

F. No. 12(7)/2021/DP/NPPA/Div.II/ Vol-IV
National Pharmaceutical Pricing Authority

Subject: Minutes of the 41st meeting of the Multidisciplinary Committee of Experts held on 08.04.2022 at 2:30 PM.

41st meeting of the "Multidisciplinary Committee of Experts" was held on 08.04.2022 at 2:30 P.M. under the convenorship of Shri Manmohan Sachdeva, Advisor (Cost), through video-conferencing. The following members attended the meeting through video conferencing:-

1. Shri A. K. Pradhan, Jt. Drugs Controller, CDSCO
2. Dr. J. J. Cherian, Scientist-D, ICMR
3. Dr. Rakesh Kr. Singh, Associate Professor, NIPER Raebareli
4. Prof. Y. K. Gupta, Principal Scientific Advisor (projects), THSTI-DBT, GoI & Ex-HoD, Pharmacology & Dean (Academics), AIIMS, New Delhi – Co-opted member
5. Dr. Pooja Gupta, Associate Professor, Department of Pharmacology, AIIMS- New Delhi,

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

1. Ms. Rashmi Tahiliani, Jt. Director (Pricing)
2. Shri Prasenjit Das, Deputy Director (Pricing), NPPA
3. Shri Mahaveer Saini, Deputy Director (Pricing), NPPA

1. Agenda No. 1 - Retail price fixation under Para 5 of DPCO, 2013 – Fixed Dose Combinations (FDCs) of Sitagliptin and Metformin tablet.

1.1 The Committee noted that seventeen applications have been received for retail price fixation of three Fixed Dose Combinations (FDCs) of Sitagliptin and Metformin tablets i.e. (i) Sitagliptin 50 mg + Metformin 500 mg tablet, (ii) Sitagliptin 50 mg + Metformin 1000 mg tablet, (iii) Sitagliptin 50 mg + Metformin 850 mg tablet and (iv) Sitagliptin 100 mg + Metformin 1000 mg (extended release) tablet. The Committee further noted that the formulation 'Sitagliptin' is on the verge of becoming off-patent.

1.2. The Committee recalled the decision taken in its 40th meeting dated 14.03.2022 and approved by the Authority in its 96th meeting dated 24.03.2022 regarding retail price fixation of FDCs of 'Sitagliptin and Metformin tablet' in which the Authority decided as follows:

(i) The Authority noted that the formulation "Sitagliptin" has become/ is on the verge of becoming off-patent and observed that, in line with the decision taken in its 89th meeting dated 28.06.2021, if the calculation is based on six month prior market data, the price of the patented period would be taken into consideration and hence the price rationalisation due to expiry of the patent may not pass on to the patients.

(ii) The Authority further noted that matter was placed before the 40th meeting of the Multidisciplinary Committee of Experts held on 14.03.2022 which in line

decision taken in the 89th Authority meeting dated 28.06.2021, recommended to fix the retail price as per the following methodology:

“...The Committee observed that the market data of the FDCs of Sitagliptin and Metformin tablet is also available and noted that if the retail price is calculated based on six month prior market data, the price of patented period would be taken into consideration and benefit of price reduction due to medicines which has become/ is on the verge of becoming off-patent would not pass not on to the consumers. The Committee deliberated upon the matter in detail and is of the opinion that the price of drugs be reduced in respect of the drugs which has become/ on the verge of becoming off-patent so as to pass the benefit of price reduction to the consumers and that a reduction of 50% be allowed on the patented component of FDCs i.e. ‘Sitagliptin’ to arrive at the retail price. Accordingly, the Committee recommended to allow retail price for the FDCs of Sitagliptin and Metformin tablet in line with the decision taken in its 33rd meeting held on 21.06.2021. However, where the calculated retail price of the FDC of formulation based on six month prior market data as per the provisions of DPCO 2013 is lower than claimed price and the calculated price, the Committee recommended that the same would be allowed.”

(iii) The Authority deliberated upon the matter in detail and accepted the recommendation of the Multidisciplinary Committee of Experts and approved the fixation of the new drugs as per the methodology stated by the Multidisciplinary Committee of Experts.

1.3 The Committee observed that the market data of the FDCs of Sitagliptin and Metformin tablet is also available and noted that if the retail price is calculated based on six month prior market data, the price of patented period would be taken into consideration and benefit of price reduction due to medicines which has become/ is on the verge of becoming off-patent would not pass not on to the consumers. The Committee deliberated upon the matter in detail and is of the opinion that the price of drugs be reduced in respect of the drugs which has become/ on the verge of becoming off-patent so as to pass the benefit of price reduction to the consumers and that a reduction of 50% be allowed on the patented component of FDCs i.e. ‘Sitagliptin’ to arrive at the retail price. Accordingly, the Committee recommended to allow retail price for the FDCs of Sitagliptin and Metformin tablet in line with the decision taken in its 40th meeting held on 14.03.2022 and approved by the Authority in its 96th meeting held on 24.03.2022.

