

No. 31015/67/2015-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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B Wing, Janpath Bhavan, New Delhi

O R D E R BY REVIEWING AUTHORITY UNDER PARA.31 OF DPCO,
2013

Subject: Review application of M/s Ranbaxy Laboratories Limited against fixation/revision of ceiling prices of Ciprofloxacin Hydrochloride injection 200 mg/100 ml vide NPPA notification S.O. No.2095 (E) dt. 20.8.2014 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013)

- Ref. 1) Applicant's Review application dated 18.9.2014
 2) NPPA notification under review S.O. No. 2095 (E) dt. 20.8.2014
 3) Record Note of discussions held in the personal hearing held in the matter on 8.10.2014
 4) Applicant's letter dated February 25, 2014 (To be read as 2015) received on 3.3.2015

Whereas National Pharmaceutical Pricing Authority (NPPA), Government of India, vide price fixation Order S.O. No. 2095 (E) dt. 20.8.2014 fixed/ revised ceiling price of Ciprofloxacin Hydrochloride injection 200 mg/100 ml under DPCO, 2013.

2. And whereas aggrieved by the above notification, M/s Ranbaxy Laboratories Ltd. (hereinafter referred to as the Petitioner) submitted review application dated 18.9.2014 under para.31 of DPCO, 2013 for the review of NPPA Price fixation Order S.O.No. 2095 (E) dt. 20.8.2014 fixing Ceiling price of Ciprofloxacin Hydrochloride injection 200 mg/100 ml under DPCO, 2013.

3. The grievance of the Petitioner raised in their review application dated 18.9.2014 were sent to NPPA and the comments of NPPA thereon were given to the Petitioner through the Record Note of discussions held in the review hearing on 8.10.2014 . 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 Government's comments on the issue is recorded subsequently against each point:

Petitioner :The petitioner representative mentioned that the price of Ciprofloxacin Hydrochloride injection 200 mg/100 ml. was fixed vide NPPA's gazette notification S.O. No. 2095(E) dt. 20.8.2014 is incorrect as the same supersedes the price as had been provided in the non-existent notification. He further submitted that NPPA had vide SO No.1157 (E) dt. 28.4.2014 fixed the price for the formulation in question at Re.0.16 per ml. Subsequently, NPPA in supersession of notification No. 1157 dt. 28.4.2014 issued another notification S.O.No. 1784 dt. 10.7.2014 and the per ml. ceiling price was fixed at Rs. 0.27. On 11.7.2014 NPPA vide SO Notification No. 1823 dt. 11.7.2014 had withdrawn notification No. 1784 dt. 10.7.2014. The petitioner representative mentioned that after withdrawal of notification dt.10.7.2014 by NPPA on 11.7.14, no price notification existed and therefore they are free to sell the formulation at any price.

The petitioner representative mentioned that once Notification dated 10.7.2014 superseded the notification No. 1157 (E) dt. 28.4.2014 by notification dated 10.7.2014, the notification dated 28.4.2014 ceased to exist. After 11.7.2014 notification withdrawing the notification dt. 10.7.2014 nothing exist as on the said date. The only notification in existence was notification dt. 10.7.2014. If the intent of NPPA was to revive the earlier notification dt. 28.4.2014 the same would have been specifically mentioned in the notification dt. 11.7.2014. In the absence of any specific mention no implied inference can be drawn. Thus on 20.8.2014 notification S O No. 1157(E) dt. 28.4.2014 was not in existence and could not have been superseded.

4. NPPA comments: NPPA representative mentioned that while issuing notification No. 1784 dt. 10.7.2014 an error was noticed and, therefore, that notification was withdrawn on 11.7.2014. Therefore, the prices notified by SO No.1157(E) dt.28.4.2014 remain effective.

5. The reviewing authority desired to know the price at which the formulation is being sold by the company from 28th April 2014 till date. The company representative mentioned that they will submit the details within 15 days from today with supporting documents.

