

No. 31015/53/2014-PI.I
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 on a review application, dated 18.09.2014, filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Ranbaxy Laboratories Ltd. (now M/s Sun Pharmaceutical Industries Limited) (hereinafter called the applicant) against the notification S.O. No. 2095(E), dated 20.08.2014 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Ciprofloxacin Hydrochloride Injection 200mg/100ml. The said review application was earlier disposed of vide this Department's review order no. 31015/53/2015-PI.I, dated 14.05.2015. Hon'ble Bombay High Court vide its order dated 30.11.2018 in W.P. No.2380/2015 found substance in the contention of the petitioner and stated that the basic principles of natural justice have been violated as the authority who heard the matter has not passed the impugned order dated 14.05.2015 and set aside the above said review order. The Bombay High Court further directed that the review application be decided afresh after giving a fresh hearing and directed the petitioner company to appear before the concerned Authority (Deptt. of Pharmaceutical) on 8th of January, 2019.

2. Accordingly, the applicant was granted a personal hearing on 08.01.2019. During the hearing, the applicant requested for some more time to make further submissions pertaining to queries raised to them. The hearing was again held on 05.02.2019.

3. Background and the applicant's submissions:-

3.1 Ranbaxy Laboratories Ltd. (now M/s Sun Pharmaceutical Industries Limited) had filed a writ petition No. 6135 of 2003 before the Hon'ble Bombay High Court against the price notification by National Pharmaceuticals Pricing Authority. In the said writ petition the Hon'ble High Court was pleased to stay the price notification of Ciprofloxacin by the NPPA. The writ petition is still pending for final hearing before the Hon'ble High Court.

3.2 During the pendency of the said proceedings, there has been a change in the Drug (Prices Control) Order. The DPCO 1995 has been repealed and superseded by the DPCO 2013. The earlier Drug Policy, 1994 has also been replaced by the National Pharmaceuticals Pricing Policy 2012.

3.3 The regulation of prices of drugs in the NPPP 2012 is on the basis of essentiality of drugs based on National List of Essential Medicines, 2011. The methodology of fixing a ceiling price of NLEM medicines, is by adopting the simple average price of all the brands having market share (on the basis of Moving Annual Turnover) of more than and

equal to 1% of the total market turnover of that medicine. The formula for calculating the said price is provided in paragraph 4 of DPCO.

3.4 The NPPA, after passing of the DPCO, 2013, had issued fresh price fixation notifications in respect of various formulations of specified dosages and strengths as given in NELM 2011, (which forms the First Schedule to the DPCO) including Ciprofloxacin formulations in terms of the provisions of the DPCO. The NPPA issued a notification S.O. 1157(E) dated 28.04.2014 for Ciprofloxacin Hydrochloric injection 200 mg./100 ml. at Rs 0.16 per ml.

3.5 The NPPA issued a further notification dated 10.7.2014, which superseded the notification dated 28.04.2014 and revised the ceiling price of Ciprofloxacin Hydrochloric injection 200mg./100 ml. at Rs 0.27 per ml. However, on the very next day i.e. on 11.07.2014, NPPA withdrew the notification dated 10.07.2014. The applicant stated that as such, the notification dated 28.04.2014 stood superseded and notification dated 10.07.2014, stood withdrawn. There was, therefore, no price fixation in respect of Ciprofloxacin Hydrochloric injection 200mg/100 ml. under DPCO.

3.6 The NPPA issued a notification S.O. No. 2095(E) dated 20.08.2014 to fix ceiling price of Ciprofloxacin Hydrochloric injection 200mg./100 ml. at Rs.0.17 per 1 ml.

3.7 On 18.09.2014, erstwhile RLL filed a review application under paragraph 31 of the DPCO against notification S.O. No. 2095(E) dated 20.08.2014 on the following grounds:

- (i) Under the said notification dated 20.08.2014, 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 dated 28.04.2014 by revising ceiling price vide notification dated 10.07.2014 and then on 11.07.2014 withdrawing of the then notification dated 10.07.2014;
- (ii) the working sheet showing calculation of fixation of price on the website of NPPA and the MAT%, PTR and price of their product was incorrect;
- (iii) in view of the stay order granted to the applicant for and in respect of Ciprofloxacin and its formulations (qua DPCO 1995), the same would cover and protect the applicant qua notification dated 20.08.2014; and
- (iv) as such, the notified price was ex-facie illegal.

