

**No.31015/4/2016-PI.I**  
**Government of India**  
**Ministry of Chemicals & Fertilizers**  
**(Deptt. of Pharmaceuticals)**

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**B Wing, Janpath Bhavan,  
New Delhi - 110 001**

**Subject: The review application of M/s J.B. Chemicals & Pharmaceuticals Ltd. dated 15/03/2016 under para 31 of DPCO against NPPA order No. S.O. 644(E) dated 02/03/2016 for price fixation of Nifedipine Capsules (5 mg & 10 mg) and Ofloxacin Tables (200 mg) – reg.**

M/s J.B. Chemicals & Pharmaceuticals Ltd. has filed a review petition dated 15<sup>th</sup> March, 2016 against the price fixation notified by NPPA vide S.O.No. 644(E) dated 02/03/2016, for their formulation “Nifedipine Capsules (5 mg & 10 mg) and Ofloxacin Tables (200 mg)”.

2. A personal hearing was given to the company on 28.4.2016 and the same was attended by Shri Pranabh Mody, President and Shri Salim Hussain, OSD, on behalf of M/s J.B. Chemicals & Pharmaceuticals Ltd. and Shri S.S.Gaur, Y.P. (Tech.) and Shri L.D. Vashishth, Junior Legal Consultant on behalf of NPPA.

3. The written comments of the company were sent to NPPA and the comments of the NPPA in the matter were placed before the company during the personal hearing. After considering written reply of NPPA, the points raised by the company during personal hearing and replies/comments of NPPA are summarised below:-

4. During the personal hearing, the company representatives stated that Government of India has notified the National List of Medicines (NLEM), 2015 on 23.12.2015 and Department of Pharmaceuticals vide S.O. No. 701(E) dated 10.03.2016 has amended Scheduled-I of DPCO, 2013 for substituting NLEM, 2015. The Company representatives further stated that in the notified NLEM 2015, their above mentioned formulations are not included, and therefore these would be considered as non-Scheduled formulations. In this regard, the representatives contended that once the product is out of Schedule I on 10.3.2016, the WPI as on 1.4.2016 will not be applicable to these products. Hence, the company is eligible to increase the price upto 10% from 1<sup>st</sup> April 2016.

5. NPPA representative submitted that the interpretation, submissions of the petitioner in para 4 above are wrong and denied. In this connection NPPA representative submitted following:-

- (i) DPCO, 2013 has been issued under Section 3 of Essential Commodities Act, 1955. The mandate under DPCO is to provide fair and affordable prices to consumers.
- (ii) Supreme Court in Glaxo Smith Kline vs UOI reported in 2014 SCC vol 2 753 ( para 47, 51, 52 ) has held that benefit of price reduction must be passed to consumers . Apex Court in catena of judgments in number of

cases such as - Cynamide case, Meenakshi mills case has held that public interest is prime consideration whenever Govt. fixes / revises prices of essential commodities such as drugs. Under E.C. ACT, drugs are essential commodity as per section 2A(1). Sec. 3(c) of EC Act provides for controlling the price at which such essential commodity may be brought or sold. Accordingly, Government /NPPA is empowered under the DPCO, 2013 to fix and regulate prices of such essential commodity i.e. Drugs.

- (iii) NPPA has notified ceiling prices of scheduled formulations on 2/3/2016 affecting price reduction due to decline in WPI .Para 16(4) of DPCO,2013 stipulates that there shall be corresponding reduction in the MRP to be affected by all manufacturers in sale of all stock including pre-manufactured stock from date of notification for revised prices . Accordingly, all manufacturers were required to revise their MRPs in terms of para 13(3) and 16(4) of DPCO, 2013. (In fact, Pharma association - IDMA had also informed in March 2016 after issuance of aforesaid notification dated 2/3/16 that such exercise was undertaken by manufacturers, copy of the said IDMA letter was furnished.)
- (iv) On 10/3/2016, Government has amended Schedule -1 of DPCO, 2013 by incorporating formulations /medicines of NLEM2015 . As a result, certain medicines stand included in Schedule -1 and some become non scheduled. NPPA has issued OM dated 06/4/2016 in respect of prices of such formulations which moves out of first schedule , to be kept frozen for 12 months and thereafter price increase upto 10 percent is allowed as per para 20 of DPCO , 2013.
- (v) NPPP 2012 in para 4(xiv), in respect of overlap of Drugs ,states that prices of medicines which are part of DPCO,1995 but not in NLEM-2011would be frozen for one year and thereafter a max. Increase of 10% per annum, as in case of other non NLEM drugs will be allowed .
- (vi) Para 10(4) of DPCO, 2013 stipulates that prices of scheduled formulations which are not specified in DPCO, 1995 but not specified in first Schedule of DPCO,2013 shall remain effective for one year from the date of notification of such prices and thereafter prices of such formulations shall be regulated as in case of other non-scheduled formulations as stated in paragraph 20 of DPCO 2013.
- (vii) Thus, OM dated 6/4/16 is in "analogy " with para10(4) and NPPP, 2012 (para 4(xiv) in respect of such overlapping of drugs .
- (viii) Prime Objective in respect of the above is to protect consumers from undue economic burden resulting due to increase in prices due to transition of such drugs from schedule -1.
- (ix) In clear analogy and precedent followed in very DPCO and in view of fact that revised ceiling prices have been notified on 2/3/16 for such drugs due to decline in WPI, it is rightly stated/ clarified in the OM dated 6/4/16 that the MRPs of such formulations shall be kept frozen and maintained

for twelve months and thereafter increase upto 10% in MRP will be allowed as per para 20 of DPCO,2013.

