

**No. 31015/74/2016-PI.I**  
**GOVERNMENT OF INDIA**  
**MINISTRY OF CHEMICALS & FERTILIZERS**  
**DEPARTMENT OF PHARMACEUTICALS**

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B Wing, Janpath Bhawan,  
New Delhi 110 001

**Subject:** Review application of M/s Glenmark Pharmaceuticals Ltd. against price fixation of Teneligliptin 20 mg + Metformin 1000mg ER tablets vide NPPA order No. S.O. 2570(E) dated 29/07/2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref:** 1) Review application dated 08.08.2016  
2) NPPA notification under review S.O. No.2570(E) dated 29.07.2016  
3) Record Note of discussions held in the personal hearing held in the matter on 09.09.2016.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Glenmark Pharmaceuticals Ltd. (hereinafter called the petitioner) against notification S.O. No.2570(E) dated 29.07.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the retail price of Teneligliptin 20 mg + Metformin 1000mg ER tablets.

2. The petitioner has contended as under:

- I. This is with reference to the aforesaid Order fixing the Retail Price for their product "Teneligliptin 20 mg + Metformin 1000mg ER Tablets" pursuant to our Form I application dated 28.03.2016.
- II. They submitted that the NPPA has not uploaded the working sheet with regard to the derivation of the Retail Price for their product to enable them to submit a detailed review and reserve their right to do as and when the working sheet is uploaded on the site or submitted to them.

- III. The Retail Price declared by NPPA is Rs.11.65 per Tablet which works out to a MRP of Rs.122.33 for a pack of 10's. Their view is that the Retail Price declared by NPPA is incorrect.
- IV. They further submitted that the NPPA has not properly worked out the average price, which according to us should be MRP Rs.10.83 per Tablet of Teneiglipitin 20 mg. They enclosed the Pharma Trac data for the month of June 2016, relied upon by them, to arrive at the said price. At a later date they would submit the carton of the competitors to substantiate the MRP for Teneiglipitin 20 mg Tablets as stated in the Pharma Trac data sheet.
- V. Taking into consideration the said price of Rs. 10.83 for Teneiglipitin 20 mg and Rs. 3.55 for Metformin 1000mg, the price works out to Rs. 14.38 per tablet. Hence the MRP for a pack of 10's would be Rs. 143.82 as against Rs. 122.33 declared by NPPA.
- VI. The workings are detailed in the table below:-

Particulars	MRP/Tab	MRP/Pack of 10's
Teneiglipitin 20 mg Tablet	10.83	108.33
Metformin 1000 mg Tablet (as per S.O. No. 1253 ( E) Dated 29.03.2016, Ceiling price 3.38+5% VAT)	3.55	35.49
<b>Teneiglipitin 20 mg + Metformin ER 1000 Tablets</b>	<b>14.38</b>	<b>143.82</b>

- VII. They requested this Department to kindly review the said order passed by the NPPA and direct them to relook at the working sheet and data relied upon by them and revise the price accordingly.

**Comments of NPPA:**

- (i) NPPA has fixed ceiling price of Rs. 1.39 per tablet vide S.O. 1351 (E) dated 02/06/2016 under para 4, 10, 11, 14, 16, 17 & 18 of DPCO, 2013 based on Pharmatrac data as per existing practice.
- (ii) On scrutinizing the representation, it is observed that PTR and MAT value in respect of X-MET 500mg tablet used in working sheet is correct and hence the representation of the company is not tenable. NPPA has informed company vide letter F.No. 10(sec. 21.4.1.4)/2016/DP/Div.II/NPPA dated 14/07/2016.

During the personal hearing, the representatives of the petitioner company further submitted that even after a lapse of nearly 6 weeks, NPPA has yet not uploaded the working sheet with regard to the Retail Price of Teneeligiptin 20 mg + Metformin 1000 mg ER Tablets fixed vide their order dated 29.07.2016.

In continuation to the Review application filed on 8<sup>th</sup> August, 2016, the petitioner company reaffirmed the price worked out at PTR and Retail Price as per their calculation. In support of the same, the company enclosed the Pharma Trac data for the month of June 2016, relied upon by them, for ready reference.

As per the Pharma Trac June 2016 data for plain Teneeligiptin, the average Price to Retailer (PTR) comes out to be Rs.8.31 per tablet of Teneeligiptin 20 mg. Consequently, the Retail Price (RP) works out to Rs.9.64 per tablet after adding 16% Retailer's Margin as provided under DPCO. Post that, if one were to add the ceiling price for Metformin 1000 which Rs.3.38 per tablet of Metformin 1000mg, the total Retail Price for Teneeligiptin 20 mg + Metformin 1000 mg ER Tablets comes to Rs.13.02 per

tablet as against Rs.11.65 declared by NPPA. The working is summarized in the table below:

<b>Particulars</b>	<b>Retail Price or Ceiling Price/Tab</b>
Teneligliptin 20 mg Tablet	9.64
Metformin 1000 mg Tablet (as per S.O. No. 1253 ( E) Dated 29.03.2016, Ceiling price 3.38)	3.38
Teneligliptin 20 mg + Metformin ER 1000 Tablets	13.02

The company once again provided the carton of major brands in the market to substantiate the MRP of Teneligliptin 20 mg Tablets as stated in the Pharma Trac data sheet.

