

**No. 31015/16/2016-PI.I**  
**GOVERNMENT OF INDIA**  
**MINISTRY OF CHEMICALS & FERTILIZERS**  
**DEPARTMENT OF PHARMACEUTICALS**

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B Wing, Janpath Bhavan,  
New Delhi 110 001

**Subject:** Review application of M/s Glenmark Pharmaceuticals Ltd. against price fixation of Telmisartan/Telma (20 mg, 40 mg, 80 mg), Metformin/X-Met (1000mg, 500 mg) & Glimepiride vide NPPA order No. S.O. 1253(E) dated 29/03/2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref:** 1) Review application dated 22.04.2016  
2) NPPA notification under review S.O. No.1253(E) dated 29.03.2016  
3) Record Note of discussions held in the personal hearing held in the matter on 16.6.2016.

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.1253(E) dated 29.03.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Telmisartan/Telma (20 mg, 40 mg, 80 mg), Metformin/X-Met (1000mg, 500 mg) & Glimepiride.

2. The petitioner has contended as under:

- (i) The notified Ceiling Prices **are at variance due to difference in PTR as considered by NPPA vis a vis PTR as on Aug 2015** coming from their records. The same is illustrated below:

Generic name/ Brand	Strength	Pack size	PTR (Rs.) as per NPPA working sheet uploaded on their website	Actual PTR as of Aug 2015 per company records
TELMISARTAN / TELMA	80 MG	15	151.68	166.03
TELMISARTAN / TELMA	40 MG	15	94.70	103.68
TELMISARTAN / TELMA	20 MG	15	50.58	55.38
METFORMIN / X-MET	500 MG	15	19.85	20.61
METFORMIN / X-MET	1000 MG	15	45.06	49.37
GLIMEPIRIDE / GLIMULIN	2 MG	15	71.74	82.67

To support their actual PTR, they submitted a copy of Form V, a copy of Invoice to the retailer and the control sample.

3. The contentions of petitioner and the NPPA were heard on 16<sup>th</sup> June, 2016.

4. In the hearing, the company submitted that erroneous and unverified PTR has been considered by the Authority while arriving at the Ceiling Price. The company submitted the control samples, Form V and Invoice copies that denote the correct PTR which should be considered for calculating the Ceiling Price. A summary of the same is given below:

Composition as per NLEM	Pack Description	Strength	Pack size	Unit	PTR (Rs.) as per NPPA working sheet	Actual PTR as of Aug 15 as per our records
TELMISARTAN   C9D4	TELMA 80 MG TABLET 15	80 MG	15	TABLET	151.68	166.03
TELMISARTAN   C9D4	TELMA 40 MG TABLET 15	40 MG	15	TABLET	94.70	103.68
TELMISARTAN   C9D4	TELMA 20 MG TABLET 15	20 MG	15	TABLET	50.58	55.38
METFORMIN   A10B6	X-MET 500 MG TABLET SR 15	500 MG	15	TABLET SR	19.85	20.61
METFORMIN   A10B6	X-MET 1000 MG TABLET SR 15	1000 MG	15	TABLET SR	45.06	49.37
GLIMEPIRIDE   A10B4	GLIMULIN 2 MG TABLET 15	2 MG	15	TABLET	71.74	82.67

The company representative further submitted that this information has already been given to NPPA on 19.05.2016.

5. NPPA representative submitted that in face of the documents presented, NPPA will reconsider its price fixation order for the medicine, in question.

6. **Decision of the Government:**

NPPA is directed to re-fix the ceiling price of “Telmisartan/Telma (20 mg., 40 mg., 80 mg.), Metformin/X-Met (1000mg., 500 mg.) & Glimepiride” after taking into consideration data furnished by the petitioner company within a period of one month from the date of issue of this Order.

Issued on this date, the 22<sup>nd</sup> day of July, 2016.

(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