1.4 Accordingly, the Committee recommended the retail price of FDCs of Sitagliptin + Metformin Hydrochloride IP tablet for various companies as detailed below:

1.4.1 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg for M/s Aristo Pharmaceuticals Pvt. Ltd. (manufacturer and marketer) at Rs. 18.34 per tablet excluding GST as detailed below:

| S. No. | Particulars | Source/Method | Amount (Rs.) |
|--------|--|---------------|--------------|
| | Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride | | |

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| | IP 500 mg | | |
| (a) | Derived retail price of Sitagliptin 50 mg tablet | Retail price (as per August, 2021 data) | 34.27 |
| (b) | 50% of (a) | | 17.135 |
| (c) | Metformin IR 500 mg | Ceiling Price [SO. 1330(E) dated 25.03.2021] | 1.51 |
| (d) | Retail Price | | 18.645 |
| (e) | Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report | | 0.302 |
| (f) | Worked out Retail Price (d)-(e) | | 18.343 |
| (g) | Claimed Retail price | | 24.15 |
| (h) | Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet' as per Pharmatrac Data for August, 2021 | | 21.67 |
| (i) | Recommended retail price | | 18.34 |

1.4.2 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg for M/s Aristo Pharmaceuticals Pvt. Ltd. (manufacturer and marketer) at Rs. 20.02 per tablet excluding GST as detailed below:

| S. No. | Particulars | Source/Method | Amount (Rs.) |
|--------|---|--|--------------|
| | Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg | | |
| (a) | Derived retail price of Sitagliptin 50 mg tablet | Retail price (as per August, 2021 data) | 34.27 |
| (b) | 50% of (a) | | 17.135 |
| (c) | Metformin IR 1000 mg | Ceiling Price [SO. 1330(E) dated 25.03.2021] | 3.61 |
| (d) | Retail Price | | 20.745 |
| (e) | Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report | | 0.72 |
| (f) | Worked out Retail Price (d)-(e) | | 20.025 |
| (g) | Claimed Retail price | | 24.75 |

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| (h) | Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg tablet" as per Pharmatrac Data for August, 2021 | 22.26 |
| (i) | Recommended retail price | 20.02 |

1.4.3 Each film coated tablet containing Sitagliptin Phosphate Monohydrate 64.25 mg eq. to Sitagliptin 50 mg + Metformin HCL IP 500 mg for M/s Bajaj Healthcare Ltd. (manufacturer) and M/s Lupin Ltd. (marketer) at Rs. 18.34 per tablet excluding GST as detailed below:

| S. No. | Particulars | Source/Method | Amount (Rs.) |
|--------|--|--|--------------|
| | Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg | | |
| (a) | Derived retail price of Sitagliptin 50 mg tablet | Retail price (as per August, 2021 data) | 34.27 |
| (b) | 50% of (a) | | 17.135 |
| (c) | Metformin IR 500 mg | Ceiling Price [SO. 1330(E) dated 25.03.2021] | 1.51 |
| (d) | Retail Price | | 18.645 |
| (e) | Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report | | 0.302 |
| (f) | Worked out Retail Price (d)-(e) | | 18.343 |
| (g) | Claimed Retail price | | 28.92 |
| (h) | Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet" as per Pharmatrac Data for August, 2021 | | 21.67 |
| (i) | Recommended retail price | | 18.34 |

1.4.4 Each film coated tablet containing Sitagliptin Phosphate Monohydrate 64.25 mg eq. to Sitagliptin 50 mg + Metformin HCL IP 1000 mg for M/s Bajaj Healthcare Ltd. (manufacturer) and M/s Lupin Ltd. (marketer) at Rs. 20.02 per tablet excluding GST as detailed below:

| S. No. | Particulars | Source/Method | Amount (Rs.) |
|--------|---|---------------|--------------|
| | Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg | | |

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| (a) | Derivedretailprice of Sitagliptin 50 mg tablet | Retail price (as per August, 2021 data) | 34.27 |
| (b) | 50% of (a) | | 17.135 |
| (c) | Metformin IR 1000 mg | Ceiling Price [SO. 1330(E) dated 25.03.2021] | 3.61 |
| (d) | Retail Price | | 20.745 |
| (e) | Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report | | 0.72 |
| (f) | Worked out Retail Price (d)-(e) | | 20.025 |
| (g) | Claimed Retail price | | 29.91 |
| (h) | Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg tablet" as per Pharmatrac Data for August, 2021 | | 22.26 |
| (i) | Recommended retail price | | 20.02 |

1.4.5 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg for M/s Intas Pharmaceuticals Ltd. (manufacturer and marketer) at Rs. 18.34 per tablet excluding GST as detailed below:

| S. No. | Particulars | Source / Method | Amount (Rs.) |
|--------|--|--|--------------|
| | Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg | | |
| (a) | Derivedretailprice of Sitagliptin 50 mg tablet | Retail price (as per August, 2021 data) | 34.27 |
| (b) | 50% of (a) | | 17.135 |
| (c) | Metformin IR 500 mg | Ceiling Price [SO. 1330(E) dated 25.03.2021] | 1.51 |
| (d) | Retail Price | | 18.645 |
| (e) | Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report | | 0.302 |
| (f) | Worked out Retail Price (d)-(e) | | 18.343 |
| (g) | Claimed Retail price | | 19.00 |