3. During the personal hearing, the company was provided with the Working Sheet of Pharma Trac data of June, 2016 of Teneligliptin 20 mg. tablets. Upon perusal, it is noted that the data of following two companies, having more than 1% market share, were missing:

S.No.	Name of company	Market Share	PTR (Rs. per tablet)
1	Wockhardt	5%	15.32
2	Alembic	3.4%	8.99

It was also pointed out by the company that the data of one company, M/s Intas had an error of PTR and the corrected PTR in respect of that company is as below :-

S.No.	Name of company	Market Share	PTR (Rs. per tablet)
1	Intas	6%	15.24

The company requested take the aforesaid data into consideration and direct NPPA to refix the price of Teneligliptin 20mg + Metformin 1000mg tablets within a period of 1 month from the date of order.

At this point, the company further stated that it would be pertinent to mention that despite a clear cut time bound order from DoP in any review matter, NPPA is found to be adopting a peculiar process nowhere defined in the DPCO and/or any office memorandum whereby for reasons best known to NPPA, they are again writing back to companies/Pharma Trac for reconfirming data which is challenged in the first place and is under review. This obviously leads to a situation, where despite an explicit review order from DoP in any matter, NPPA continues to wait indefinitely for the said external parties/agencies to respond, pending which the review matter is not put to a time bound closure.

As regards the point raised by the company regarding working sheet, NPPA representative submitted that since subject formulation was launched first time in 2016, hence there was no market data available to arrive at the ceiling price as per DPCO, 2013. Hence, there was no working sheet. Accordingly, the price was fixed on the principles of Pharmacoeconomics as per Para 15(3) of DPCO, 2013.

As regards non-inclusion/wrong inclusion of Pharma Trac data in the working sheet while calculating the price of Teneeligiptin 20 mg. tablets, the matter will be examined, after furnishing of data by the company.

NPPA generally implement the review order after getting the relevant information and verification of the same.

#### **4. Examination:**

The petitioner company filed review application against NPPA Order No.SO 2570(E), dated 29.07.2016 for price fixation of their formulation Teneeligiptin 20 mg + Metformin 1000mg ER tablets. The company submitted Form I application on 8.03.2016

for fixing the Retail Price for their product “Teneligliptin 20 mg + Metformin 1000mg ER Tablets”. NPPA Rs.11.65/tablet which works out to a MRP of Rs.122.33 for a pack of 10’s. The company aggrieved with the price, requested for providing the calculation sheet.

NPPA fixed the price based on the principles of Pharmacoeconomics as per para 15(3) of DPCO, 2013, in the 6<sup>th</sup> Meeting of Standing Committee of Experts held on 20.7.2016. The Standing Committee of Experts considered the data of M/s Glenmark Pharmaceuticals Ltd. & Ajanta Pharma Ltd. and marketed by various companies. The said companies claimed retail price ranging from Rs.13.52 to Rs.22.00 per tablet. The formulation is DCG(I) approved.

The Committee observed that although as per paragraph 9(4) of DPCO, 2013, the market based data for fixing the retail price of new drug available in the market, shall be the data available for the month ending immediately before six months of receipt of application for fixing the price of the new drug. However, the Committee observed that since Teneligliptin is a new molecule which has been launched recently by different companies, for computation, the data of Teneligliptin tablet 20 mg based on current data of Pharmatrac June, 2016 may be considered. Accordingly, NPPA fixed the retail price of composition Teneligliptin 20 mg. + Metformin 1000 mg ER tablets as per tabulation given below:-

<b>Formulation</b>	<b>Basis</b>	<b>Amount (Rs.)</b>
Teneligliptin 20 mg	Price computed as per para 4 of DPCO, 2013 based on current data of Pharmatrac June, 2016	8.27
Metformin 1000 mg (CR)	Ceiling price fixed under NLEM 2015 vide SO 1253(E), dated 29.3.2016	3.38
	<b>TOTAL</b>	<b>11.65</b>

The company submitted its own calculation and based on Pharma Trac June 2016 data for plain Teneligliptin, the average Price to Retailer (PTR) comes out to be Rs.8.31 per tablet of Teneligliptin 20 mg. Consequently, the Retail Price (RP) works out to Rs.9.64 per tablet after adding 16% Retailer's Margin as provided under DPCO. Post that, if one were to add the ceiling price for Metformin 1000 which Rs.3.38 per tablet of Metformin 1000mg, the total Retail Price for Teneligliptin 20 mg + Metformin 1000 mg ER Tablets comes to Rs.13.02 per tablet as against Rs.11.65 declared by NPPA. The company provided with the Working Sheet of Pharma Trac data of June, 2016 of Teneligliptin 20 mg. tablets, and on perusal it is noted that the data of following two companies, viz. Wockhardt and Alembic, having more than 1% market share, were missing. It was also noted that the wrong PTR data of one company, i.e. M/s Intas, was taken while fixing the retail price.

In view of the above, it is observed that NPPA has erred in taking the correct data while fixing the retail price of the subject formulations. Hearing Authority is of the view that NPPA may be directed to examine the data/information submitted by the company, on merit, and to re-fix the retail price of the subject formulation within a period of one month from the date of Order by the Reviewing Authority.

6. **Decision of the Government:**

**“NPPA is hereby directed to examine the data/information submitted by the company, and to re-fix the retail price of Teneligliptin 20 mg + Metformin 1000mg ER tablets, on merit, within a period of one month from the date of issue of this Order.”**

Issued on this date, the 5<sup>th</sup> day of January, 2017.

**(M.K. Bhardwaj)**  
**Deputy Secretary**  
**For and on behalf of the President of India**

**To**

- 1. M/s. Glenmark Pharmaceuticals Ltd.  
7-D, Atmaram House, 1, Tolstoy Marg,  
New Delhi-110 001.**
- 2. The Member Secretary,  
National Pharmaceutical Pricing Authority,  
YMCA Cultural Centre Building, New Delhi-110001**

**Copy to :**

- 1. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.**
- 2. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.**
- 3. T.D., NIC for uploading the order on Department's Website**