

No. 31015/41/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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A- Wing, Shastri Bhawan,
New Delhi 110 001

Order

1. This is an order disposing of an application dated 10.03.2017, filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Sun Pharmaceutical Industries Limited (hereinafter called the applicant) against notification S.O. No.443(E), dated 14.02.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling prices of Ciprofloxacin 0.3% Drops.

2. The applicant has contended as under:-

2.1 Background:-

(i) The notification SO No.1017(E) dated 02.04.2014 has fixed the ceiling price for Ciprofloxacin Hydrochloride drops 0.30%. The notification was afflicted by the following illegalities:

(a) while fixing the said ceiling price the NPPA erred to take into account the applicant's formulation despite the applicant having a 12% share in the market;

(b) as against the total of 6 manufacturers and 9 packs having market share in excess of 1% as per IMS data, and whose prices were to be taken into consideration, only data pertaining to 5 manufacturers and 5 packs have been taken into consideration by the NPPA; and

(c) as a result of erroneous exercise which has been carried out by the NPPA, a ceiling price much less than the ceiling price which should have been notified in terms of para 4 & 10 of DPCO 2013 has been notified by the NPPA.

(ii) The applicant being aggrieved by the notification had filed a review application dated 25th April 2014 before the Ministry under paragraph 31 of the DPCO, 2013 to review the notification. In the review application filed by the applicant before the Ministry: it was urged that (a) in view of the interim order dated 20.10.2003 passed by the Hon'ble Bombay High Court in CWP No. 6135/2003, the notification could not have been issued; (b) in any event and without prejudice, the applicant had also pointed on the basis of IMS data that the price fixed by NPPA was totally incorrect and fixed erroneously by ignoring the relevant data.

(iii) On 1st May 2014, Ministry and the Secretary of the Ministry (in their capacity as Reviewing Authorities) issued a notice to the applicant fixing a personal hearing of the review application on 22nd May 2014. On 26th May 2014, the applicant filed a

further submission before the Ministry stating that the data taken into account for fixation notification was incorrect; this was more particularly in relation to the applicant's product; and as such, the ceiling price fixed under the notification was incorrectly calculated. The applicant also asserted that the notification was otherwise arbitrary; erroneous; and as such, was liable to be reviewed.

- (iv) On 22nd May 2014, the hearing of the applicant's review application took place. It is pertinent to note that there was no challenge raised to the authority of Ministry and Secretary to review the notification.
- (v) On 22nd May, 2014, the applicant received an order purporting to be record of the personal hearing dated 22nd May 2014 granted by Ministry and Secretary i.e. Reviewing Authority ("the Reviewing Authority") inter alia directing NPPA to take Law Ministry's opinion on Reviewing Authority's competence to hear and pass orders on the applicant's review application. In view thereof, the hearing of applicant's review application had been postponed.
- (vi) The applicant, being aggrieved by the order dated 22.05.2014, had filed the Writ Petition (Lodging) No.1799/2014 before the Hon'ble Bombay High Court. The Hon'ble Court vide its order dated 24.07.2014 was pleased to dispose off the Writ Petition on a statement being made by the Ministry that the Reviewing Authority will decide the applicant's application independently and without reference to the opinion of the Law Ministry.
- (vii) Thereafter, the Ministry, vide its letter dated 28.07.2014, sought for certain clarifications alleging that there were certain discrepancies in the IMS data as had been received by NPPA and the IMS data as had been submitted by the applicant.
- (viii) Thereafter, vide letter dated 31.07.2014, the Ministry sought clarifications in respect of the continuation of the stay granted to the applicant vide order dated 20.10.2003. In response to the letter dated 28.07.2014 of the Ministry, the applicant vide its communication dated 14th August, 2014 submitted a clarification in respect of the variation in the IMS data as taken into account by NPPA and as submitted by the applicant.
- (ix) The applicant, vide letter dated 08.08.2014 of the Ministry, received a notice of personal hearing on 13.08.2014. In the course of the personal hearing on 13th August, 2014, the applicant pointed out:
 - (a) the various shortcomings in the price fixation notification and prayed for the same to be recalled;
 - (b) that the prior price fixation notification pertaining to the drug in question were currently under challenge before the Hon'ble Supreme Court of India. The adjudication of the petition before the Supreme Court would have a direct bearing on the exercise of price fixation as was required to be carried out in terms of DPCO, 2013.

