

No. 31015/15/2014-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 an application, dated 25.04.2014, 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 notification S.O. No. 1017(E), dated 02.04.2014 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Ciprofloxacin Hydrochloride Drop 0.3%. The said review application was earlier disposed off vide this Department's review order no. 31015/15/2014-PI.I dated 16/09/2014. Bombay High Court vide its order dated 13/10/2016 has quashed and set aside the above said review order dated 16/09/2014 and directed to give hearing to the company. As per Bombay High Court's Order, dated 13.10.2016, the company was given a personal hearing on 24.05.2018.

2. Background:-

M/s Ranbaxy Laboratories Limited (now M/s Sun Pharmaceutical Industries Limited) had filed a review application dated 25/04/2014 under para 31 of DPCO, 2013 against NPPA's S.O. No. 1017(E) dated 02/04/2014 for Price fixation of Ciprofloxacin 0.3% Drops. The said review application was disposed off vide this Department's review order no. 31015/15/2014-PI.I dated 16/09/2014. Further, Bombay High Court vide its order dated 13/10/2016 has quashed and set aside the above said review order dated 16/09/2014 and directed to give hearing to the company. As per Bombay High Court's Order, dated 13.10.2016, the company was given a personal hearing on 24.05.2018.

3. Company's Submission:

3.1 Vide their application dated 25/04/2014, Company has submitted the following:

(i) Company is maintaining status quo with regard to the price of Ciprofloxacin and its formulations by virtue of the stay granted by the Bombay High Court and as such the matter is subjudice. This fact is also recognized vide Note (a) to the notification S.O. No.1354(E) dated 25th Nov, 2003. The said note on the notification clearly provides that order shall be applicable to all manufacturers except for M/s. Ranbaxy Laboratories Ltd., Registered Office: Sahibzada Ajit Singh Nagar-160055, Distt. Ropar (Punjab).

(ii) Subsequently, when S.O. 1354(E) dated 25th Nov, 2003 was superseded by S.O. 865(E) dated 6th April, 2010, the exemption available to the company in the previous notification was continued vide Note (b). The said note on the notification clearly

provides that "The prices fixed are the maximum retail prices (inclusive of excise duty, sales tax/VAT and local taxes if any) in, column (6) of table-1, for the specified pack and packs of similar strength, and manufacturer / marketing company cannot claim exemption on any ground therefrom, unless specifically permitted by the Government/NPPA through an order.

(iii) And now NPPA has superseded S.O. 865(E) dated 16th April, 2010 by the captioned notification dated 2nd April, 2014 in which the said exemption vide Note (a) to the notification S.O. No.1354 (E) dated 25th Nov 2003 and Note (b) to the notification S.O. 865(E) dated 16th April, 2010 should be continued as the matter is still subjudice.

(iv) Further, the working sheet showing calculation of Ceiling Price is also not correct. The calculation has not taken into account all the Eye / Ear Drops containing Ciprofloxacin 0.3% available in the market including company's product Cifran Eye / Ear Drops 10ml.

(v) Company submitted that this review application including compliance of price pursuant to paragraph 31 of DPCO 2013 without prejudice company's rights and contentions taken in WP 3499 of 1996 and WP 6135 of 2003 before Hon'ble Bombay High Court and the Transfer Petition (civil) No. 161/2013 and 164/2013 before the Hon'ble Supreme Court of India.

3.2 In view of the above, company requested this Department to kindly amend notification under reference in the context of the above position as the said notification is not applicable to the company in view of the High Court stay granted to them in respect of Ciprofloxacin and its formulations.

4. During the personal hearing, the company representative submitted following further submissions :-

4.1 Ranbaxy Laboratories Ltd. (RLL), was engaged in the manufacture, supply, distribution, export and dealing of pharmaceutical products and was a manufacturer of Ciprofloxacin, the drug we are concerned in the present proceedings. In respect of the price notification by NPPA of Ciprofloxacin, RLL had filed writ petition 6135 of 2003 before the Bombay High Court challenging inclusion of the drug Ciprofloxacin in DPCO 1995 on the ground that the petitioner company's bulk drug Ciprofloxacin meets with the exclusion criteria (iii) in para 22.7.2 of the Drug Policy 1994 and hence ought to have been excluded from price control. In the said writ petition Hon'ble High Court was pleased to stay the price notification of Ciprofloxacin by NPPA. The matter along with another writ petition 3449 of 1996 was transferred to Supreme Court vide transfer petition 161/2013 and 164 /2013 and again transferred back to Bombay High Court. The writ petition is still pending for final hearing before Bombay High Court.