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| (h) | Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet" as per Pharmatrac Data for August, 2021 | 21.67 |
| (i) | Recommended retail price | 18.34 |

1.4.6 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg for M/s Intas Pharmaceuticals Ltd. (manufacturer and marketer) at Rs. 20.00 per tablet excluding GST as detailed below:

| S. No. | Particulars | Source / Method | Amount (Rs.) |
|--------|---|--|--------------|
| | Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg | | |
| (a) | Derived retail price of Sitagliptin 50 mg tablet | Retail price (as per August, 2021 data) | 34.27 |
| (b) | 50% of (a) | | 17.135 |
| (c) | Metformin IR 1000 mg | Ceiling Price [SO. 1330(E) dated 25.03.2021] | 3.61 |
| (d) | Retail Price | | 20.745 |
| (e) | Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report | | 0.72 |
| (f) | Worked out Retail Price (d)-(e) | | 20.025 |
| (g) | Claimed Retail price | | 20.00 |
| (h) | Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg tablet" as per Pharmatrac Data for August, 2021 | | 22.26 |
| (i) | Recommended retail price | | 20.00 |

1.4.7 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg for M/s Optimus Pharma Pvt. Ltd. (manufacturer) and M/s Mankind Pharma Ltd. (marketer) at Rs. 18.34 per tablet excluding GST as detailed below:

| S. No. | Particulars | Source/Method | Amount (Rs.) |
|--------|--|---------------|--------------|
| | Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg | | |

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|-----|--|--|--------|
| (a) | Derived retail price of Sitagliptin 50 mg tablet | Retail price (as per August, 2021 data) | 34.27 |
| (b) | 50% of (a) | | 17.135 |
| (c) | Metformin IR 500 mg | Ceiling Price [SO. 1330(E) dated 25.03.2021] | 1.51 |
| (d) | Retail Price | | 18.645 |
| (e) | Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report | | 0.302 |
| (f) | Worked out Retail Price (d)-(e) | | 18.343 |
| (g) | Claimed Retail price | | 20.00 |
| (h) | Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet' as per Pharmatrac Data for August, 2021 | | 21.67 |
| (i) | Recommended retail price | | 18.34 |

1.4.8 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg for M/s Optimus Pharma Pvt. Ltd. (manufacturer) and M/s Mankind Pharma Ltd. (marketer) at Rs. 20.02 per tablet excluding GST as detailed below:

| S. No. | Particulars | Source / Method | Amount (Rs.) |
|--------|---|--|--------------|
| | Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg | | |
| (a) | Derived retail price of Sitagliptin 50 mg tablet | Retail price (as per August, 2021 data) | 34.27 |
| (b) | 50% of (a) | | 17.135 |
| (c) | Metformin IR 1000 mg | Ceiling Price [SO. 1330(E) dated 25.03.2021] | 3.61 |
| (d) | Retail Price | | 20.745 |
| (e) | Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report | | 0.72 |
| (f) | Worked out Retail Price (d)-(e) | | 20.025 |
| (g) | Claimed Retail price | | 25.00 |

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| (h) | Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg tablet" as per Pharmatrac Data for August, 2021 | 22.26 |
| (i) | Recommended retail price | 20.02 |

1.4.9 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 850 mg for M/s Optimus Pharma Pvt. Ltd. (manufacturer) and M/s Mankind Pharma Ltd. (marketer) at Rs. 19.14 per tablet excluding GST as detailed below:

| S. No. | Particulars | Source / Method | Amount (Rs.) |
|--------|--|---|--------------|
| | Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 850 mg | | |
| (a) | Derived retail price of Sitagliptin 50 mg tablet | Retail price (as per August, 2021 data) | 34.27 |
| (b) | 50% of (a) | | 17.135 |
| (c) | Metformin IR 850 mg | Retail price as per Para 4 of DPCO 2013 based on August 2021 data | 2.51 |
| (d) | Retail Price | | 19.645 |
| (e) | Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report | | 0.502 |
| (f) | Worked out Retail Price (d)-(e) | | 19.143 |
| (g) | Claimed Retail price | | 22.00 |
| (h) | Retail price of FDC of 'Sitagliptin 50mg + Metformin 850mg tablet" as per Pharmatrac Data for August, 2021 | | N.A. |
| (i) | Recommended retail price | | 19.14 |