- (c) by virtue of interim orders that had been passed in favour of the applicant, the applicant had been permitted to sell the formulation in question subject to the outcome of the pending proceedings. The applicant had, thus, requested that in light of the subsisting interim orders passed in its favour, the notification was not applicable to the applicant;
- (d) incourse of the hearing, the doubts as raised by the Ministry vide their letter dated 31.07.2014 regarding the subsistence and continuity of the interim orders passed in favor of the applicant were also duly clarified; and
- (e) Without prejudice to its aforementioned contentions that the notification did not apply to the applicant in light of the pending litigations, the errors and infirmities in the said order were also duly pointed out by the applicant. The applicant provided IMS certified data which clearly evidences that the price fixation exercise in terms of DPCO, 2013, as had been carried out by the NPPA, was incorrect. As against a total of 9 packs which were available in the market and the price of which were ought to be taken into consideration as per para 4 of the DPCO 2013, the NPPA had only taken into consideration 5 manufacturers and 5 Packs as against the 6 manufacturers and 9 Packs. Furthermore, the error in the Price-to-Retailer as considered by NPPA was also brought to its notice. The applicant had also submitted a representation/ clarification in reply to the letter 28.07.2014 of the Ministry in respect of the data dated 23rd May, 2014.
- (x) The Ministry has proceeded to pass the arbitrary and erroneous order dated 16.09.2014 (“the order no.1”). Whilst the applicant’s contention with respect to infirmities in the IMS data and the benefit with respect to the whole sale price index have been accepted by the Ministry and NPPA, the other contentions have been erroneously not considered/rejected by the Ministry and NPPA.
- (xi) Being aggrieved by the notification bearing SO No. 1017(E) dated 02.04.2014 (“the notification no.1”) and/or by the order dated 16.09.2014 (“the order”), the applicant had filed a Writ Petition bearing no.2950 of 2014 impugning the same. After filing of the aforesaid Petition, Ministry and NPPA had issued further price fixation orders dated 10th December 2014, 26th February 2015 and 2nd March 2016 inter alia purporting to revise the price of formulation of Ciprofloxacin Hydrochloride drops and had revised the ceiling price from Rs.1.30 per ml to Rs. 1.38 per ml; then Rs. 1.49 to Rs. 1.55 per ml; and thereafter, from Rs. 1.55 to 1.51 per ml on account of impact of increase of Wholesale Price Index for the year 2013, 2014 and 2015 respectively. It was applicant’s submission that the price fixation orders dated 10th December 2014, 26th February 2015 and 2nd March 2016 suffered from and/or were afflicted by the same vices, illegalities, and/or unconstitutionality which afflicts the notification no.1 and/or the order. The notifications were challenged by the applicant, who was the applicant therein, in the Writ Petition no. 2950 of 2014 on the following grounds which were without prejudice to each other.
- (xii) The above said Writ Petition no. 2950 of 2014 was disposed of by order dated 13th October 2016 passed by the Division Bench comprising of their Lordship the Hon’ble Mr. Justice S.C. Dharmadhikari and His Lordship the Hon’ble Mr. Justice B.P. Colabawalla in the following terms:

“1. It is in the light of this statement made by Dr. Sharma that we proceed to quash and set aside the order dated 16-9-2014, to the writ petition. That is set aside on the footing that the Government itself does not treat it as a final order and which, in any event, does not satisfactorily deal with and dispose of the review application.