4.2 In the meantime, by virtue of the order dated 24th March 2015 of Punjab & Haryana High Court and Gujarat High Court, RLL was merged into SPIL.

4.3 Status quo is being maintained by the company with regard to the price of Ciprofloxacin and its formulations by virtue of the stay granted by the Bombay High Court and as such the matter is subjudice.

4.4 Subsequently, when S.O. 1354(E) dated 25th Nov, 2003 was superseded by S.O. 865(E) dated 16th April, 2010, the exemption available to us in the previous notification was continued vide Note (b). The said note on the notification clearly provides that “The prices fixed are the maximum retail prices (inclusive of excise duty, sales tax/VAT and local taxes if any) in column (6) of table-I, for the specified pack and packs of similar strength, and manufacturer / marketing company cannot claim exemption on any ground therefrom, unless specifically permitted by the Government/NPPA through an order.

4.5 On 15th May 2013, Government notified The Drugs (Prices Control) Order, 2013 as under

S.O. 1221(E).– In exercise of the powers conferred by section 3 of the Essential Commodities Act, 1955, (10 of 1955), and supersession of the Drug (Prices Control) Order, 1995, except as respect to things done or omitted to be done before such supersession, the Central Government hereby makes the following Order, namely:-
1. Short title and commencement.– (1) This Order may be called the Drugs (Prices Control) Order, 2013.....

Stay Order granted by Bombay High Court is continued till decided.

4.6 Thereafter, NPPA has superseded S.O. 865(E) dated 16th April, 2010 by the captioned notification dated 2nd April, 2014 in which the said exemption vide Note (a) to the notification S.O. No.1354 (E) dated 25th Nov 2003 and Note (b) to the notification S.O. 865(E) dated 16th April, 2010 should be continued as the matter is still subjudiced.

4.7 Further, the working sheet showing calculation of Ceiling Price displayed on the website of National Pharmaceutical Pricing Authority (NPPA) on 9th April, 2014 is also not correct since price was fixed without considering price of our product Cifran Eye Drops 10ml which had a market share of 12% during the relevant period. The calculation has shown only 12 packs and not taken into account all the Eye / Ear Drops containing Ciprofloxacin 0.3% available in the market including our product Cifran Eye Drops 10ml.

4.8 In September 2013, all the Eye / Ear Drops containing Ciprofloxacin 0.3% available in the market except our product Cifran Eye / Ear Drops 10ml were covered by S.O. 865(E) dated 16th April, 2010 notified under DPCO 1995.

4.9 Company requested that the Hon'ble Authority be pleased to direct NPPA to

- i. Review, recalculate and revise the Ceiling Price of the drug CIPROFLOXACIN 0.3% DROPS in accordance with the provisions of Paragraph 4 of DPCO – 2013 after taking into consideration the actual price of our product Cifran Eye Drops 10ml as shown by IMS Data and
- ii. Exempt us by adding a footnote in the notification based on the Stay Order granted by Bombay High Court.

5. Comments of NPPA:

5.1 NPPA considered this case in the 12th and 13th Meeting of the Authority wherein the provisions of para 10 (1) and para 10 (2) were discussed in detail. The Authority after due deliberations decided that as per para 10 (1) of DPCO, 2013, the cases where prices were notified upto 31st May 2012, alone are to be considered for price fixation and new prices be notified in April 2014. In all other cases where prices were notified after 31st May 2012 under DPCO, 1995 prices in such cases will have to be notified only in April 2015 or in the month of April of succeeding financial year as the case may be, as per the provisions of para 10 (2) of DPCO, 2013 because prices fixed under DPCO, 1995 are required to remain frozen for a period of 1 year and thereafter as provided the manufacturers themselves may revise the prices as per the annual WPI for the previous calendar year.

5.2 It was informed to the Authority that price fixation of Ciprofloxacin based formulation is subjudice under DPCO, 1995 and the case is pending in Hon'ble Supreme Court therefore, price fixation/ revision of ciprofloxacin based formulation was not carried out in DPCO, 1995. The Authority decided that the price fixation of ciprofloxacin formulations may be carried out in accordance with the provisions of DPCO, 2013 as this formulation pack is indicated in the list of NLEM and is a scheduled medicine under DPCO, 2013.