1.4.10 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP 64.25mg eq. to Sitagliptin 50mg + Metformin Hydrochloride IP 500 mg for M/s Windlas Biotech Limited (Manufacturer) and M/s Wockhardt Limited (marketer) at Rs. 8.92 per tablet excluding GST as detailed below:

| S. No. | Particulars | Source/Method | Amount (Rs.) |
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| | Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg | | |
| (a) | Derived retail price of Sitagliptin 50 mg tablet | Retail price (as per August, 2021 data) | 34.27 |
| (b) | 50% of (a) | | 17.135 |
| (c) | Metformin IR 500 mg | Ceiling Price [SO. 1330(E) dated 25.03.2021] | 1.51 |
| (d) | Retail Price | | 18.645 |
| (e) | Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report | | 0.302 |
| (f) | Worked out Retail Price (d)-(e) | | 18.343 |
| (g) | Claimed Retail price | | 8.92 |
| (h) | Retail price of FDC of "Sitagliptin 50mg + Metformin 500mg tablet" as per Pharmatrac Data for August, 2021 | | 21.67 |
| (i) | Recommended retail price | | 8.92 |

1.4.11 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP 64.25mg eq. to Sitagliptin 50mg + Metformin Hydrochloride IP 1000 mg for M/s Windlas Biotech Limited (Manufacturer) and M/s Wockhardt Limited (marketer) at Rs. 9.82 per tablet excluding GST as detailed below:

| S. No. | Particulars | Source / Method | Amount (Rs.) |
|--------|---|--|--------------|
| | Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg | | |
| (a) | Derived retail price of Sitagliptin 50 mg tablet | Retail price (as per August, 2021 data) | 34.27 |
| (b) | 50% of (a) | | 17.135 |
| (c) | Metformin IR 1000 mg | Ceiling Price [SO. 1330(E) dated 25.03.2021] | 3.61 |
| (d) | Retail Price | | 20.745 |
| (e) | Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report | | 0.72 |

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| (f) | Worked out Retail Price (d)-(e) | | 20.025 |
| (g) | Claimed Retail price | | 9.82 |
| (h) | Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg tablet" as per Pharmatrac Data for August, 2021 | | 22.26 |
| (i) | Recommended retail price | | 9.82 |

1.4.12 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg for M/s Sun Pharma Laboratories Limited (manufacturer and marketer) at Rs. 18.34 per tablet excluding GST as detailed below:

| S. No. | Particulars | Source/Method | Amount (Rs.) |
|--------|--|--|--------------|
| | Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg | | |
| (a) | Derived retail price of Sitagliptin 50 mg tablet | Retail price (as per August, 2021 data) | 34.27 |
| (b) | 50% of (a) | | 17.135 |
| (c) | Metformin IR 500 mg | Ceiling Price [SO. 1330(E) dated 25.03.2021] | 1.51 |
| (d) | Retail Price | | 18.645 |
| (e) | Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report | | 0.302 |
| (f) | Worked out Retail Price (d)-(e) | | 18.343 |
| (g) | Claimed Retail price | | 22.91 |
| (h) | Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet" as per Pharmatrac Data for August, 2021 | | 21.67 |
| (i) | Recommended retail price | | 18.34 |

1.4.13 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg for M/s Sun Pharma Laboratories Limited (manufacturer and marketer) at Rs. 20.02 per tablet excluding GST as detailed below:

| S. No. | Particulars | Source / Method | Amount (Rs.) |
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| | Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg | | |
| (a) | Derived retail price of Sitagliptin 50 mg tablet | Retail price (as per August, 2021 data) | 34.27 |
| (b) | 50% of (a) | | 17.135 |
| (c) | Metformin IR 1000 mg | Ceiling Price [SO. 1330(E) dated 25.03.2021] | 3.61 |
| (d) | Retail Price | | 20.745 |
| (e) | Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report | | 0.72 |
| (f) | Worked out Retail Price (d)-(e) | | 20.025 |
| (g) | Claimed Retail price | | 23.80 |
| (h) | Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg tablet" as per Pharmatrac Data for August, 2021 | | 22.26 |
| (i) | Recommended retail price | | 20.02 |

1.4.14 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as extended release form) for M/s Sun Pharma Laboratories Limited (manufacturer and marketer) at Rs. 19.81 per tablet excluding GST as detailed below:

| S. No. | Particulars | Source / Method | Amount (Rs.) |
|--------|---|--|--------------|
| | Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride (as extended release form) IP 1000 mg | | |
| (a) | Derived retail price of Sitagliptin 100 mg tablet | Retail price (as per August, 2021 data) | 37.27 |
| (b) | 50% of (a) | | 18.635 |
| (c) | Metformin CR 1000 mg | Ceiling Price [SO. 1330(E) dated 25.03.2021] | 3.66 |
| (d) | Retail Price | | 22.295 |
| (e) | Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee | | 0.732 |

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| (f) | Worked out Retail Price (d)-(e) | | 21.563 |
| (g) | Claimed Retail price | | 22.02 |
| (h) | Retail price of FDC of 'Sitagliptin 100mg + Metformin (ER) 1000mg tablet" as per Pharmatrac Data for August, 2021 | | 19.81 |
| (i) | Recommended retail price | | 19.81 |