2. The Competent Authority to decide the review application shall be an officer not below the rank of Deputy Secretary in the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India. He shall grant a personal hearing to the applicants and thereafter pass a reasoned order in accordance with law. All this shall be done as expeditiously as possible and within a period of three months from today.

3. We clarify that it would be open for the authority deciding the review application to pass such interim orders during the pendency of the review application or otherwise as are permissible in law.

4. Needless to clarify that every action in furtherance taken till date will have to abide by the order on the review application.

5. We clarify that we have not expressed any opinion on the merits of the review application and that should be decided uninfluenced by any observations or conclusions in the order.

6. Needless to clarify that the applicants initial review application will encompass all the further steps and the measures and the applicants shall be heard on the merits of the initial orders/notifications and those issued subsequent to the order dated 16-9-2014, which we have quashed and set aside.

The writ petition accordingly stands disposed of.” [emphasis supplied]

2.2 In terms of the order dated 13th October 2016, applicant was not only not granted a personal hearing in the matter, but the NPPA has now gone ahead and issued ceiling price notification on captioned formulation vide NPPA S.O. No. 443 (E) dated 14th February 2017 which was the subject matter of the Writ Petition no. 2950 of 2014. The directions issued by the Hon’ble Bombay High Court have been blatantly flouted and such acts border on contempt of Court. On this ground alone, the notification under review is liable to be set aside.

2.3 Furthermore, without prejudice to the aforesaid, applicant, vide its letter dated 02.11.2016, submitted that the draft working sheet dated 21.10.2016 has not been taken into consideration for fixing the ceiling price of their product pack CIFRAN EYE DROPS 10ML and CIPLOX EYE EAR DROPS 10ML.

2.4 In view of the above, the applicant requested this Department to direct NPPA to withdraw the notifications viz. Notification SO No. 1017E dated 02.04.2014, the price fixation orders dated 10th December 2014, 26th February 2015 and 2nd March 2016 and S.O. No. 443 (E) dated 14.02.2017 with immediate effect.

3. Comments of NPPA:

3.1 The ceiling price of Ciprofloxacin 0.3% drops has been fixed and notified as Rs.1.41/ml vide S.O. 443(E), dated 14.02.2017 in accordance with the provisions of DPCO, 2013. The submission/contentions raised in the review application are mis-conceived, wrong and denied. As regards contentions raised by review applicant in respect of WP(C) 3449/1996 and 6135/2003, reply/submissions have been filed by NPPA in those writ petitions and requested the same may become part and parcel of NPPA reply in this case also.

3.2 As regards the review application in respect of WP(C) 6135/2003, they are also mis-conceived hence, denied on the basis of factual grounds. The said writ petition (c) 6135/2003 was dismissed for want of prosecution on 14.01.2005. The said writ petition after restoration was again dismissed on 22.06.2006 for want of prosecution. The applicant could not produce any subsisting interim order thereafter in said WP(C) 6135/2003.

3.3 The Government filed transfer cases in respect of aforesaid cases before the Hon'ble Supreme Court of India. The said transferred cases have been remanded back by the Hon'ble Supreme Court on 20.07.2016 with liberty to the Government/NPPA to recover overcharged amount from the writ petitioners which includes review application herein. The Hon'ble Supreme Court has upheld price notification of Ciprofloxacin based formulation in judgement dated 21.10.2016 in CA 329/2005, UOI vs. M/s Cipla Ltd. Thus, it was obligatory for the review applicant to comply with notified prices for Ciprofloxacin based formulation under the DPCO, 1995. The review applicant has been issued overcharging notices in respect of Ciprofloxacin based formulations for relevant period and it is liable to deposit overcharged amount thereof.

3.4 The Hon'ble Supreme Court in GlaxoSmithKline vs. UOI reported in (2014) SCC Volume 2 753 has held that ceiling prices fixed under the DPCOs have to be implemented from date of notification.