- (x) In aforesaid Glaxo case supra, the Hon'ble Supreme Court has held that DPCO is a beneficial legislation and benefit of price must be available to consumers. The above said OM is in line with principle laid down by Apex Court.
- (xi) Para 26 of DPCO, 2013 clearly stipulates that no person can sell any formulation to consumer at a price exceeding current price list or price indicated on label or pack , whichever is less. Govt. / NPPA is empowered under DPCO 2013 issued under section 3 of EC Act to fix and regulate prices of all formulations / medicines including non scheduled ( ref para 19, 20 , 25, and 26 of DPCO, 2013) .

6. Company representative further contended that the price of their products was fixed by NPPA on 2.3.2016 and the applicability of this price is effective from 1.4.2016. As the products under reference were outside the price control on 1.4.2016, SO No. 644(E) issued by NPPA is invalid because NPPA cannot fix ceiling price for non-scheduled formulations. Though NPPA was aware that certain products were moving out of Schedule I based on the revised NLEM issued in December 2015 but they still revised the prices of those products. Company further stated that the IDMA circular was for the reduction of all products and not specific to products moving out of Schedule 1. Company representative believes that the above OM is not in line with the DPCO 13 and hence not applicable. Company representative further contended that their interpretation of the above para refers to the WPI related issues and does not refer to the product list.

7. NPPA representative reiterated their submission as mentioned in the paragraph 5 and emphasized that the OM dated 6/4/2016 is in consonance with the objective of the DPCO issued under the EC Act 1955 and public interest.

8. In regard to review application filed by M/s J.B. Chemicals, it is seen that S.O.No.644(E) fixing ceiling price of 530 formulations was issued on 2.3.2016 and its applicability was to take effect from 1.4.2016. In the meanwhile, schedule I of DPCO 2013 was substituted by NLEM 2015 as on 10.3.2016. As the five formulation of the said petitioner company was not in NLEM 2015, and revised Schedule I of DPCO, 2013 as on 10.3.2016, the WPI w.e.f. 1.4.2016 is not applicable in the instant case.

NPPA has relied upon para 10(4) of the DPCO 2013 in justifying the application of WPI impact in the instant case.

Para 10(4) of DPCO 2013 states as under :

***“The prices of scheduled formulations, which are specified in the Drugs (Prices Control) Order, 1995 but not specified in the First Schedule of this order, fixed and notified under the provisions of the said order, after 31<sup>st</sup> May, 2012, shall remain effective for one year from the date of notification of such prices and thereafter prices of such formulations shall be regulated as in case of other non-scheduled formulations as stated in paragraph 20 of this Order.”***

From the above, it is seen that para 10(4) stated above is applicable when there is change in DPCO i.e. switch over from DPCO 1995 to DPCO 2013. In the instant case, there is no change in DPCO but only there is Schedule I as substitution of NLEM 2015 in DPCO 2013. The para 10(4) of DPCO 2013 may thus not be applicable in this case.

In view of the above, it is felt that price revision due to change in WPI made by NPPA vide their Notification dated 02<sup>nd</sup> March, 2016 may not be applicable to the five formulations referred to by the applicant on the ground that all these formulations are not included in the revised schedule to the DPCO, 2013, issued vide S.O.No.701(E) dated 10.3.2016.

9. So far as regulation of non-scheduled drug is concerned, para 20(1) of DPCO,2013 states as under :-

***“The Government shall monitor the maximum retail prices (MRPs) of all the drugs, including the non-scheduled formulations and ensure that no manufacturer increases the maximum retail price of a drug more than ten percent of maximum retail price, it shall reduce the same to the level of ten percent of maximum retail price for next twelve months.”***

In view of the above, the Government has decided that price revision due to change in WPI to be effective from 1.4.2016 made by NPPA vide their Notification dated 02<sup>nd</sup> March, 2016 may not be applicable to the five formulations referred to by the applicant on the ground that all these formulations are not included in the revised schedule to the DPCO, 2013, issued vide S.O.No.701(E) dated 10.3.2016. The formulation, therefore, are in the category of non-scheduled drugs w.e.f. 10.3.2016.

The products may, therefore, be regulated as non-scheduled formulations in terms of para 20 of DPCO, 2013 w.e.f. 10.3.2016.

Issued on this day, 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 J.B. Chemicals & Pharmaceuticals Ltd., Neelam Centre, B Wing, 4<sup>th</sup> Floor, Hind Cycle Road, Worli, Mumbai-400030.
2. The Member Secretary, NPPA, YMCA Cultural Centre Building, New Delhi – 110 001.

Copy to:

- (i) PS to Hon'ble Minister (C&F), Shastri Bhavan, New Delhi for information.
- (ii) PSO to Secretary (Pharma), Shastri Bhavan, New Delhi for information.
- (iii) Technical Director (NIC) for uploading the order on Department's Website.