

No. 31015/58/2014-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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B Wing, Janpath Bhavan, New Delhi

ORDER BY REVIEWING AUTHORITY UNDER PARA 31 OF DPCO, 2013

Subject: Review Application of M/s RPG Life Sciences Limited against fixation/revision of ceiling price of Spironolactone (25mg) tablet vide NPPA Notification No. S.O. 2360 (E) dated 15.9.2014 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013).

Ref. 1) Applicant's Review Application dated 11.10.2014 received on 13.10.2014
2) NPPA notification under review S.O. No.2360(E) dated 15.9.2014
3) Record Note of discussions held in the personal hearing held in the matter on 17.11.2014

Whereas National Pharmaceutical Pricing Authority (NPPA), Government of India, vide price fixation Order S.O. No.2360(E) dated 15.9.2014 fixed/revised ceiling price of Rs. 1.22 per tablet of Spironolactone (25mg) tablet under DPCO, 2013, included at section 16.0.1.4 in Schedule-I of the Order.

2. And whereas aggrieved by the above notification, M/s RPG Life Sciences Limited. (hereinafter referred to as the Petitioner) submitted review application dated 11.10.2014 under para.31 of DPCO, 2013 for review of NPPA Price fixation Order S.O.No.2360 (E) Dated 15.9.2014 fixing ceiling price of Spironolactone (25mg) tablet under DPCO, 2013.

3. The grievance of the Petitioner raised in their review application dated 11.10.2014 was sent to NPPA and the comments of NPPA thereon were given to the Petitioner through the Record Note of discussions held in the hearing on 17.11.2014. Record note of discussion is made integral part of the review order. After considering the comments of NPPA the Petitioner has raised the following points, on which comments given by NPPA representative during the hearing and Department's comments on the issue is recorded subsequently against each point:

4. Petitioner:

(i) The petitioner's representative mentioned that the formulation was under price control under DPCO 1995 and continues to be under price control under DPCO 2013. Petitioner has given a working sheet based on which earlier PTR i.e. before DPCO, 2013 came into force, worked out to Rs.1.421 per tablet. The company representative mentioned that they were selling the same formulation at the same PTR i.e. Rs.1.421 per tablet.

The petitioner alleged that PTR taken by NPPA is not correct.

(ii) The petitioner's representative also mentioned that as allowed in Para 10(1) of the DPCO, 2013, they had availed WPI on 7.31% under the new DPCO as shown in calculation sheet already attached with the minutes. Their PTR works out to Rs.1.517 per tablet.

(ii) The petitioner's representative further mentioned that as per para 6(2) of DPCO,2013, the formulations, which were under price control under DPCO 1995, the provisions of sub para of para 6(1) shall not apply, thereby the monopoly conditions applied by NPPA are not correct.

5. NPPA's comments

(i) NPPA's representative mentioned that they have taken the price as given in Pharma Track and IMS.

(ii) NPPA's representative further mentioned that in NPPA's view, para 6(2) in the present context related to companies specific price issued under DPCO 1995 and in case of ceiling prices, NPPA is applying the monopoly conditions.

Government's Comments and decision:

6. The point raised by the company is that their PTR with ED was Rs. 1.421 per tablet and NPPA has not taken the correct PTR. NPPA's representative, however, mentioned that they have taken the price as given in Pharma Track and IMS. Under Para 9(1) of DPCO 2013, NPPA is mandated to validate such data by appropriate survey or evaluation. NPPA may revalidate the data as per the provisions contained in para 9(1) of DPCO 2013.

7. Under para 10(1) of DPCO 2013, the companies were authorized to avail WPI immediately after cooling off period of one year i.e. on 30.5.2013 in all those cases which were notified under DPCO 1995 upto 31.5.2012. The notification under DPCO 1995 was issued on 28.4.2011, therefore the company was entitled for WPI increase for the previous calendar year after 30.5.2013 and thereafter the formula as in 4(1) of DPCO 2013 was to be applied by NPPA. During the review hearing, the NPPA's representative did not mention as to whether the price is taken by them after the company had availed the WPI for the previous calendar year or not. The NPPA may, therefore, be directed to consider the WPI for the previous year during the year 2013 in all those cases where the companies had availed it.

8. The NPPA, as per the calculation sheet, has applied the monopoly conditions i.e. no reduction in price due to absence of competition under para 6 (1) of DPCO 2013. However, as per the provisions contained in para 6(2), in cases where the prices have been fixed and notified by the Government under DPCO 1995, the provisions of sub-para (1) i.e. monopoly conditions are not to be applied.

During the discussion, NPPA's representative mentioned that para 6 (2) in the present context related to company's specific prices issued under DPCO 1995 and in case of ceiling prices NPPA is applying the monopoly conditions.

Para 6(2) of DPCO 2013 does not make any distinction as to whether the prices were fixed for the company specific or ceiling price under DPCO 1995. NPPA has, therefore, erred in price fixation under para 6 (1) of DPCO 2013 i.e. no reduction of price due to absence of competition. NPPA may be directed to fix prices under para 4 (1) and not under para 6 (1) of DPCO 2013.

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

- (1) NPPA to revalidate the data as mandated under para 9 (1) of DPCO 2013
- (2) NPPA to take into account the WPI for the previous calendar year in all those cases where the companies had availed the same in 2013.
- (3) NPPA to fix the price under para 4 (1) of DPCO 1995 and not under para 6 (1) of DPCO 2013.

Issued on this 5th February, 2015

(Anil Jain)
Under Secretary to the Government of India
For and on behalf of the President of India

To

1. The Member Secretary,
National Pharmaceutical Pricing Authority,
YMCA Cultural Centre Building, New Delhi-110001
2. M/s RPG Life Sciences Limited,
RPG House, 463, Dr. Annie Besant Road,
Worli, Mumbai – 400030.

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. T.D, NIC for uploading the order on Department's Website.