3.8 The applicant requested the department to direct NPPA to review, recalculate and revise the Ceiling Price of the drug Ciprofloxacin Infusion 200mg/100ml in accordance with the provisions of Paragraph 4 of DPCO after taking into consideration the prevailing price of the applicant's product Cifran Infusion 200mg per 100ml and all other omitted formulations from the initial calculation of Ceiling Price dated 28.04.2014.

3.9 By notification S.O. 1157(E) dated 28.04.2014, the NPPA erroneously superseded the notification S.O. 438(E) dated 10.06.1997 instead of notification S.O. 1354(E) 25.11.2003, which was effective as on the date of the notification S.O. 1157(E) dated 28.04.2014. As per notification S.O. 1354(E), dated 25.11.2003, the ceiling price

of Ciprofloxacin Hydrochloric injection was Rs 0.1776 per ml pack. However, the NPPA considered the ceiling price of notification S.O. 438(E) dated 10.06.1997 instead of considering the ceiling price notified under notification S.O. 1354(E), dated 25.11.2003.

3.10 Under the notification S.O. 1157(E) dated 28.04.2014, PTR of brands were restricted superseding the notification dated 10.06.1997 at Rs 0.15 per ml, whereas as per notification S.O. 1354(E) dated 25.11.2003 the ceiling price was Rs 0.1776 per ml.

3.11 The notification S.O. 1157(E) dated 28.04.2014 for Ciprofloxacin Hydrochloric injection did not consider the PTR of applicant's product Cifran infusion in spite of having market share of more than 1%.

3.12 Further, the NPPA issued a notification S.O. 1784(E) dated 10.07.2014, which superseded the notification S.O. 1157(E) dated 28.04.2014 and revised the ceiling price of Ciprofloxacin Hydrochloric injection 200mg/100 ml. at Rs 0.27 (from of Rs 0.16 per 1 ml.). However, on the very next day i.e. on 11.07.2014, NPPA withdrew the notification S.O. 1784(E) dated 10.07.2014.

3.13 The applicant maintained the price basis the exemption granted to the applicant vide notification S.O. 1354(E) dated 25.11.2003.

3.14 The applicant, in its additional submissions, also raised the issue of pendency of its review application dated 26th May, 2014, which was filed against SO 1157(E) dated 28.04.2014.

3.15 The applicant requested the Reviewing Authority to direct the NPPA to fix ceiling price of Ciprofloxacin Hydrochloric injection 200mg/100 ml considering the price data furnished by the applicant and in accordance with para 4 of the DPCO.

4. Comments of NPPA:

4.1 The retail prices of formulation ciprofloxacin hydrochloride injection 200mg/100 ml was fixed by NPPA as Rs 0.17 per ml vide SO 2095(E) dated 20.08.2014.

4.2 The applicable notification SO 1157(E) dated 28.04.2014 was superseded by SO 1784(E) dated 10.07.2014. However, SO 1784(E) dated 10.07.2014 was withdrawn on 11.07.2014 vide SO 1823(E). With the withdrawal of SO 1784(E) dated 10.07.2014 vide SO 1823(E), dated 11.7.2014, the SO dated 28.04.2014 was applicable prior to SO dated 20.08.2014.

4.3 The stay order was granted under DPCO, 1995 and the ceiling price was fixed under DPCO, 2013.

4.4 DoP vide SO 438(E) dated 10.06.1997 fixed the price of "ciprofloxacin hydrochloride injection 200mg/100ml" under DPCO, 1995. Further, NPPA vide SO 1354(E) dated 25.11.2003 fixed the price of formulations "ciprofloxacin-2mg per ml + sodium chloride 0.9%" and "ciprofloxacin-2mg per ml + Dextrose 5%" under DPCO, 1995. Subsequently, under DPCO, 2013 NPPA vide SO 1157(E) dated 28.04.2014 fixed the price of same formulation i.e. "ciprofloxacin Hydrochloride injection

200mg/100ml” at Rs 0.16 per ml, by correctly superseding SO 438(E) dated 10.06.1997 since both formulations are same.

4.5 In view of the above explanation, the NPPA considered the ceiling price of notification SO 438(E) dated 10.06.1997 for restriction purpose.

4.6 The NPPA has considered PTR of their product Cifran Infusion, while notifying the ceiling price at Rs 0.16 per ml vide SO 1157(E) dated 28.04.2014.

4.7 The SO 1354(E) dated 25.11.2003 was issued under the DPCO, 1995 where exemption was granted to M/s Ranbaxy Laboratories Ltd. However, the SO 1157(E) dated 28.04.2014 was issued under the DPCO, 2013 where no exemption was granted to M/s Ranbaxy Laboratories limited. Accordingly applicant was required to follow the notified price.

