price  |   | 14.40 |
| Recommended price  |   | 14.40 |

**13. Agenda no. 13 - Retail price fixation under Para 5 of DPCO, 2013 – Each uncoated tablet containing Flunarizine Dihydrochloride eq. to Flunarizine 5 mg & Domperidone 10 mg for M/s Mankind Pharma Ltd. (marketer) and M/s Windlas Biotech Pvt. Ltd (manufacturer/ importer).**

13.1 The Committee deliberated upon the matter in detail and recommended the retail price of each uncoated tablet containing Flunarizine Dihydrochloride eq. to Flunarizine 5 mg & Domperidone 10 mg for M/s Mankind Pharma Ltd. (marketer) and M/s Windlas Biotech Pvt. Ltd (manufacturer/ importer) at Rs. 4.68 per tablet excluding GST as detailed below:



| Computation of Retail Price per Tablet  | Source/Method          | Rs.   |
|---|------------------------|-------|
| Composition – Each uncoated tablet contains Flunarizine Dihydrochloride eq. to Flunarizine 5 mg + Domperidone 10 mg |                        |       |
| a. Flunarizine 5 mg   | Notified Ceiling Price | 2.75  |
| b. Domperidone 10 mg  | Notified Ceiling Price | 2.41  |
| Worked out Retail Price   |                        | 5.16  |
| c. Less 20% of the lowest of (a) and (b) similar to formula recommended in the Pronab Sen Committee report          |                        | 0.48  |
| Net Retail Price (a+b-c)  |                        | 4.68  |
| Company Claimed Price   |                        | 10.00 |
| Recommended price   |                        | 4.68  |

**14. Agenda no. 14 - Retail price fixation under Para 5 of DPCO, 2013 - Budesonide 400 mcg, Glycopyrronium 25 mcg and Formoterol Fumerate 12 mcg Powder for inhalation in which each capsule containing Budesonide IP 400 mcg , Glycopyrronium (as Glycopyrrolate IP) 25 mcg and Formoterol Fumarate Dihydrate IP 12 mcg for M/s Cipla Ltd. (manufacturer and marketer).**

14.1 The Committee deliberated upon the matter in detail and recommended the retail price of Budesonide 400 mcg, Glycopyrronium 25 mcg and Formoterol Fumerate 12 mcg Powder for inhalation in which each capsule containing Budesonide IP 400 mcg , Glycopyrronium (as Glycopyrrolate IP) 25 mcg and Formoterol Fumarate Dihydrate IP 12 mcg for M/s Cipla Ltd. (manufacturer and marketer) at Rs. 13.63 per capsule as detailed below:

| Computation of Retail Price per dose  | Source/Method                                    | Amount (Rs.) |
|---|--|--------------|
| Composition – Budesonide 400mcg + Glycopyrronium (as Glycopyrrolate IP) 25mcg + Formoterol Fumarate Dihydrate IP 12 mcg |  |              |
| a. Budesonide 400mcg + Formoterol Fumarate Dihydrate IP 12 mcg  | Retail price (as per February 2020 data)         | 8.12         |
| b. Glycopyrronium (as Glycopyrrolate IP) 25mcg  | Derived Retail price (as per February 2020 data) | 6.89         |
| Worked out Retail Price   |  | 15.01        |
| d. Less 20% of the lowest of (a) to (b) as recommended in the Pronab Sen Committee report                               |  | 1.38         |
| Net Retail Price (a+b-c)  |  | 13.63        |
| Company Claimed Price   |  | 18.73        |
| Recommended price   |  | 13.63        |

Derived retail price as per recommendation of pronab sen committee:

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

Where :  $P(s)$  = Price ceiling of the strength  $s$

$P^*$  = price ceiling for reference strength  $s^*$

$s$  = strength in terms of API content

$s^*$  = reference strength

$a$  = 0.8 for tablet / capsule and 0.7 for injectibles.