1.4.15 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg for M/s Exemed Pharmaceuticals (manufacturer) and M/s Eris Life Sciences Limited (marketer) at Rs. 18.34 per tablet excluding GST as detailed below:

| S. No. | Particulars | Source/Method | Amount (Rs.) |
|--------|--|--|--------------|
| | Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg | | |
| (a) | Derived retail price of Sitagliptin 50 mg tablet | Retail price (as per August, 2021 data) | 34.27 |
| (b) | 50% of (a) | | 17.135 |
| (c) | Metformin IR 500 mg | Ceiling Price [SO. 1330(E) dated 25.03.2021] | 1.51 |
| (d) | Retail Price | | 18.645 |
| (e) | Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report | | 0.302 |
| (f) | Worked out Retail Price (d)-(e) | | 18.343 |
| (g) | Claimed Retail price | | 25.89 |
| (h) | Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet" as per Pharmatrac Data for August, 2021 | | 21.67 |
| (i) | Recommended retail price | | 18.34 |

1.4.16 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg for M/s Exemed Pharmaceuticals (manufacturer) and M/s Eris Life Sciences Limited (marketer) at Rs. 20.02 per tablet excluding GST as detailed below:

| S. | Particulars | Source / Method | Amount |
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| No. | | | (Rs.) |
|-----|---|--|--------|
| | Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg | | |
| (a) | Derived retail price of Sitagliptin 50 mg tablet | Retail price (as per August, 2021 data) | 34.27 |
| (b) | 50% of (a) | | 17.135 |
| (c) | Metformin IR 1000 mg | Ceiling Price [SO. 1330(E) dated 25.03.2021] | 3.61 |
| (d) | Retail Price | | 20.745 |
| (e) | Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report | | 0.72 |
| (f) | Worked out Retail Price (d)-(e) | | 20.025 |
| (g) | Claimed Retail price | | 29.46 |
| (h) | Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg tablet' as per Pharmatrac Data for August, 2021 | | 22.26 |
| (i) | Recommended retail price | | 20.02 |

1.4.17 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 850 mg for M/s Exemed Pharmaceuticals (manufacturer) and M/s Eris Life Sciences Limited (marketer) at Rs. 19.14 per tablet excluding GST as detailed below:

| S. No. | Particulars | Source / Method | Amount (Rs.) |
|--------|--|---|--------------|
| | Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 850 mg | | |
| (a) | Derived retail price of Sitagliptin 50 mg tablet | Retail price (as per August, 2021 data) | 34.27 |
| (b) | 50% of (a) | | 17.135 |
| (c) | Metformin IR 850 mg | Retail price as per Para 4 of DPCO 2013 based on August 2021 data | 2.51 |
| (d) | Retail Price | | 19.645 |
| (e) | Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report | | 0.502 |

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| (f) | Worked out Retail Price (d)-(e) | 19.143 |
| (g) | Claimed Retail price | 27.67 |
| (h) | Retail price of FDC of 'Sitagliptin 50mg + Metformin 850mg tablet" as per Pharmatrac Data for August, 2021 | N.A. |
| (i) | Recommended retail price | 19.14 |

2. Agenda No. 2 - Retail price fixation under Para 5 of DPCO, 2013 - Each film coated tablet containing Linagliptin + Metformin Hydrochloride IP.

2.1 The Committee noted that five applications have been received for retail price fixation of three Fixed Dose Combinations (FDCs) of Linagliptin and Metformin tablets i.e. (i) Linagliptin 2.5 mg + Metformin 500 mg tablet, (ii) Linagliptin 2.5 mg + Metformin 850 mg tablet and (iii) Linagliptin 2.5 mg + Metformin 1000 mg tablet. The Committee further noted that the formulation 'Linagliptin' has become/ on the verge of becoming off-patent.

2.2. The Committee recalled the decision taken in its 40th meeting dated 14.03.2022 and approved by the Authority in its 96th meeting dated 24.03.2022 regarding retail price fixation of FDCs of 'Linagliptin and Metformin tablet' in which the Authority decided as follows:

(i) The Authority noted that the formulation "Linagliptin" has become/ is on the verge of becoming off-patent and observed that, in line with the decision taken in its 89th meeting dated 28.06.2021, if the calculation is based on six month prior market data, the price of the patented period would be taken into consideration and hence the price rationalisation due to expiry of the patent may not pass on to the patients.

(ii) The Authority further noted that matter was placed before the 40th meeting of the Multidisciplinary Committee of Experts held on 14.03.2022 which in line with decision taken in the 89th Authority meeting dated 28.06.2021, recommended to fix the retail price as per the following methodology:

" The Committee observed that the market data of the FDCs of Linagliptin and Metformin tablet is also available and noted that if the retail price is calculated based on six month prior market data, the price of patented period would be taken into consideration and benefit of price reduction due to medicines which has become/ is on the verge of becoming off-patent would not pass not on to the consumers. The Committee deliberated upon the matter in detail and is of the opinion that the price of drugs be reduced in respect of the drugs which has become/ on the verge of becoming off-patent so as to pass the benefit of price reduction to the consumers and that a reduction of 50% be allowed on the patented component of FDCs i.e. 'Linagliptin' to arrive at the retail price. Accordingly, the Committee recommended to allow retail price for the FDCs of Linagliptin and Metformin tablet in line with the decision taken in its 33rd meeting held on 21.06.2021. However, where the calculated retail price of the FDC of formulation based on six month prior market data as per the provisions of DPCO 2013 is lower than claimed price and the calculated price, the Committee recommended that the same would be allowed."

