

No. 31015/8/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

B Wing, Janpath Bhawan,
New Delhi 110 001

Subject: Review application of M/s FDC Ltd. against price fixation of “Metformin (1000 mg), Flunarizine, Ramipril etc.” vide NPPA order No. S.O. 1253(E) dated 29.03.2016 and SO 1405(E) dated 12.4.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 19.04.2016
2) NPPA notification under review S.O. No.1253(E) dated 29.03.2016 and SO No.1405(E) dated 12.4.2016
3) Record Note of discussions held in the personal hearing held in the matter on 17.5.2016.

1. 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.1253(E) dated 29.03.2016 and SO No.1405(E) dated 12.4.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Metformin (1000 mg), Flunarizine, Ramipril etc.

2. The petitioner has contended as under:

- (i) Separate notifications should be issued for existing scheduled medicines & others for which prices are notified for the first time. In para 4 of DPCO, 2013, there is no provision to add or subtract ceiling price due to increase or decrease in WPI index. As mostly ceiling prices have been fixed for the first time, WPI index linked reduction is not applicable.
- (ii) In Notification No. 1253, certain existing scheduled medicines have been included such as Atorvastatin 10 mg, Metoprolol 25 mg and Metoprolol 50 mg. For such medicines, price reduction linked to WPI index is proper. However, in rest of cases where ceiling price is notified for the first time under para 4, reducing ceiling price linked to WPI index is uncalled for and is in contravention of DPCO provisions (particularly para 4 and para 16).
- (iii) Majority of 173 medicines (103+70) covered under Notifications 1253(E) and 1405(E) dated 29/03/2016 and 12/04/2016 respectively are medicines which were hitherto non-scheduled and by virtue of Notification no. S.O. 701 (E) dated 10/03/2016 (NLEM 2015) have become DPCO Schedule I drugs. In all these cases, WPI linked price reduction cannot be made.
- (iv) Ceiling price fixed under para 4 should be strictly based on prescribed formula of simple average price to retailer plus 16% retail margin. That it should not be adjusted for WPI index.
- (v) Para 16(1) of the DPCO 2013 clearly points out that WPI index is Annual for a calendar year i.e. from 1st January to 31st December, that means, WPI linked price adjustment is only for calendar year to calendar year. In other words, WPI

index 2.7105% denotes fall in Wholesale Price Index for calendar year for 2015 over calendar year 2014. However, the ceiling prices notified under above notifications have been calculated based on Pharmatrac MAT (Moving Annual Total) sales to retailer for the period September 2014 to August 2015. **In other words, MAT sales data is not for the calendar year 2015.**

In view of magnitude and severity of uncalled for reduction linked to WPI index, which is contrary to the DPCO para 4 & 16, the company requested this Department to direct the NPPA at the earliest to amend/correct/withdraw the above ceiling price notifications.

Comments of NPPA:

DPCO, 2013 came into existence w.e.f. 15/05/2013 & NPPA has fixed that ceiling price for Betaxolol Hydrochloride drops 0.5% vide S.O No. 1677(E) dated 14/06/2013. The benefit of WPI was admissible after the expiry of one year. As regards points No.5 to 11 of the review application dated 19.4.2016 of the company, NPPA submitted that Para 4, 10, 11, 14, 16, 17 & 18 of DPCO, 2013 to be referred.

DPCO, 2013 has been issued under Section 3 of Essential Commodities Act, 1955. NPPA is mandated to fix fair, reasonable and affordable prices for all scheduled medicines under DPCO, 2013. Therefore, Company's requests cannot be considered, as they do not seem to have merit.

4. In the personal hearing held on 17.5.2016, in addition to the written submissions, the company submitted that the separate notifications should be issued for existing scheduled medicines & others for which prices are notified for the first time. DPCO para 14(1) makes it obligatory for the Government to notify the ceiling prices of scheduled formulations as per para 4. In para 4 of DPCO, 2013 there is no provision to add or subtract ceiling price due to increase or decrease in WPI index. As mostly ceiling prices have been fixed for the first time. Therefore, WPI index linked reduction is not applicable.

In Notification No. 1253, certain existing scheduled medicines have been included such as Atorvastatin 10 mg, Metoprolol 25 mg and Metoprolol 50 mg. For such medicines, price reduction linked to WPI index is proper. However, in rest of cases where ceiling price is notified for the first time under para 4, reducing ceiling price linked to WPI index is uncalled for & in contravention of DPCO provisions (particularly para 4 and para 16).

The representatives of the company observed that majority of 173 medicines (103+70) covered under Notifications 1253 (E) and 1405 (E) dated 29/03/2016 and 12/04/2016 respectively are medicines which were hitherto non-scheduled and by virtue of Notification no. S.O. 701 (E) dated 10/03/2016 (NLEM 2015) have become DPCO Schedule I drugs. In all these cases, WPI linked price reduction cannot be made.