5.3 With regard to non considering of their product in price calculation sheet, it is submitted that the prices were fixed based on the data provided by the IMS and in line with the provisions of DPCO, 2013. As their product was not mentioned in the data provided by IMS therefore it was not considered while calculating the ceiling price.

6. Examination:

6.1 The main issues, raised by M/s Ranbaxy Laboratories Limited (now M/s Sun Pharmaceuticals Industries Limited), comprised of :-

- i. The validity of inclusion of the Ciprofloxacin based formulations under DPCO 2013.
- ii. Non-consideration of the PTR of Ciprofloxacin based formulations marketed by M/s Ranbaxy Laboratories Limited (now M/s Sun Pharmaceutical Industries Limited) during August 2013-the reference date for which PTR related data has to be considered for such of the manufacturers that have more than 1% market share.
- iii. The Court Orders restraining the Government from enforcing the NPPA notified prices on the ground that being sub-judice in nature, earlier price notification accorded exemption to Ranbaxy Laboratories Limited from the notified prices.

6.2 The applicant company did file a review application against the NPPA Notification No. 1017(E) dated 2nd April 2014 vide their application filed on 25th April 2014. The then Reviewing Authority organized personal hearings on 22nd May 2014 as well as 13th August 2014 where the contentions of the company were duly considered. The DoP issued its Review Order dated 16th September 2014 whereby the main claim of the company about non-applicability of the NPPA notified prices was not acceded to and

the company was directed to implement the notified prices. Simultaneously, the NPPA was also directed to look into the procedural issues raised by the company on account of non-inclusion of their product packs in the working sheet uploaded by the NPPA on its website.

6.3 Not satisfied with the DoP's Review Order, the company approached the High Court and the matter was also later transferred to the Hon'ble Supreme Court. The Hon'ble Supreme Court later on directed the matter to be returned to the Bombay High Court, who finally passed its Order on 13th October 2016 quashing the DoP's Review Order dated 16th September 2014 and directed the DoP to decide the original Review Application of the company filed during April 2014 after a personal hearing by an officer not below the range of Deputy Secretary in the DoP within a period of 3 months.

6.4 In the light of the above judgment of the Hon'ble Bombay High Court, the applicant company was expected to approach the Reviewing Authority to dispose of their old (and already decided) Reviewing Application in pursuance to the directions of the Bombay High Court. However, instead of timely approaching the DoP for necessary action in the matter, the applicant chose not to bring the matter before the Reviewing Authority. The matter has now been brought to the notice of the DoP only through the another Review Application dated 10th March 2017 filed by M/s Sun Pharma Industries Limited (who acquired the erstwhile Ranbaxy Laboratories Limited during 2015) against NPPA Order SO No. 443 (E) dated 14th February 2017 in respect of Ciprofloxacin 0.3% Drops.

6.5 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 2013 due to Stay Orders of any of the Courts. 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 criterion for inclusion of any medicine within the purview of price fixation (regularization) is the prevailing National List of Essential Medicine (NLEM).

6.6 The objective of the DPCO, being to ensure affordability and availability of the essential medicines, all medicines included in the NLEM are automatically need to be 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.

6.7 The issue of non-consideration of the PTR along with the variations reflected in the considered PTR by NPPA in working sheet may be considered to be examined based upon the evidence and additional supporting material preferred by the applicant company.

7. Decision:

(a) "Review application of Ranbaxy Laboratories Limited (now M/s Sun Pharmaceutical Industries Ltd.), questioning the validity of inclusion of their Ciprofloxacin based formulations (which enjoyed protection due to Court interventions under the provisions of DPCO 1995), under the provisions of DPCO 2013 and the claims about Court orders restraining the Government from enforcing the NPPA notified prices, do not merit consideration in the present context and prevailing policy provisions enshrined in the DPCO, 2013 read with the NPPP 2012 and are not being acceded to.

(b) NPPA is also directed to interact with the applicant company and get the necessary documents about the market share of its product, Cifran Eye Drops 0.3% in 10 ml bottles, and after verification and satisfying itself about the veracity of the claim, re-examine the ceiling price of Ciprofloxacin 0.3% Eye Drops on merit, within a period of thirty days from the date of issue of this Order."

Issued on this date, the 4th day of September, 2018.

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