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(iii) The Authority deliberated upon the matter in detail and accepted the recommendation of the Multidisciplinary Committee of Experts and approved the fixation of the new drugs as per the methodology stated by the Multidisciplinary Committee of Experts.

2.3 The Committee observed that the market data of the FDCs of Linagliptin and Metformin tablet is also available and noted that if the retail price is calculated based on six month prior market data, the price of patented period would be taken into consideration and benefit of price reduction due to medicines which has become/ is on the verge of becoming off-patent would not pass on to the consumers. The Committee deliberated upon the matter in detail and is of the opinion that the price of drugs be reduced in respect of the drugs which has become/ on the verge of becoming off-patent so as to pass the benefit of price reduction to the consumers and that a reduction of 50% be allowed on the patented component of FDCs i.e. 'Linagliptin' to arrive at the retail price. Accordingly, the Committee recommended to allow retail price for the FDCs of Linagliptin and Metformin tablet in line with the decision taken in its 40th meeting held on 14.03.2022 and approved by the Authority in its 96th meeting held on 24.03.2022.

2.4 Accordingly, the Committee recommended the retail price of FDCs of Linagliptin + Metformin Hydrochloride IP tablet for various companies as detailed below:

2.4.1 Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 500mg for M/s Mankind Pharma Limited (Marketer) and M/s Mediforce Healthcare Private Limited (Manufacturer) at Rs. 14.65 per tablet excluding GST as detailed below:

| S. No. | Particulars | Source/Method | Amount (Rs.) |
|--------|--|--|--------------|
| | Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 500mg | | |
| (a) | Derived retail price of Linagliptin 5mg | Retail price (as per August 2021 data) | 44.81 |
| (b) | Derived retail price of Linagliptin 2.5mg as per Pronab Sen Committee Report (Note) | | 26.886 |
| (c) | 50% of (b) | | 13.443 |
| (d) | Metformin 500 mg | Ceiling Price | 1.51 |
| (e) | Sub of (c) and (d) | | 14.953 |
| (f) | Less: 20% of the lowest of (c) and (d) as recommended in the Pronab Sen Committee report | | 0.302 |
| (g) | Worked Out Retail Price (e) – (f) | | 14.651 |
| (h) | Claimed Retail Price | | 30.00 |
| (i) | Retail Price as per Pharmatrac based on August, 2021 data | | 23.93 |

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| (j) | Recommended Retail Price | 14.65 |
|-----|--------------------------|-------|

Note: Derived retail price of Linagliptin 2.5mg as per Pronab Sen Committee Report

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

Where: P(s) = Price of the strength s
P* = Price of the reference strength s*
S = Strength in terms of API content
S* = reference strength
A = 0.8 for pack / capsule and 0.7 for injectibles
P(s) = 44.81 [1+0.8{2.5-5/5}] = 26.886

2.4.2 Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 500mg for M/s Alkem Laboratories Limited (Marketer) and M/s AlkemHealthscience (A unit of Alkem Laboratories Limited) (Manufacturer) at Rs. 14.65 per tablet excluding GST as detailed below:

| S. No. | Particulars | Source/Method | Amount (Rs.) |
|--------|--|--|--------------|
| | Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 500mg | | |
| (a) | Derived retail price of Linagliptin 5mg | Retail price (as per August 2021 data) | 44.81 |
| (b) | Derived retail price of Linagliptin 2.5mg as per Pronab Sen Committee Report (Note) | | 26.886 |
| (c) | 50% of (b) | | 13.443 |
| (d) | Metformin 500 mg | Ceiling Price | 1.51 |
| (e) | Sub of (c) and (d) | | 14.953 |
| (f) | Less: 20% of the lowest of (c) and (d) as recommended in the Pronab Sen Committee report | | 0.302 |
| (g) | Worked Out Retail Price (e) – (f) | | 14.651 |
| (h) | Claimed Retail Price | | 18.75 |
| (i) | Retail Price as per Pharmatrac based on August, 2021 data | | 23.93 |
| (j) | Recommended Retail Price | | 14.65 |

Note: Derived retail price of Linagliptin 2.5mg as per Pronab Sen Committee Report

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



Where: P(s) = Price of the strength s
P* = Price of the reference strength s*
S = Strength in terms of API content
S* = reference strength
A = 0.8 for pack / capsule and 0.7 for injectibles
P(s) = 44.81 [1+0.8{2.5-5/5}] = 26.886