Department's comments:

Background of the case:

6.. Ciprofloxacin Hydrochloride injection 200 mg/100 ml was a scheduled drug under DPCO 1995. Its inclusion in DPCO 1995 was challenged by the company and the matter is pending in the Hon'ble Supreme Court wherein several petitions on inclusion/exclusion have been transferred from Hon'ble Bombay High Court to the Hon'ble Supreme Court. The company has claimed in their letter dated 25.2.2015 that they are maintaining

the status quo price by virtue of stay granted by the Bombay High Court in their pending writ petition No. 6135 of 2003. Copy of the Court order dated 20.10.2003 placed at p.36-38/c which show that the Hon'ble Bombay High Court restrained NPPA to take any action to make M/s Ranbaxy to comply with the price notification (issued under DPCO,1995). The case 6135/2003 was dismissed for want of prosecution on 14.1.2005. Civil Application was also dismissed on 22.6.2006 for want of prosecution. It is understood that the case was restored. Further, there is an order of the Hon'ble Supreme Court of coercive action in all linked matters. The stay granted was with respect to the price notification issued under DPCO, 1995 and not DPCO, 2013. The statement of the company that they are maintaining the 1995 prices is overcharging the consumers as there has been no stay granted by any Court to the company under DPCO 2013.

7. Under DPCO 2013 NPPA had fixed the ceiling price of Ciprofloxacin Hydrochloride injection 200 mg/100 ml at Rs. 0.16 per ml vide notification No. SO 1157(E) dt. 28.4.2014. This notification was superseded by notification No. SO 1784 (E) dt. 10.7.2014 with a per ml price of Rs.0.27. As there was an error in fixing the price NPPA vide notification NO. 1823(E) dt. 11 July 2014 (i.e. next day) had withdrawn the order issued on 10.7.2014.

8. Vide notification No.2095(E) dated 20.8.2014 NPPA fixed the prices of Ciprofloxacin Hydrochloride injection superseding the notification first issued i.e. SO 1157(E) and revised the prices from Rs. 0.16 per ml to Rs. 0.17 per ml. The contention of the company is that once notification dated 10.7.2014 has been withdrawn by NPPA on 11.7.2014 there was no price notification in existence since then and therefore, they are free to sell the formulation at any price. The sequence of events clearly shows that on 11.7.2014 the notification dt. 28.4.2014 was not withdrawn. The notification dt. 10.7.2014 superseding notification of 28.4.2014 itself has been withdrawn. The withdrawal effect is total i.e. the price as well as the superseding effect. The notification dt. 28.4.2014 will remain operational. Therefore the notification dt. 28.4.2014 was in existence till 20th August 2014 when the prices were revised from Rs.0.16 to Rs.0.17 per ml.

9. To a specific query during the review hearing regarding the price at which the formulation is being sold by the company from 28.4.2014 till date of hearing the company representative promised to give the information within 15 days with supporting documents. Unfortunately after about 1 month i.e. 7th November 2014 the company sought another 15 days time to submit the same. After two reminders the company sent a final letter dated 25.2.2014 (wrong date mentioned – received on 3.3.2015) wherein they did not specify the price at which the formulation is being sold by them i.e. MRP. The company had stated that they are maintaining the status quo of DPCO 1995 price wherein they were granted stay. Further the company did not give any supporting documents which were promised by them during the personal hearing. This shows intention of the company to overcharge the consumers by taking plea of Court stay which was never granted to them under DPCO 2013 and also non-existence of any price notification.

10. NPPA has quoted Supreme Court judgement dt. 9.12.2013 in the Glaxo Smithkline viz UOI reported in (2014) SCC vol. II, 753, current price list is one issued as notified price by Government and the same has been considered. As they are continuing to overcharge the patients under the cover of Court stay order which has never been granted to them under DPCO 2013 despite the fact that the price has been fixed by NPPA on 28.4.2014 under DPCO 2013. The company has withheld the documentary evidence through which they have been overcharging patients though their counsel was specifically ordered under DPCO 1995 that they will maintain strict records of their sales.

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

“The point raised by the petitioner has no merit and therefore, the review petition deserves to be rejected. NPPA to examine the issue of overcharging by the company under DPCO, 2013 and take further action in consultation with Ministry of Law”.

Issued on this date of 14th May, 2015

(A. K. Sah)

Under Secretary to the Govt. of India
For and on behalf of the President of India

To

1. M/s Ranbaxy Laboratories Limited
Plot No.90, Sector 32,
Gurgaon -122001(Haryana)
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. TD, NIC for uploading the Order on the Department's website