3.5 The instant review matter relates to price fixation under the DPCO, 2013 for which contentions of the applicant are misplaced, wrong and denied. It is obligatory for the applicant to comply with the notified prices.

3.6 NPPA further stated that the ceiling price of Ciprofloxacin 0.3% drops was fixed based on the data available on AIOCD-AWACS/Pharmatrac for the month of August, 2015. Thus, review application is devoid of any merit and deserves to be rejected.

4. Examination:

4.1 The applicant has mentioned three writ petitions filed by him in his review application, viz. WP 3449/1996, W.P. 6135/2003 and Writ Petition 2950/2014.

4.2 CWP 3449/1996 was filed on 17.4.1996, challenging inclusion of ciprofloxacin on the ground that there were more than 5 bulk drug producers and more than 10 formulations and none having more than 40% market share in retail, of the single ingredient formulation. The Bombay High court granted the stay on 10.12.1996 restraining the Ministry from taking any further measures against the applicant pursuant

to the price fixation of the drug Ciprofloxacin and formulations thereon till the final disposal of CWP 3449/1996.

4.3 Another WP 6135 / 2003 was filed by the applicant challenging the inclusion of the formulation and prayed for interim relief to restrain the ministry to take any coercive measure and in furtherance of price fixation notification passed by them. On 20.10.2003, the Hon'ble High court stayed the operation and implementation of Govt's order and press release dated 14th August 2003 and take any steps against the petitioner in pursuant to the above orders and calling upon the petitioner to comply with the above orders. This WP was dismissed on 22.06.2016 for want of prosecution. The applicant has not submitted any subsisting stay order thereafter in this writ petition.

4.4 CWP 2950/2014 has been disposed of vide order dated 13.10.2016 vide which the DoP was asked to pass an order afresh after hearing the applicant. DoP has complied with this order and passed a fresh review order on 04.09.2018.

4.5 The basic procedural issue purported to be relied upon by the applicant is about Ciprofloxacin based formulations not qualifying to be included under the purview of the ceiling price fixation under DPCO. In this connection the submissions of the applicant need to be ignored in the present context of the DPCO 2013. The DPCO 2013 is based upon the National Pharmaceutical Pricing Policy (NPPP), 2012. According to the NPPP 2012, the deciding criteria for inclusion of any medicine within the purview of price fixation (regularization) is the prevailing National List of Essential Medicines (NLEM).

4.6 The applicant in its review application raised another issue that its products Cifran Eye Drops 10ml and Ciplox Eye Ear Drops 10ml. have not been considered in spite of having market share of more than 1%. NPPA was justified in not taking into account the prevalent high market prices of CIFRAN eye drops and CIPLOX eye ear drops for the purpose of calculating the ceiling price of subject formulations as the applicant (marketer of these brands) was not following the ceiling price fixed by NPPA.

5. Decision:

The contention of applicant regarding validity of inclusion of the Ciprofloxacin based formulations under DPCO 1995 / DPCO 2013 do not merit consideration in the context of prevalent drug pricing policy and provisions of DPCO, 2013.

Further, NPPA was also justified in not taking into account the prevalent high market prices of CIFRAN eye drops and CIPLOX eye ear drops for the purpose of calculating the ceiling price of subject formulations as the applicant (marketer of these brands) was not following the ceiling price fixed by NPPA. Therefore, the review application, devoid of any merit, stands rejected.

Issued on this date, the 04th day of February, 2019.

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

Copy to :-

1. M/s. Sun Pharmaceutical Industries Limited, Sun House, Plot No.201 B/1, Western Express Highway, Goregaon (E), Mumbai-400063.
2. Member Secretary, National Pharmaceutical Pricing Authority, YMCA Cultural Centre Building, 1, Jai Singh Road, New Delhi-110001.
3. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.
4. PS to MoS(C&F), Shastri Bhawan, New Delhi for information.
5. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
6. T.D., NIC for uploading the order on Department's Website