2.4.3 Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 1000mg for M/s Alkem Laboratories Limited (Marketer) and M/s AlkemHealthscience (A unit of Alkem Laboratories Limited) (Manufacturer) at Rs. 16.33 per tablet excluding GST as detailed below:

| S. No. | Particulars | Source/Method | Amount (Rs.) |
|--------|--|--|--------------|
| | Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 1000mg | | |
| (a) | Derived retail price of Linagliptin 5mg | Retail price (as per August 2021 data) | 44.81 |
| (b) | Derived retail price of Linagliptin 2.5mg as per Pronab Sen Committee Report (Note) | | 26.886 |
| (c) | 50% of (b) | | 13.443 |
| (d) | Metformin 1000 mg | Ceiling Price | 3.61 |
| (e) | Sub of (c) and (d) | | 17.053 |
| (f) | Less: 20% of the lowest of (c) and (d) as recommended in the Pronab Sen Committee report | | 0.722 |
| (g) | Worked Out Retail Price (e) – (f) | | 16.331 |
| (h) | Claimed Retail Price | | 25.89 |
| (i) | Retail Price as per Pharmatrac based on August, 2021 data | | 24.88 |
| (j) | Recommended Retail Price | | 16.33 |

Note: Derived retail price of Linagliptin 2.5mg as per Pronab Sen Committee Report

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

Where: P(s) = Price of the strength s
P* = Price of the reference strength s*
S = Strength in terms of API content
S* = reference strength
A = 0.8 for pack / capsule and 0.7 for injectibles

$$P(s) = 44.81 [1+0.8\{2.5-5/5\}] = 26.886$$

2.4.4 Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 1000mg for M/s Mankind Pharma Limited (Marketer) and M/s Mediforce Healthcare Private Limited (Manufacturer) at Rs. 16.33 per tablet excluding GST as detailed below:

| S. No. | Particulars | Source/Method | Amount (Rs.) |
|--------|--|--|--------------|
| | Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 1000mg | | |
| (a) | Derived retail price of Linagliptin 5mg | Retail price (as per August 2021 data) | 44.81 |
| (b) | Derived retail price of Linagliptin 2.5mg as per Pronab Sen Committee Report (Note) | | 26.886 |
| (c) | 50% of (b) | | 13.443 |
| (d) | Metformin 1000 mg | Ceiling Price | 3.61 |
| (e) | Sub of (c) and (d) | | 17.053 |
| (f) | Less: 20% of the lowest of (c) and (d) as recommended in the Pronab Sen Committee report | | 0.722 |
| (g) | Worked Out Retail Price (e) – (f) | | 16.331 |
| (h) | Claimed Retail Price | | 40.00 |
| (i) | Retail Price as per Pharmatrac based on August, 2021 data | | 24.88 |
| (j) | Recommended Retail Price | | 16.33 |

Note: Derived retail price of Linagliptin 2.5mg as per Pronab Sen Committee Report

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

Where: P(s) = Price of the strength s
P* = Price of the reference strength s*
S = Strength in terms of API content
S* = reference strength
A = 0.8 for pack / capsule and 0.7 for injectibles

$$P(s) = 44.81 [1+0.8\{2.5-5/5\}] = 26.886$$

2.4.5 Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 850mg for M/s Mankind Pharma Limited (Marketer) and M/s Mediforce Healthcare Private Limited (Manufacturer) at Rs. 15.45 per tablet excluding GST as detailed below:



| S. No. | Particulars | Source/Method | Amount (Rs.) |
|--------|--|--|--------------|
| | Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 850mg | | |
| (a) | Derived retail price of Linagliptin 5mg | Retail price (as per August 2021 data) | 44.81 |
| (b) | Derived retail price of Linagliptin 2.5mg as per Pronab Sen Committee Report (Note) | | 26.886 |
| (c) | 50% of (b) | | 13.443 |
| (d) | Metformin 850 mg (August, 2021) | Retail Price | 2.51 |
| (e) | Sub of (c) and (d) | | 15.953 |
| (f) | Less: 20% of the lowest of (c) and (d) as recommended in the Pronab Sen Committee report | | 0.502 |
| (g) | Worked Out Retail Price (e) – (f) | | 15.451 |
| (h) | Claimed Retail Price | | 35.00 |
| (i) | Retail Price as per Pharmatrac based on August, 2021 data | | 24.36 |
| (j) | Recommended Retail Price | | 15.45 |

Note: Derived retail price of Linagliptin 2.5mg as per Pronab Sen Committee Report

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

Where: P(s) = Price of the strength s
P* = Price of the reference strength s*
S = Strength in terms of API content
S* = reference strength
A = 0.8 for pack / capsule and 0.7 for injectibles

$$P(s) = 44.81 [1+0.8\{2.5-5/5\}] = 26.886$$



3. Agenda No. 3 - Application by M/s AxaParenterals Ltd. for separate price under Para 11(3) of DPCO 2013 with respect to (i) Dextrose Injection 25%w/v in 100 ml pack in Non-glass with special feature for in LDPE container with Euro Head (ii) Mannitol injection 20 gm per 100ml in 100 ml pack in Non-glass with special feature for in LDPE container with Euro Head (iii) Metronidazole Injection IP 500mg/100ml in 100ml 100 ml pack in Non-glass with special feature for in LDPE container with Euro Head

3.1 The Committee was appraised that M/s AxaParenterals Ltd vide its e-mail dated 08.04.2022 requested that due to unavoidable circumstances they would make demonstration of the product regarding claim for special pricing of the special feature bottle in the next meeting. Accordingly, the Committee decided to defer the agenda till the next meeting and directed that M/s AxaParenterals Ltd to make presentation in the next meeting.

