

No. 31015/40/2017-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 Injection 200mg/100ml.

2. The petitioner has contended as under:-

2.1 Background:

(i) On 28th April 2014, NPPA issued a notification S. O No. 1157 (e) dated 28.04.2014 (notification-I) purporting to fix ceiling price for Ciprofloxacin Hydrochloric injection 200 mg./100 ml. at Rs.0.16 per unit (1 ml.).

(ii) The Company filed a Data Representation on 7th May, 2014 for data correction in the ceiling price calculation. In spite of NPPA having issued on its website, circulars dated 24th September, 2013 and 9th October 2013 to deal with such representations for data correction within 15 days, nothing was heard from the NPPA for over 15 days. The Company being aggrieved by the notification - I filed a Review Application dated 26th May, 2014 before the Ministry under paragraph 31 of the DPCO, 2013 to review the notification on the following grounds:

(a) the notification-1 did not consider the Company's product Cifran infusion market price data;

(b) the working sheet showing the calculation of ceiling price reflected in notification-1 was not correct;

(c) the values of MAT; MAT%; PTR; and the price per unit of Company's product Cifran infusion 200mg/100 ml. was not correctly reflected;

(d) The notification -1 purported to supersede the notification dated 10th June 1997 instead of 25th November 2003. As such, the products which were considered for calculation of ceiling price were as per notification dated 10th June 1997 which was clearly erroneous;

(e) the Company already had a stay order qua the notification issued for and in respect of Ciprofloxacin under DPCO 1995 and as such, the same continued to operate in the Company's favour; and

(f) no guidelines were issued by the Union of India, through the Ministry for and in respect of price fixation and the same was resulting in erroneous and inconsistent price fixation decision by NPPA.

(iii) On 11th June 2014, Ministry issued a hearing notice to the Company in view of its Review Application-1 against notification-1. In the course of this hearing, the Secretary and NPPA noted that the Company had already challenged price fixation in respect of Ciprofloxacin Hydrochloric drops and the Hon'ble Bombay High Court had issued a stay order dated 20th October 2003 for and in respect of Ciprofloxacin and its formulations. The Ministry, therefore, had called upon NPPA to take legal advice from Law Ministry. This legal advice was awaited.

(iv) On 10th July 2014, NPPA issued a further notification dated 10th July, 2014, which superseded notification-1 and revised the ceiling price of Ciprofloxacin Hydrochloric injection 200mg/100 ml. at Rs. 0.27 (instead of Rs. 0.16 per 1 ml.). By virtue thereof, the notification-1 was superseded and did not survive/exist. On the very next day i.e. on 11th July 2014, NPPA withdrew the notification dated 10th July 2014. As such, notification-1 stood superseded and notification dated 10th July 2014 stood withdrawn. There was therefore, no price fixation for and in respect of Ciprofloxacin Hydrochloric injection 200mg./100 ml. under DPCO, 2013.

(v) On 20th August 2014, another notification S. O. No. 2095 (E) dated 20.08.2014 (notification -2) was issued purporting to fix ceiling price of Ciprofloxacin Hydrochloric injection 200mg/100 ml. (amongst others) at Rs. 0.17 per 1 ml.

(vi) On 18th September 2014, the company filed a Review Application under para 31 of the DPCO 2013 against S. O. No. 2095 (E) dated 20.08.2014 (notification -2). In Review Application-2, the company complained against notification-2 on the grounds:

(a) that under notification-2, the Ministry/NPPA could not seek to revise the price of Ciprofloxacin Hydrochloric injection 200mg/100 ml. since, there was no price fixation under DPCO, 2013. This was in view of the supersession of notification-1 and withdrawal of notification dated 10th July 2014;

(b) the working sheet showing calculation of fixation of price on the website of Respondent No.3 and the MAT%, PTR and price of Company's product was incorrect;

(c) in view of the stay order granted to the Company for and in respect of Ciprofloxacin and its formulations (qua DPCO 1995), the same would cover and protect the Company qua notification-2; and

(d) as such, the notified price was ex-facie illegal.

(vii) On 8th October 2014, a hearing was held before the Ministry on Review Application-2. Thereafter, by an order dated 14th May 2015 (issued over 7 months after hearing), Ministry rejected the Company's Review Application-2.

