

No. 31015/27/2015-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

B Wing, Janpath Bhavan, New Delhi

O R D E R BY REVIEWING AUTHORITY UNDER PARA 31 OF DPCO, 2013

Subject: Review applications of M/s. FDC Ltd. against fixation/revision of ceiling prices of “Voglibose + Metformin tablets (Zibose M 0.2 and Zibose M.0.3)” vide NPPA notification S.O. No. 1206(E) dated 6/5/2015 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013).

Ref. 1) The Review application dated 14.05.2015
 2) NPPA notification under review S.O. No. 1206(E) dated 6/5/2015
 3) Record Note of discussions held in the personal hearing held in the matter on 30.06.2016

This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s FDC Ltd. (hereinafter called the petitioner) against notification S.O. No.1206(E) dated 06.05.2015 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of “**Voglibose + Metformin tablets (Zibose M 0.2 and Zibose M.0.3)**”.

2. During the personal hearing held on 30.6.2016, the petitioner has contended as under:

Company’s Comment:

3. The company representative referred to para 9.4 of DPCO 2013 and mentioned that as per the provisions of para 9.4 the market based data should have been followed for the month ending immediately 6 months before receipt of application. The company had filed a new drug application on 12.11.2014 and therefore the data of 6 months before i.e. May 2014 should have been considered which NPPA has not. The company representative also mentioned that they have not been provided with the work sheet of the price fixation.

4. The company representative mentioned that as per 14th meeting of the Authority the companies which intend to market new drug should be informed to file form I application for new drug and if such companies intend to market their new drug at already notified retail price for any other drug in the past, such companies be permitted to proceed with new drug launch at that retail price. Further the company be permitted to increase their new drug retail price by 10% under price 20(1) of DPCO 2013.

NPPA comments:

5. In this regard, NPPA representative stated that NPPA in its 14th Authority meeting held on 23.04.2014 decided that “in case of From I application, price fixed by NPPA shall be valid for one year for the formulation having same composition & strength and no increase in price will be allowed. However, in case the current price worked out/claimed by the company to be lower than the existing notified prices, the benefit of lower price has to be passed on the consumers”. The earlier notified prices for formulation ‘Metformin 500mg + Voglibose 0.2mg’ notified vide S.O. 1793(E) dated 10.07.2014 and for formulation ‘Metformin 500mg + Voglibose 0.2mg’ notified vide S.O 1318(E) dated 19.05.2014 has been extended to M/s FDC also (which is the same i.e. Rs. 52.38 pack of 10 Tablets) in line with NPPA’s Authority decision in public interest.

6. NPPA representative mentioned that a decision taken by NPPA in its 14th Authority meeting was in consumer interest to give the benefit of lowest of three prices i.e. lowest notified price, worked out price and company claimed price. NPPA did not intend to make a new drug price to be a ceiling price or permit automatic approval of price for launch of any new drug. Further the increase in price can be taken after the launch of the product and the companied cannot claim that benefit linked to the formulation launched by any other company.

7. During the personal hearing on 30.6.2016, the petitioner company further submitted that identical retail price fixation for two different dosages is not appropriate. Further, the NPPA stand of following retail price fixed for new drug for one year is not consistent with paragraph 9(4) of the DPCO 2013. Moreover, the first time Rs.52.38 retail price was fixed for Abbott on 17.2.2014, which has been applied to their company also in May, 2015, which is more than 15 months later.

8. **NPPA representative mentioned** that decision taken by NPPA was in consumer interest to give the benefit of lowest of three prices, i.e. lowest notified price, worked out price and company claimed price. NPPA did not intend to make a new drug price to be a ceiling price or permit automatic approval of price for launch of a new drug. On being clarification sought by the Department on this issue, the NPPA placed the matter in the 23rd Authority Meeting held on 30th July, 2015. The Authority deliberated on this issue and considered that the abovesaid decision of one year was taken in right spirit, keeping in view the larger interest of the consumers, as WPI is eligible only after completion of one year from the date of Notification.

Examination:

9. As per provision of para 5(1) read with para 9(4) of DPCO 2013 NPPA is required to consider the PTR of available drugs in the market, take simple average of all those who have more than 1% market share and consider the new drug price as per the simple average formula contained in para 4(1) of DPCO 2013. The decision of the Authority to apply any other formula amounts to amending the provisions of DPCO 2013 for which NPPA has no authority. Further while deciding that NPPA will consider the already notified price if it happens to be lower to the new drug applicant does not make it clear about the annual increase which is a subjective decision of NPPA. NPPA may be directed not to invent new methods of allowing prices which are not mentioned in DPCO 2013 and if NPPA strongly feels about it then they should write to the

Government for amending the provisions of DPCO 2013 by following due procedure for amendment.

Decision of the Government:

10. Based on the above and other documents on record, the Government has decided as under:

“Review application of the company is accepted and NPPA is directed to fix the price as per the provisions of DPCO 2013 rather than deciding the ceiling prices on its own principles which are not as per the provisions of DPCO 2013.”

Issued on this date 30th day of August, 2016.

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

To

1. **M/s. FDC Ltd.,
142-48, S.V. Road
Jogeshwari(W)
Mumbai-400102**
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. **Sr. PPS to Secretary (Pharma), Shastri Bhawan, New Delhi for information.**
3. **Technical Director, NIC with the request to upload the review order on the Department's website**