4. Agenda No. 4 - Application by M/s AxaParenterals Ltd. for separate price for Non-Glass with special feature for (i) Ciprofloxacin Injection IP, Compound Sodium lactate Injection IP (Ringer Lactate Solution for injection IP), Dextrose Injection IP (10% w/v), Dextrose Injection (5% w/v) and Fluconazole Injection USP 100 ml in LDPE container with Euro Head

4.1 The Committee was appraised that M/s AxaParenterals Ltd vide its e-mail dated 08.04.2022 requested that due to unavoidable circumstances they would make demonstration of the product regarding claim for special pricing of the special feature bottle in the next meeting. Accordingly, the Committee decided to defer the agenda till the next meeting and directed that M/s AxaParenterals Ltd to make presentation in the next meeting.

5. Agenda No. 5 - Application by M/s AxaParenterals Ltd. for separate price non-glass innovative single use eye drops (preservative free)

5.1 The Committee was appraised that M/s AxaParenterals Ltd vide its e-mail dated 08.04.2022 requested that due to unavoidable circumstances they would make demonstration of the product regarding claim for special pricing of the special feature bottle in the next meeting. Accordingly, the Committee decided to defer the agenda till the next meeting and directed that M/s AxaParenterals Ltd to make presentation in the next meeting.

6. Agenda No. 6 - Retail price fixation under Para 5 of DPCO, 2013- Each hard gelatin PR capsule contains Tacrolimus IP 3 mg for M/s Cadila Healthcare Ltd. (manufacturer and marketer)

6.1 The Committee noted the clarification dated 07.04.2022 received from the Office of the Central Drugs Standard Control Organisation (CDSCO) that they have not received any application of M/s Cadila Healthcare Ltd for manufacture/ import of Tacrolimus Prolonged Release hard gelatine capsules 3 mg. The Committee also observed Para 2(w) (iv) and Explanation to Para 2(w) of New Drugs and Clinical Trials Rules, 2019 which states as follows:

Para 2(w)(iv) – a modified or sustained release form of a drug or novel drug delivery system of any drug approved by the Central Licensing Authority, or



Explanation: The drugs, other than drugs referred to in sub-clauses (iv) and (v), shall continue to be new drugs for a period of four years from the date of their permissions granted by Central Licensing Authority"

The Committee deliberated upon the matter in detail and is of the opinion that since Tacrolimus Prolonged Release hard gelatine capsule 3 mg would continue to be new drugs after promulgation of New Drugs and Clinical Trials Rules, 2019, M/s Cadila Healthcare Ltd would require specific approval from CDSCO to import/ manufacture the formulation Tacrolimus Prolonged Release hard gelatine capsule 3 mg in India. Accordingly, the Committee decided to reject the application of M/s Cadila Healthcare Ltd for retail price fixation of Tacrolimus Prolonged Release hard gelatine capsules 3 mg since CDSCO has not given approval to M/s Cadila Healthcare Ltd to import/ manufacture the formulation Tacrolimus Prolonged Release hard gelatine capsule 3 mg.

7. Agenda No. 7 - Fixation of Ceiling Price of Clotrimazole 1% mouth paint under DPCO 2013 (NLEM 2015).

7.1 The Committee noted the clarification dated 07.04.2022 received from the Office of the Central Drugs Standard Control Organisation (CDSCO) that the formulation Clotrimazole 1% mouth paint is not approved by CDSCO. The Committee deliberated upon the matter in detail and is of the opinion that since Clotrimazole 1% mouth paint is not approved by CDSCO, it cannot be categorised as scheduled formulation as per Explanation-I of DPCO 2013. Accordingly, the Committee decided that Clotrimazole 1% mouth paint is not a scheduled formulation as per Explanation-I of DPCO 2013 and hence its ceiling price not to be fixed.

8. Agenda No. 8 – Other issues

8.1 The Committee is of the conscious view that the benefit of price reduction due to expiry of the patents is to be passed on the consumers for which the reduction of 50% on the patented component of the scheduled formulation is allowed in respect of FDCs of 'Sitagliptin+ Metformin tablet' and 'Linagliptin+ Metformin tablet'. The Committee deliberated upon the matter in details and is of the opinion that the benchmark of 50% may be examined on case-to-case basis by the Committee for the medicines which has become/ is on the verge of becoming off-patent. Accordingly, the Committee decided that the issue may be undertaken in its next meeting for deliberation so as take considered view on the matter.

The meeting ended with a vote of thanks to all.



(Prasenjit Das)
Deputy Director (Pricing)

Copy to:
All members of the Committee.

