

No. 31015/26/2015-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. Lupin Limited against fixation/revision of ceiling prices of “Rifampicin Capsule and Rifampicin Syrup” vide NPPA notification S.O. No. 1202(E) dated 6/5/2015 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013).

Ref. 1) The Review application dated 15.05.2015
 2) NPPA notification under review S.O. No. 1202(E) dated 6/5/2015
 3) Record Note of discussions held in the personal hearing held in the matter on 08.06.2016

This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Lupin Limited (hereinafter called the petitioner) against notification S.O. No.1202(E) dated 06.05.2015 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of “Rifampicin Capsule and Rifampicin Syrup”.

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

Petitioner: The petitioner representative referred to the notification No SO 1202 (E) dt. 6.5.2015 and stated that the price of their formulations i.e. Rifampicin Capsules and Rifampicin Syrup were fixed under DPCO 1995 on 20.12.13. As per para 10 of DPCO 2013 the prices were to be freezed for one year and thereafter they were entitled for a WPI increase which they had taken on 1st January 2015. As per DPCO 2013 under para 10(2) they were allowed an increase of WPI again on 1st April 2015. But NPPA has not allowed a WPI increase with effect from 20.12.2014. The petitioner representative requested that the WPI as per DPCO provisions may be allowed while fixing the price notification. The petitioner representative also stated that the stand of NPPA that allowing 6.32% WPI would amount to giving 2 WPI increase in one year which is incorrect as the increases are for two different financial year.

NPPA comments: NPPA representative stated that para 9 of DPCO 2013 specifies the reference data and source of market based data. The reference data for new drug has been stated to be 6 months before the receipt of application for new drug. In case of first time introduced formulations under DPCO 2013 the reference data of May 2012 has been specified under DPCO 2013 which is 6 months before the date of announcement of National Pharmaceuticals Pricing Policy 2012. In case of revision in first schedule reference date would be 6 months before the date of notification of revision of first schedule. Para 9(6) states that the reference date for the common formulations shall be as per provision of para 10 of DPCO 2013. However, reference

date relevant to reference data has not been specified in para 10. In a nutshell, there must be a reference date/data to be considered for price fixation. DPCO 2013 only prescribes 6 months criteria.

NPPA representative stated that NPPA in its 12th Authority Meeting decided that cases where ceiling prices were fixed prior to May 2012 in DPCO 1995 would be notified in April 2014 and cases where ceiling prices were fixed after May 2012 in DPCO 1995 would be notified in April 2015. Accordingly, NPPA started notifying ceiling price under DPCO 2013 from April 2014 onwards for common formulations where ceiling prices were fixed prior to May 2012 by considering reference data of September 2013. The data of September 2013 was uniformly considered for all common formulations irrespective of actual date of fixation to have uniformity. Similarly, the reference data for common formulations where ceiling prices in DPCO 1995 were fixed after May 2012 (June,2013 / December,2013 for concerned formulations), reference data for September 2014 i.e. 6 months prior to April 2015 was considered.

NPPA representative mentioned that para 16 relating to revision of ceiling price of scheduled formulations is relevant in this context. As per para 16(1) of the DPCO,2013, the government shall revise the ceiling prices of scheduled formulations as per the annual Wholesale Price Index (WPI) for preceding calendar year on or before 1st April of every year. Para 16(2) states that the manufacturers may increase the MRP of scheduled formulations once in a year i.e. in the month of April.

3. **Examination:**

Para 9(6) of DPCO 2013 reads as under:-

“Notwithstanding anything contained in this order, the reference date for the formulations which are part of the Drugs (Price Control) Order,1995 shall be as per the provisions of paragraph 10 of this Order.”

Further para 10(2) of DPCO 2013 is also reproduced below:-

“The price of scheduled formulations, which are also specified in the First Schedules to the Drugs (Price Control) Order, 1995, fixed and notified under the provisions of Drugs (Prices Control) Order,1995 after 31st May, 2012, shall remain effective for one year from the date of notification of such prices under Drugs (Prices Control) Order, 1995 and immediately thereafter the manufacturers may revise the prices as per the annual wholesale price index for the previous calendar year announced by Department of Industrial Promotion and Policy and on the 1st April of succeeding financial year, the formula as in sub-paragraph (1) of paragraph 4 of this Order shall be applied for fixing the ceiling prices of such schedule formulations.”

It is seen from the provisions of DPCO 2013 mentioned above that the drugs which were under scheduled category under DPCO 1995 and are also under scheduled category under DPCO 2013 i.e. common scheduled formulations in both the DPCOs there has been a differential treatment given i.e. these formulations will remain under cooling period for one year i.e. no increase from the date of notification and

immediately after one year the companies were allowed a WPI for the previous calendar year. Thereafter they will come on board with other scheduled formulations and be eligible for WPI with effect from 1st April of next year.

NPPA has erred in considering the data pertaining to 6 months before i.e. 30th September of the previous year by which they have ignored the WPI availed by the petitioner under para 10(2) quoted above. NPPA is also not correct in presuming that two WPI cannot be given in one year. DPCO, 2013 under para 9(6) and 10(2) contains special provision of WPI for common formulations under both DPCO 1995 and DPCO 2013 i.e. first after one year of cooling and second in the beginning of the next financial year. Moreover in the instant case the WPI availed by the petitioner in December 2014 after one year of the notification date and second on 1st April, 2015 i.e. in the next financial year. Therefore, the point of two WPI in one year by NPPA has no merit.

4. **Government Decision:**

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

“NPPA may be directed to revise the prices of the subject formulations after the petitioner had availed WPI in December 2014 as per provisions of para 9(6) and 10(2) of DPCO 2013. The petitioner will be entitled for WPI again w.e.f. 1.4.2015 under para 16(1)”.

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

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

To

1. M/s. Lupin Limited,
C/4, Laxmi Tower, Bandra Kurla Complex (East),
Mumbai-400 051.
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