Derived Retail Price for Glycopyrronium (as Glycopyrrolate IP) 25mcg Capsule

Retail Price of Glycopyrronium (as Glycopyrrolate IP) 50mcg Capsule = Rs. 11.48

Derived Retail price Glycopyrronium (as Glycopyrrolate IP) 25mcg Capsule =  $11.48[1 + 0.80\{(25-50)/50\}] = \text{Rs. } 6.89$  per capsule

**15.1 Agenda no. 15(i) – Retail price fixation under Para 5 of DPCO, 2013 – Each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 500mg (as sustained release form) for M/s Emcure Pharmaceuticals Ltd. (marketer) and M/s Mascot Health Series Pvt. Ltd. (manufacturer/ importer).**

15.1.1 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.

15.1.2 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.

15.1.3 The Committee observed that based on the methodology decided by the Authority in its 72nd meeting dated 20.01.2020, as specified in 15.1.2 above, the retail price of Vildagliptin 50 mg + Metformin 500 mg tablet comes to Rs. 6.17 per tablet excluding GST.

15.1.4 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 form) 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 15.1.1 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 15.1.2, i.e. Rs. 6.17 and recommend the same.

15.1.5 Accordingly, the Committee recommended the retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 500mg (as sustained release form) for M/s Emcure Pharmaceuticals Ltd. (marketer) and M/s Mascot Health Series Pvt. Ltd. (manufacturer/ importer) at Rs. 6.58 per tablet excluding GST.

**15.2 Agenda no. 15(ii) - Retail price fixation under Para 5 of DPCO, 2013 - Each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 500mg (as sustained release form) for M/s Mascot Health Series Pvt. Ltd. (marketer & manufacturer/ importer).**

15.2.1 The Committee noted that M/s Mascot Health Series Pvt. Ltd has applied for withdrawal of the application for retail price fixation of - Each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 500mg (as sustained release form). Accordingly, the Committee decided to close the application.

**15.3 Agenda no. 15(iii) - Retail price fixation under Para 5 of DPCO, 2013 - Each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 500mg (as sustained release form) for M/s Intas Pharmaceuticals Ltd. (marketer) and M/s Exemed Pharmaceuticals (manufacturer/ importer).**

15.3.1 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.

15.3.2 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.*

15.3.3 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 15.3.2 above, the retail price of Vildagliptin 50 mg + Metformin 500 mg tablet comes to Rs. 6.17 per tablet excluding GST.

15.3.4 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 form) 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 15.3.1 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 15.3.2, i.e. Rs. 6.17 and recommend the same.

15.3.5 Accordingly, the Committee recommended the retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 500mg (as sustained release form) for M/s Intas Pharmaceuticals Ltd. (marketer) and M/s Exemed Pharmaceuticals (manufacturer/ importer) at Rs. 6.58 per tablet excluding GST.

**15.4 Agenda no. 15(iv) - Retail price fixation under Para 5 of DPCO, 2013 - Each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 500mg (as sustained release form) for M/s J. B. Chemicals & Pharmaceuticals Limited (marketer) and M/s Mascot Health Series Pvt. Ltd. (manufacturer/ importer).**

15.4.1 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.

15.4.2 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 Vildigliptin tablets were proposed to be calculated as per two options, as follows:*

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

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

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

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

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

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

15.4.3 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 15.4.2 above, the retail price of Vildagliptin 50 mg + Metformin 500 mg tablet comes to Rs. 6.17 per tablet excluding GST.

15.4.4 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 form) 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 15.4.1 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 15.4.2, i.e. Rs. 6.17 and recommend the same.

15.4.5 Accordingly, the Committee recommended the retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 500mg (as sustained release form) for M/s J. B. Chemicals & Pharmaceuticals Limited (marketer) and M/s Mascot Health Series Pvt. Ltd. (manufacturer/ importer) at Rs. 6.58 per tablet excluding GST.

**16.1 Agenda no. 16(i) – Retail price fixation under Para 5 of DPCO, 2013 – Each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 1000mg (as sustained release form) for M/s Emcure Pharmaceuticals Ltd. (marketer) and M/s Mascot Health Series Pvt. Ltd. (manufacturer/ importer).**

16.1.1 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.

16.1.2 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 Vildiglipitin tablets for various companies, in which it was decided as follows:

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

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

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

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

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

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

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

16.1.3 The Committee observed that based on the methodology decided by the Authority in its 72nd meeting dated 20.01.2020, as specified in 16.1.2 above, the retail price of Vildagliptin 50 mg + Metformin 1000 mg tablet comes to Rs. 6.66 per tablet excluding GST.

