

No. 31015/60/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

B Wing, Janpath Bhavan,
New Delhi 110 001

Subject: Review application of M/s Glenmark Pharmaceuticals Ltd. against price fixation of Metformin 500 mg. vide NPPA order No. S.O. 1351(E) dated 02.06.2016 (Corrected as 1951(E) vide OM No.8(31)/2016/DP/NPPA/Div.II, dated 3.8.2016) issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 30.06.2016
2) NPPA notification under review S.O. No.1351(E) dated 02.06.2016 [corrected SO 1951(E)]
3) Record Note of discussions held in the personal hearing held in the matter on 22.7.2016.

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.1351(E) dated 02.06.2016 [corrected SO 1951(E)] issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Metformin 500 mg.

2. The petitioner has contended as under:

The review is against S.O. No.1351(E) dated 02.06.2016 [corrected SO 1951(E)], which has notified Ceiling Price that are at variance due to difference in PTR as considered by NPPA vis a vis PTR as on August 2015 available from their records. The same is illustrated below:-

Composition as per NLEM	Pack Description	Strength	Pack Size	PTR (Rs.) as per NPPA working sheet	Actual PTR	MAT Aug'15 Sales Value* (cr)
METFORMIN/A10 B6	X-MET 500 MG Tablet 15	500 MG	15	19.85	20.61	1.50

I. They enclosed copies of Form V, Invoice and a control sample of August 2015 and requested this Department to look into the matter.

Comments of NPPA:

(i) NPPA has fixed ceiling price of Rs.1.39 per tablet vide S.O. 1351(E) dated 02.06.2016 [corrected SO 1951(E)] 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 company confirmed that they have implemented the price notified by NPPA vide their SO No.1351(E) dated 2.6.2016 [corrected SO 1951(E)] before filing the review petition.

In addition to the written submissions made earlier, the company representative further submitted that as per their understanding, the PTR considered by the Authority while arriving at the Ceiling Price is erroneous, as is captured in the table below:

Composition as per NLEM	Pack Description	Strength	Pack size	PTR (Rs.) as per NPPA working sheet	Actual PTR claimed by Glenmark	MAT Aug'15 Sales Value* (Cr)
METFORMIN A10B6	X-MET 500 MG TABLET 15's	500 MG	15	19.85	20.61	1.50

*Sales value as per ORG IMS

The company further contended that even though they are in receipt of a reply from NPPA wherein NPPA has found the representation of the company as “untenable” without giving any reason. The company would like to reiterate that the evidences today being once again brought on record, namely, copies of invoice, copy of Form-V - duly receipted by NPPA on 6th July, 2015 and a copy of the actual physical pack, all point to the fact that the PTR claimed by the company, namely, Rs.20.61 is the actual PTR and the PTR considered by NPPA supposedly by placing singular reliance on Pharma Trac data, is wrong.

The company requested to consider the above points and help re-fixing the correct ceiling price at the soonest.

NPPA representative submitted that the ceiling price of Metformin IR tablets 500 mg has been fixed based on Pharma Trac data as per provisions of DPCO 2013. M/s Glenmark Pharmaceuticals Ltd. represented about the inaccuracy of PTR and MAT data of their product in the working sheet and provided their version of PTR and MAT

data along with supporting documents. The documents were sent to Pharma Trac for verification/confirmation as per the existing practice of the Authority. Pharma Trac confirmed that the data provided by them (which was considered in the working sheet) is correct. As such, the representation of the company is not considered by the Authority.

4. Examination:

The petitioner company has requested for review of NPPA SO No.1351(E), dated 02.06.2016 [corrected SO 1951(E)] wherein ceiling price of their product "Metformin 500 mg" has been fixed. They have requested for re-fixation of the same on the following grounds :-

The NPPA captured erroneous PTR of Rs.19.85 as against actual PTR of Rs.20.61 claimed by the company.

The petitioner company is not satisfied with the reply of NPPA, dated 14.7.2016 that the representation of the company is not tenable as NPPA has taken correct data.

It is seen from the record note of the hearing in the matter that NPPA has re-confirmed the PTR taken in their working sheet from original data source, i.e. Pharma Trac only. However, it would be appropriate if NPPA takes into account the documentary evidences furnished by the petitioner company on merit and reconsider its decision.

5. Government Decision:

NPPA is directed to examine the documentary evidence furnished by the petitioner company on merit and issue the order for re-fixation of price of the formulation "Metformin 500 mg." within one month of the issue of this Order.

In view of the above, the present review petition stands disposed off.

Issued on this date, the 14th day of September,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**