The representatives further mentioned that ceiling price fixed under para 4 should be strictly based on prescribed formula of simple average price to retailer plus 16% retail margin. That it should not be adjusted for WPI index.

They also mentioned that Para 16(1) of the DPCO 2013 clearly points out that WPI index is Annual for a calendar year i.e. from 1st January to 31st December. That is, WPI linked price adjustment is only for calendar year to calendar year. In other words, WPI index 2.7105% denotes fall in Wholesale Price Index for calendar year for 2015 over calendar year 2014. However, the ceiling prices notified under above notifications have been calculated based on Pharmatrac MAT (Moving Annual Total) sales to retailer for the period September 2014 to August 2015. **In other words MAT sales data is not for the calendar year 2015.**

As ceiling price notifications under DPCO, 2013 in respect of NLEM 2011 was made as per para 4 without factoring WPI, same analogy should be followed for medicines brought under price control for the first time in respect of NLEM 2015. They also further stated that at the time of filing review application on 19.4.2016 only two notifications were in vogue namely notification NO.1253 and 1405. Thereafter, four more notifications viz. notification NO.1560, 1561, 1686 and 1687 were issued on 27th April, 2016 and 9th May, 2016.

The company representative pointed out that para 16 linked WPI increase/decrease presuppose existence of ceiling price and thereafter ceiling price is maintained for one year.

In view of magnitude and severity of uncalled for reduction linked to WPI index and which is contrary to the DPCO para 4 & 16, they requested this Department to direct the NPPA at the earliest to amend/correct/withdraw the above ceiling price notifications.

The representative of NPPA quoted para 16(4) of DPCO, 2013 which states that "In case of decline in wholesale price index, there shall be a corresponding reduction in the maximum retail price and in case of scheduled formulations produced or available in the market before the date of notification of revised ceiling price, the manufacturers shall ensure within a period of forty-five days of the date of such notification that the maximum retail price (MRP) of such scheduled formulation about the revision shall be sent to the Government in either electronic or physical form in Form-II within a period of fifteen days of such revision.

The NPPA representative also stated para 13(3) which provided that in case of decline in wholesale price index, a corresponding reduction in the prices shall be made as per the provision of sub-paragraph (4) of paragraph 16. Hence NPPA has applied the WPI impact in respect of products of FDC to pass on the benefits to the consumers.

6. Examination:

The petitioner company has challenged the S.O. No.1253(E) dated 29.03.2016 and 1405(E) dated 13.04.2016 on the following grounds:-

1. A separate Notification should be issued for the existing scheduled medicines and others for which prices are notified for the first time.
2. For such non-scheduled medicines which have become scheduled medicines in terms of revised schedule-I of DPCO, 2013 the ceiling price for such medicines

are to be fixed for the first time under Para 4 of the DPCO, 2013 and not in terms of Para 16 which envisages for ceiling price revision due to WPI.

The petitioner company has, therefore, requested that the 11 medicines notified by the aforementioned SOs of NPPA are violative of DPCO, 2013 provisions and should be reviewed.

It is seen that the impact of WPI should be taken into consideration in case of revision of prices under Para 16(1), which reads as under::

“The Government shall revise the ceiling prices of scheduled formulations as per the annual Wholesale Price Index (WPI) for preceding year on or before 1st April of every year and notify the same on the 1st day of April every year.”

The grievance of the company is examined under the provisions of DPCO, 2013, and it is seen that **para 13(3) provides that in case of decline in wholesale price index, a corresponding reduction in the prices shall be made as per the provisions of sub-paragraph (4) of paragraph 16.** Since the subject formulations of the petitioner company became scheduled formulation by virtue of Notification No.SO 701(E), dated 10.3.2016 (NLEM 2015), the NPPA has rightly applied the WPI impact in respect of products of FDC to pass on the benefits to the consumers.

As regards, SO 1405(E), dated 12.4.2016, while notifying the said SO, NPPA has not taken into account the WPI impact.

In view of the above, NPPA has fixed the ceiling prices strictly as per the provisions of DPCO, 2013, and the grievances raised by petitioner company has no merit and the review application may be rejected.

Government decision:

“NPPA has fixed the ceiling prices strictly as per the provisions of DPCO, 2013, and the grievances raised by petitioner company have no merit and the review application stands rejected”.

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

Issued on this date of 29th Day of November, 2016.

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

To

- 1. M/s. FDC Ltd.
6th Floor, Tower B,
Vatika Tower, Sector 54,
GURGAON-122 002.**
- 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**