2.2 Being aggrieved by the notifications bearing S.O No. 1157(E) dated 28.04.2014 ("the notification no.1") and S.O. No. 2095(E) dated 20.08.2014 (the notification no.2") and/or by the order dated 14.05.2015 ("the order"), the Company had filed a Writ Petition bearing no. 2380 of 2015 impugning the same. After filing of the aforesaid Petition, Ministry and NPPA had issued further price fixation orders dated 26th February 2015 and 2nd March 2016 inter alia purporting to revise the price of formulation of Ciprofloxacin Hydrochloride injection 200 mg/100 ml and had revised the ceiling price from Rs. 0.17 per ml to Rs. 0.18 per ml and thereafter, from Rs. 0.18 per ml to Rs. 0.17512 per ml on account of impact of decrease of Wholesale Price Index for the year 2015. It was the Company's submission that the price fixation orders dated 26th February 2015 and 2nd March 2016, the notifications were challenged by the Company, in the Writ Petition no. 2380 of 2015.

2.3 The aforesaid Writ Petition No. 2380 of 2015 is pending adjudication the Hon'ble Bombay High Court.

2.4 Furthermore, without prejudice to the aforesaid, company has, vide letter dated 09.12.2016, submitted that the draft working sheet dated 29.11.2016 has not been taken into consideration for fixing the ceiling price of their product CIFRAN 200 MG INFUSION 100 ML.

2.5 In view of the above, company requested this Department to direct NPPA to withdraw the notifications viz. Notification S. O No. 1157(E) dated 28.04.2014, Notification S. O No. 2095(E) dated 20.08.2014, the price fixation orders dated 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 Injection 200mg/100ml has been fixed as Rs.0.15659/ml vide S.O. 443(E) dated 14.02.2017 and revised to Rs.0.15968/ml vide S.O. 1039(E) dated 01.04.2017 and Rs.0.15314/ml vide S.O. 2058(E) dated 30.06.2017 in accordance with the provisions of DPCO, 2013. Ciprofloxacin Injection 200mg/100ml was scheduled formulation under DPCO, 1995, under NLEM, 2011 and NLEM, 2015 of DPCO, 2013. Company have not been following ceiling/notified price fixed by NPPA, therefore, NPPA restricted the PTR to Rs.0.16/ml for subject formulation. The representation the company has been considered in line with the existing review order dated 14.05.2015 in which the same comments were raised by the company and the same was rejected by DOP. Therefore, submission/contentions raised in the review application was mis-conceived, wrong and denied. DOP also upheld the decision of NPPA vide review order 31015/67/2015-PI.I dated 14.05.2015. As regards contentions raised by review applicant in respect of WP(C) 2380/2015, the matter is still sub-judice.

3.2 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.

3.3 The instant review matter relates to price fixation under the DPCO, 2013 for which contentions of the company was misplaced, wrong and denied. It is obligatory for the company to comply with the notified prices. NPPA also refer to the earlier review order dated 14.05.2015 passed by the department and its findings recorded therein on the above.

3.4 The ceiling price of Ciprofloxacin Injection 200mg/100ml 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 main issues of the company raised during the presentation of their grievances revolve around following contentions: -

- i. The validity of inclusion of the Ciprofloxacin based formulations under DPCO 1995 and DPCO 2013.
- ii. Contention that there is no price fixed for Ciprofloxacin injections on the ground that the NPPA notification dated 28th April 2014 already stood superseded by notification dated 10th July 2014, which also stood withdrawn vide notification dated 11th July 2014.
- iii. The claim about Court Orders restraining the Government from enforcing the NPPA notified prices.
- iv. NPPA did not consider correct PTR of the company's product CIFRAN INFUSION 200MG/100ML. NPPA has captured PTR of Rs.41.30/100 ml, however, in final calculation, PTR of only 0.16/ml has been considered for the captioned product which is not in line of para 4 of DPCO, 2013.

4.2 The company has filed three writ petitions No.3449/1996 and 6135/2003 under DPCO 1995 and Writ Petition 2380/2015 under DPCO 2013 in the High Court of Bombay against the fixation of ceiling price of Ciprofloxacin Injection 200mg/100ml.

4.3 Applicant filed CWP 3449/1996 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 applicants pursuant to their price fixation of the drug Ciprofloxacin and formulations thereon till the final disposal of CWP 3449/1996.

4.4 The company filed another WP 6135 / 2003 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.

4.5 On 15.5.2013, the DPCO, 2013 came into existence superseding DPCO, 1995. Thereafter, NPPA issued Notification SO 1157(E) dated 28.04.2014, fixing the Ceiling price of Ciprofloxacin Injection, being scheduled formulation. Company filed another Writ Petition bearing no. 2380 of 2015 pleading for impugning the same taking the ground that in view of the stay order granted to the Company for and in respect of Ciprofloxacin and its formulations (qua DPCO 1995), the same would cover and protect the Company.

