

National Pharmaceutical Pricing Authority

Subject: Minutes of the 27th meeting of Multidisciplinary Committee of Experts held on 10.02.2021 at 3:00 PM in NPPA

27th meeting of the “Multidisciplinary Committee of Experts” was held on 10.02.2021 under the Convenorship of Sh. N.I. Chowdhury, Adviser (Cost), in NPPA. The following members attended the meeting through video conferencing:-

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

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

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

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

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

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

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

- (i) Under para 5 of DPCO 2013 by taking the data of six month prior to the date of application*
- (ii) By adding 16% retailer margin to the average Price To Retailer (PTR) based on the Form-V data submitted by the companies for whom retail prices were earlier approved for these subject FDCs.*

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

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

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

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

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

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

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

1.5. The Committee also observed that the Authority in its 80th meeting dated 26.10.2020 approved the recommended methodology, as mentioned in para 1.4 above, towards fixation of retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 500mg (as sustained release form) for various companies. The Committee also observed that similar decision was also taken by the Authority in its 81st, 82nd and 83rd meeting dated 24.11.2020, 23.12.2020 and 27.01.2021 respectively.

1.6 The Committee deliberated upon the matter in detail and decided to derive the retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 500mg (as sustained release) by adding the maximum of the difference in presently applicable notified ceiling price of Metformin IR & CR 500mg and 1000 mg tablet i.e. Rs. 0.41, as mentioned in para 1.1 above, with the retail price calculated based on the methodology decided by the Authority in its 72nd meeting dated 20.01.2020, as specified in 1.2, i.e. Rs. 6.45 and recommend the same.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2.5. The Committee also observed that the Authority in its 80th meeting dated 26.10.2020 approved the recommended methodology, as mentioned in para 2.4 above, towards fixation of retail price of each uncoated bilayered tablet containing Vildagliptin 50mg and Metformin Hydrochloride 1000mg (as sustained release form) for various companies. The Committee also observed that similar decision was also taken by the Authority in its 81st, 82nd and 83rd meeting dated 24.11.2020, 23.12.2020 and 27.01.2021 respectively.

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

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

3. Agenda no. 3 - Retail price fixation for companies in respect of formulations to which exemption granted under para 32 of DPCO 2013 has been expired.

3.1 The Committee noted that the exemption granted under para 32 of DPCO 2013 to M/s Torrent Pharmaceuticals Ltd and M/s Wockhardt Ltd were expired as detailed below:

| Sl. No. | Company | Products | Applicable provision of DPCO, 2013 | SO. No. and Date | Applicability of the exemption as per SO. | Date from which the exemption is ineffective |
|---------|---------------------------------|--|------------------------------------|------------------------------|--|--|
| (A) | (B) | (C) | (D) | (E) | (F) | (G) |
| 1 | M/s Torrent Pharmaceuticals Ltd | FDC of Prasugrel Hydrochloride 10 mg (as film coated) plus Aspirin 75 mg (as enteric coated) | Para 32(iii) | SO. 2110(E) dated 21.08.2014 | Period of five years with effect from 15.01.2014 | 15.01.2019 |
| 2 | M/s Wockhardt Ltd | (i) Insulin Human Injection, | Para 32(iii) | SO. 3131(E) dated | Period of five years with effect from | 08.01.2020 |

| | | | | | | |
|--|--|---|--|------------|------------|--|
| | | 200IU/ml (ii) Isophane Insulin Human Suspension 200IU/ml (iii) 70% Isophene Insulin Human Suspension and 30% Insulin Human Injection 200IU/ml | | 20.11.2015 | 08.01.2015 | |
|--|--|---|--|------------|------------|--|

3.2 The Committee further noted that neither M/s Torrent Pharmaceuticals Ltd nor M/s Wockhardt Ltd applied retail price fixation for the formulations “FDC of Prasugrel Hydrochloride 10 mg (as film coated) plus Aspirin 75 mg (as enteric coated) capsule” and “(i) Insulin Human Injection, 200IU/ml (ii) Isophane Insulin Human Suspension 200IU/ml and (iii) 70% Isophene Insulin Human Suspension and 30% Insulin Human Injection 200IU/ml” respectively after the expiry of the exemption granted under Para 32 of DPCO 2013, even being an existing manufacturers/ marketers. The Committee also noted that M/s Torrent Pharmaceuticals Ltd and M/s Wockhardt Ltd has intimated NPPA about the price of their formulations “FDC of Prasugrel Hydrochloride 10 mg (as film coated) plus Aspirin 75 mg (as enteric coated) capsule” and “(i) Insulin Human Injection, 200IU/ml and (ii) 70% Isophene Insulin Human Suspension and 30% Insulin Human Injection 200IU/ml” after the expiry of the exemption granted under para 32 of DPCO 2013. M/s Wockhardt Ltd further stated that they have not launched/ manufactured “Isophane Insulin Human Suspension 200IU/ml”.