16.1.4 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 form) 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 16.1.1 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 16.1.2, i.e. Rs. 6.66 and recommend the same.

16.1.5 Accordingly, the Committee recommended the retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 500mg (as sustained release form) for M/s Emcure Pharmaceuticals Ltd. (marketer) and M/s Mascot Health Series Pvt. Ltd. (manufacturer/ importer) at Rs. 7.07 per tablet excluding GST.

**16.2 Agenda no. 16(ii) - Retail price fixation under Para 5 of DPCO, 2013 - Each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 1000mg (as sustained release form) for M/s Mascot Health Series Pvt. Ltd. (marketer & manufacturer/ importer).**

16.2.1 The Committee noted that M/s Mascot Health Series Pvt. Ltd has applied for withdrawal of the application for retail price fixation of - Each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 1000mg (as sustained release form). Accordingly, the Committee decided to close the application.

**16.3 Agenda no. 16(iii) - Retail price fixation under Para 5 of DPCO, 2013 - Each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 1000mg (as sustained release form) for M/s Intas Pharmaceuticals Ltd. (marketer) and M/s Exemed Pharmaceuticals (manufacturer/ importer).**

16.3.1 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.

16.3.2 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.*

16.3.3 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 16.3.2 above, the retail price of Vildagliptin 50 mg + Metformin 1000 mg tablet comes to Rs. 6.66 per tablet excluding GST.

15.3.4 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 form) 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 16.3.1 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 16.3.2, i.e. Rs. 6.66 and recommend the same.

16.3.5 Accordingly, the Committee recommended the retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 500mg (as sustained release form) for M/s Intas Pharmaceuticals Ltd. (marketer) and M/s Exemed Pharmaceuticals (manufacturer/ importer) at Rs. 7.07 per tablet excluding GST.



**16.4 Agenda no. 16(iv) - Retail price fixation under Para 5 of DPCO, 2013 - Each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 1000mg (as sustained release form) for M/s J. B. Chemicals & Pharmaceuticals Limited (marketer) and M/s Mascot Health Series Pvt. Ltd. (manufacturer/ importer).**

16.4.1 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.

16.4.2 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.*

16.4.3 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 16.4.2 above, the retail price of Vildagliptin 50 mg + Metformin 1000 mg tablet comes to Rs. 6.66 per tablet excluding GST.

16.4.4 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 form) 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 16.4.1 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 16.4.2, i.e. Rs. 6.66 and recommend the same.

16.4.5 Accordingly, the Committee recommended the retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 1000mg (as sustained release form) for M/s J. B. Chemicals & Pharmaceuticals Limited (marketer) and M/s Mascot Health Series Pvt. Ltd. (manufacturer/ importer) at Rs. 7.07 per tablet excluding GST.

**17. Agenda no. 17 - Application for grant of separate price/ special price for “Synchrobreathe inhaler device” under the provision of Para 11(3) or para 32(3) of DPCO 2013**

17.1 The Committee deliberated upon the matter in detail and also observed the demonstration made by M/s Cipla Ltd. Accordingly, the Committee directed that the technical details of “Synchrobreathe inhaler device” together with study report and journal be provided by M/s Cipla Ltd for further deliberation on the matter.

**18. Agenda no. 18 - Application for upward price revision of Mannitol Injection 20% under para 19 of DPCO 2013 by Rusuma Laboratories Ltd**

Record note of discussion to be circulated separately to the members.

**19. Agenda no. 19 - Ceiling price fixation of Pheniramine Maleate Injection 22.75 mg/ ml in 33 ml and 100 ml pack.**

19.1 The Committee noted that Pheniramine Maleate Injection 22.75 mg/ ml is a scheduled formulation under DPCO 2013 and the ceiling price of the formulation in 2 ml pack and 10ml pack has been fixed. The Committee deliberated upon the matter in detail and decided that the matter be again placed in the next meeting for further deliberation on the matter.

The meeting ended with a vote of thanks to all.

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

Copy to:  
All members of the Committee.