5. Examination:

5.1 The Drugs (Prices Control) Order 2013 came into existence with effect from 15.05.2013 in supersession of the DPCO, 1995. The formulation Ciprofloxacin Hydrochloride Injection was included as a scheduled drug in NLEM, 2011 at section 6.2.2. Accordingly, the NPPA fixed the retail price of Ciprofloxacin Hydrochloride Injection vide SO 1157(E) dated 28.04.2014. The said notification SO 1157(E) dated 28.04.2014 was superseded by SO 1784(E) dated 10.07.2014. However, SO 1784(E) dated 10.07.2014 was withdrawn on 11.07.2014 vide SO 1823(E). The NPPA observed that SO 1784(E), dated 10.07.2014 was issued inadvertently as it is a ceiling price case and M/s Ranbaxy Laboratories Ltd. had gone to court against Ciprofloxacin bulk drugs and the case was subjudiced at that time. Accordingly, the NPPA decided to withdraw the notification on 11.07.2014.

5.2 The sequence of events clearly shows that on 11.07.2014, the notification dated 10.07.2014 was withdrawn and therefore the notification dated 28.4.2014 continued to remain operational. Therefore, the notification dated 28.4.2014 was in existence till issue of notification SO 2095(E), dated 20.08.2014 revising the ceiling price of the subject formulation from Rs 0.16 to Rs 0.17 per ml. Therefore, there is no merit in the contention of the applicant that the NPPA could not revise the ceiling price of the subject formulation as the ceiling price was non-existent on the date of revision i.e. 20.08.2014.

5.3 The NPPA also clarified that the DoP vide SO 438(E) dated 10.06.1997 fixed the price of “ciprofloxacin hydrochloride injection 200mg/100ml” under the DPCO, 1995. Further, the NPPA vide SO 1354(E) dated 25.11.2003 fixed the price of formulations “ciprofloxacin-2mg per ml + sodium chloride 0.9%” and “ciprofloxacin-2mg per ml+Dextrose 5%” under the DPCO, 1995. Subsequently, under the DPCO, 2013 the NPPA vide SO 1157(E) dated 28.04.2014 fixed the price of same formulation i.e. “ciprofloxacin Hydrochloride injection 200mg/100ml”, by correctly superseding SO 438(E) dated 10.06.1997 since both formulations were same. Hence, the NPPA has rightly considered the ceiling price notified under the DPCO 1995 vide 438(E), dated 10.06.1997, while notifying the ceiling price of Ciprofloxacin Hydrochloride Injection under the DPCO 2013 vide SO 1157(E), dated 28.04.2014.

5.4 The exemption was given to the applicant by the NPPA vide its notification dated 25.11.2003 because that notification was issued under the DPCO, 1995 and the applicant had already obtained a stay order from Hon'ble High Court on inclusion of Ciprofloxacin under the DPCO, 1995. No such stay has been obtained by the applicant for inclusion of Ciprofloxacin as a scheduled drug under the DPCO, 2013. Therefore, the NPPA rightly did not give any exemption to the applicant from the ceiling price fixed by it vide notification S.O. 2095(E), dated 20.08.2014.

5.5 The NPPA has considered PTR of applicant's product CIFRAN Infusion, while notifying the ceiling price vide SO 1157(E) dated 28.04.2014. The PTR was restricted as per ceiling price notification SO 438(E) dated 10.06.1997. The stand taken by the NPPA of restricting the PTR of applicant's product CIFRAN as per ceiling price notification SO 438(E), dated 10.06.1997 while notifying the ceiling price of Ciprofloxacin Injection vide SO 1157(E), dated 28.4.2014 is in order. Therefore, the contention of the applicant has got no merit.

5.6 The review application dated 26th May 2014 against SO 1157(E), dated 28.4.2014 was filed on the similar grounds which were raised in subsequent review application dated 18.09.2014 against SO 2095(E), dated 20.08.2014. The issues raised in the review application, dated 26th May 2014 have already been covered while examining the review application dated 18.09.2014.

6. Decision:

The review application of Ranbaxy Laboratories Limited (now M/s Sun Pharmaceutical Industries Ltd.) is devoid of merit and is therefore rejected.

Issued on this date, the 2nd day of January, 2020.

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

Copy to :-

1. M/s Ranbaxy Laboratories Limited (M/s Sun Pharmaceutical Industries Ltd.), 8-C, 8th Floor, Hansalaya Building, 15-Barakhamba Road, Connaught Place, New Delhi-110 001.
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. Joint Secretary(Pharma), Shastri Bhawan, New Delhi for information.
7. T.D., NIC for uploading the order on Department's Website