4.6 All the three petitions are still pending adjudication in the Hon'ble High Court.

4.7 The issues raised by the company are examined point-wise as under:-

Point No.(i):

The basic procedural issue purported to be relied upon by the company is about Ciprofloxacin based formulations not to qualify to be included under the purview of the ceiling price fixation under DPCO. In this connection, the submissions of the company need to be ignored in the present context of the DPCO 2013. The basic premise of the DPCO 2013 is irrespective of any inclusion/exclusion criteria that might have been relevant or followed until the time the DPCO 1995 was in force. It needs to be highlighted that the DPCO 2013 was issued 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 Medicine (NLEM).

The objective of the DPCO, being to ensure affordability and availability of the essential medicines, all medicines included in the NLEM are automatically subjected to the price control. As such all techno legal issues raised about the applicability of the price fixation regime to Ciprofloxacin based formulations, have no merit and need to be discarded/ignored.

Point No.(ii):

Contention that there is no price fixed for Ciprofloxacin injections on the ground that the NPPA notification dated 28th April 2014 already stood superseded by notification dated 10th July 2014, which also stood withdrawn vide notification dated 11th July 2014. In this connection the inference purported to be drawn by the applicant is misplaced. Any existing Order intended to be superseded by a subsequent Order, which further stands withdrawn through yet another Order, in effect has the implication of revival of the original Order. In the instant case, the price notified on 28th April, 2014 would prevail.

Point No.(iii):

All the proceedings before any of the Courts are predominantly incidental to various provisions of the DPCO 1995 which was issued in line with the New Drug Policy 1994. All sub judice matters relied upon by the applicant to support their contentions need not contradict the price fixation orders issued in pursuance to the DPCO 2013 which is based upon the NPPP 2012.

On the same issue, the review application dated 18.9.2014 filed by M/s Ranbaxy Laboratories Limited (which has now been taken over by M/s Sun Pharmaceutical Industries Limited), for the same formulation was rejected by DoP vide its review order No.31015/67/2015-PI.I, dated 14th May, 2015.

Point No.(iv):

The company contended that NPPA has captured PTR of Rs.41.30/100 ml, however, in final calculation, PTR of only 0.16/ml has been considered for the captioned product which is not in line of para 4 of DPCO, 2013. It is observed on perusal of the calculation sheet that there is stark difference in the PTR of the brand of the applicant company with 8 other brands of the subject formulation, whose data has been relied upon by the NPPA for working out the ceiling price of Ciprofloxacin Hydrochloride 200 mg/100 ml Injection. The PTR of 8 competing brands are between a narrow range of Rs.9.34 to Rs.16.98 per pack of 100 ml. In contrast to this price range, the PTR of Cifran brand of erstwhile M/s Ranbaxy Laboratories Ltd. is Rs.41.30 per pack. *In none of the submissions before various Courts and Government agencies, the applicant has cared to narrate the justification for such abnormally high PTR of their brand.*

The ceiling price of Ciprofloxacin Hydrochloride Injection 200mg was fixed as Rs.0.17512 per ml (rounded off to Rs.0.18/ml) vide SO 644(E), dated 24th March, 2016. NPPA, while fixing the ceiling price of the formulation vide SO 443(E), dated 14.2.2017, on revision of Schedule I of DPCO, 2013, restricted the Price to Retailer of the subject formulation at Rs.0.16/ml, after excluding 16% retailer margin.

No manufacturer/marketer company can market the scheduled formulation at a price higher than the notified ceiling price. The formulation Ciprofloxacin Hydrochloride Injection was scheduled drug in NLEM 2011 as well as in NLEM 2015. The ceiling price before notification was Rs.0.17512/ml, (rounded off to Rs.0.18/ml). Therefore, restricting the PTR (after excluding 16% retailer margin) of Cifran 200mg, containing Ciprofloxacin, being manufactured by M/s Sun Pharmaceutical Industries Ltd., from Rs.0.41/ml to Rs.0.16/ml, is in order. Hence, the issue raised by the applicant about non-consideration of their PTR of Ciprofloxacin Hydrochloride Injection 200mg has got no merit.

4.8 In the light of the above examination, the review application of M/s Sun Pharmaceutical Industries Limited do not merit consideration in the present context and prevailing policy provisions enshrined in the DPCO, 2013 read with the NPPP 2012. Accordingly, the review application filed by the company in respect of Ciprofloxacin Injection 200mg/100ml deserves to be rejected.

5. Decision:

Review application of M/s Sun Pharmaceutical Industries Limited do not merit consideration in the present context and prevailing policy provisions enshrined in the DPCO, 2013 read with the NPPP 2012. Accordingly, the review application filed by the company in respect of Ciprofloxacin Injection 200mg/100ml stands rejected.

Issued on this date, the 17th day of December, 2018.

(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. The Member Secretary, National Pharmaceutical Pricing Authority, YMCA Cultural Centre Building, 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