3.3 The Committee also noted the representation of the companies that the price approvals are not required for the formulations since it is an old drug/ not new launch. The Committee observed that the representations of the companies are not tenable since on being granted exemption under Para 32 of DPCO 2013, none of the provisions of DPCO 2013 is applicable during the exemption period. However, on expiry of the period of exemption, the provisions of DPCO 2013 becomes applicable and accordingly the price approval is required for manufacturing/ marketing of “FDC of Prasugrel Hydrochloride 10 mg (as film coated) plus Aspirin 75 mg (as enteric coated) capsule” and “(i) Insulin Human Injection, 200IU/ml (ii) Isophane Insulin Human Suspension 200IU/ml and (iii) 70% Isophene Insulin Human Suspension and 30% Insulin Human Injection 200IU/ml” by M/s Torrent Pharmaceuticals Ltd and M/s Wockhardt Ltd respectively, both being an existing manufacturer.

3.4 The Committee deliberated upon the matter in detail and is of the view that the retail price is to be fixed for “FDC of Prasugrel Hydrochloride 10 mg (as film coated) plus Aspirin 75 mg (as enteric coated) capsule” and “(i) Insulin Human Injection, 200IU/ml (ii) Isophane Insulin Human Suspension 200IU/ml and (iii) 70% Isophene Insulin Human Suspension and

30% Insulin Human Injection 200IU/ml” for M/s Torrent Pharmaceuticals Ltd and M/s Wockhardt Ltd respectively.

3.5. The Committee noted the data of the formulations are available in AIOCD-AWACS (Pharmatrac) database. The Committee observed that with respect to the “FDC of Prasugrel Hydrochloride 10 mg (as film coated) plus Aspirin 75 mg (as enteric coated) capsule” there are manufacturers/ marketers other than M/s Torrent Pharmaceuticals Ltd. The Committee further observed that with respect to “(i) Insulin Human Injection, 200IU/ml and (ii) 70% Isophane Insulin Human Suspension and 30% Insulin Human Injection 200IU/ml”, the data of only M/s Wockhardt Ltd is available. The Committee also observed that ““(i) Insulin Human Injection, 200IU/ml (ii) Isophane Insulin Human Suspension 200IU/ml and (iii) 70% Isophane Insulin Human Suspension and 30% Insulin Human Injection 200IU/ml” are not comparable with the insulin specified in Schedule-I of DPCO 2013 for fixation of price. Accordingly, the Committee deliberated upon the matter relating to fixation of the retail price of the formulations and decided to fix the retail price as per Para 5 of DPCO 2013 by taking the data for the month which is six month prior to the month of the meeting in which the price is recommended i.e. the data for the month of July 2020.

3.6 The Committee also decided not to fix the retail price of ‘Isophane Insulin Human Suspension 200IU/ml’ for M/s Wockhardt Ltd since the company have not launched/ manufactured the formulation.

3.7 Accordingly, the Committee recommended the retail price as detailed below:

a. M/s Torrent Pharmaceuticals Ltd

i. ‘Prasugrel Hydrochloride 10 mg (as film coated) plus Aspirin 75 mg (as enteric coated) capsule’ – Rs. 20.16 per capsule excluding GST.

b. M/s Wockhardt Ltd

(i) Insulin Human Injection, 200IU/ml – Rs. 106.65 per ml excluding GST

(ii) 70% Isophane Insulin Human Suspension and 30% Insulin Human Injection 200IU/ml – Rs. 106.65 per ml excluding GST

3.8 The Committee further desired that a suitable guidelines regarding action to be taken by the company on expiry of the exemption granted under para 32 of DPCO 2013 be framed and put up in public domain.

The meeting ended with a vote of thanks to all.

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

Copy to:
All members of the Committee.

