

**No. 31015/7/2013-PI.I**  
**GOVERNMENT OF INDIA**  
**MINISTRY OF CHEMICALS & FERTILIZERS**  
**DEPARTMENT OF PHARMACEUTICALS**

B Wing, Janpath Bhawan, New Delhi

**ORDER BY REVIEWING AUTHORITY UNDER PARA 22 OF DPCO, 1995**

**Subject: Application of M/s Ranbaxy Laboratories Ltd. for fixation/revision of ceiling prices of Histec EVT tablets and Fucibet cream in 15 gm Aluminium tube under Drugs (Prices Control) Order, 1995 (DPCO, 1995).**

- Ref. 1. Applicant's application dated 20.2.2013  
2. NPPA's closure of petitioner's applications filed in Form III on account of announcement of National Pharmaceutical Pricing Policy (NPPP) 2012 vide their letter dated 10.01.2013  
3. Record Note of discussions held in the personal hearing held in the matter on 25.11.2014

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Whereas National Pharmaceutical Pricing Authority (NPPA), Government of India, vide letter No. 8(37)/2012/DP/Div.II/NPPA dated 10.1.2013 closing petitioner's form III applications in respect of the formulations mentioned above.

And whereas aggrieved by the above letter, M/s Ranbaxy Laboratories Ltd. (hereinafter referred to as the Petitioner) submitted review application dated 20.2.2013 under para 22 of DPCO, 1995 for the review of NPPA's decision to close the petitioner's form III applications vide NPPA's letter No. 8(37)/2012/DP/Div.II/NPPA dated 10.1.2013. As per the provisions of para 22 of DPCO 1995 review powers extend to the notification issued or order made under paragraphs 3,5,8,9 and 10 of DPCO 1995. In the instant case the company had filed application under form III of DPCO 1995 i.e. application for fixation or revision of prices of scheduled formulations and the non-action by NPPA on form III application of the company. Therefore, no review lies before the Reviewing authority under para 22 of DPCO 1995.

2. The grievance of the Petitioner raised in their review applications dated 20.2.2013 were sent to NPPA and the comments of NPPA thereon were given to the Petitioner through the record note of discussions held in the hearing on 25.11.2014. Record notes of discussions are 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 Department's comments on the issue is recorded subsequently against each point:-

**Petitioner:**

3. The Petitioner representative sought liberty to reiterate the written points raised by the company as according to him the same had not been responded to by NPPA.

The Petitioner representative mentioned that they had filed an application in form III for price fixation on 4.4.12 pertaining to Histec EVT tablets on the ground that the prices of bulk drugs were revised by NPPA on 11.10.2010. In the said application in Form III the company had also contended that the prices of the said formulation should be revised in view of the increase in the excise duty levied by the Central Govt.

The Petitioner representative mentioned that they had also filed another application in Form III dated 18.10.2012 for price revision of price fixation Order SO No. 1937(E) dt. 3.8.2009 pertaining to Fucibet Cream 15 gm Aluminium tube.

He further mentioned that despite the application was pending with NPPA they did not revise the prices on the basis of their request. However, they received a letter dt. 10.1.13 that their Form III application was considered as closed in the light of National Pharmaceutical Pricing Policy (NPPP) 2012. A reminder letter dated 28.12.2012 was also sent to the Ministry and NPPA for this.

The Petitioner representative mentioned that as per DPCO provisions contained in para 8(4) of DPCO 1995 their prices were required to be fixed /revised by NPPA within two months of the receipt of complete information. The two months period had expired much before the date of issue of Pricing Policy i.e. 7.12.2012 even though that has no relevance.

It has been submitted by the Company that being aggrieved by the incorrect closure of its application under para 8(4) of DPCO, 1995, on the basis of NPPP, 2012, and the non adjudication of its representation dated 20.02.2013, it had filed Writ Petition Nos.7030/2014 and 7035/2014 before the Hon'ble High Court of Delhi.

The said writ petitions have been disposed on 15.10.2014 with a direction to the Reviewing authority to consider the grievances of the Company with respect to price fixation as requested by the Company under paragraph 8(4) of DPCO 1995.

#### NPPA comments:

4. The NPPA representative stated that the case of Histac was considered in 126<sup>th</sup> Authority meeting held on 11.9.2012 and the Authority decided that the manufacturers may be asked to furnish detailed and specific justification for 100% MAPE claim alongwith actual expenditure incurred by them over and above the ex-factory cost. Accordingly the letters were issued to the manufacturers and letter pertaining to M/s Ranbaxy was issued on 25.9.2012. NPPA representative provided a copy of the speed post records from the office register. The case was again included in agenda of 127<sup>th</sup> Authority meeting held on 6.11.2012 alongwith the agenda note for allowing of 100% MAPE. The case was again deferred since no information on 100% MAPE was provided by the Petitioner. The case of Histac tablet as well as Fucibet cream was again included in 128<sup>th</sup> meeting of the Authority held on 21.12.2012 and both cases were closed since NPPP 2012 was notified on 7.12.2012.

NPPA representative mentioned that as per para 8(4) two months time from the date of receipt of complete information is permitted. NPPA has not received complete information from M/s Ranbaxy till date in respect of Histac tablet. Further in respect of the application dt. 18.10.12 for Fucibet cream, NPPP 2012 was notified prior to the expiry of two months from the date of application.

#### Petitioner:

5. The Petitioner representative stated that letter dated 25.9.2013 stated to have been sent by NPPA was not received by them. Without prejudice however the Petitioner's application has been rejected due to change in policy and not for want of information as had been sought by the stated letter. The Petitioner representative further submitted that the query of NPPA seeking justification for grant of 100% MAPE, is incorrect, as the same is contrary to Order dt. 27.11.2013 passed by the Reviewing Authority in a Review application filed by IPCA. The same legal principle needs to extend to the Petitioner as well.

The Petitioner representative stated that NPPA reference and reliance upon NPPP 2012 and the decision as stated to have been taken in various meetings is incorrect and contrary to the submissions which were advanced before the Delhi High Court at the time of adjudication of writ petition No.7030 and 7035 of 2014. On the date of closure i.e. 10.1.2013 only the NPPP 2012 had been framed and law pursuant to the said policy had not been enacted or notified. DPCO 2013 was enacted much later on 15.5.2013. The mere issuance of a policy by the Govt. cannot act as justification to close all pending application. Furthermore, even the preamble of DPCO 2013 specifically safeguards acts which have been done or omitted to be done. Pending proceedings on the date of notification of DPCO 2013 were to continue to be adjudicated under DPCO 1995. The Petitioner's applications were pending on the date of notification of DPCO 2013 and the same were required to be adjudicated in accordance with the provisions of DPCO 1995. The Ministry has also directed NPPA to adjudicate all pending applications in accordance with DPCO 1995 vide its letter dt.28.12.2012. All information as required and/or sought for by NPPA had been duly provided to NPPA in the case of Histac by 9.8.2012 and in the case of Fucibet cream on 18.10.2012. Without prejudice it was submitted that the Petitioner is willing to furnish such other and further information as may be required by NPPA to decide the application under para 8(4).

Petitioner representative mentioned that NPPA had even pursuant to notification of NPPP 2012 in certain cases allowed application for revision of prices. Even after DPCO 2013 having been notified, certain price fixation notifications under DPCO 1995 were notified. Equal treatment should have been provided to the Petitioner.

#### NPPA comments:

6. NPPA representative stated that in the 130<sup>th</sup> meeting of the Authority held on 22.3.2013 the Authority decided to consider only those cases of price fixation/revision of formulations where the bulk drug prices were recently revised upward by the NPPA.

#### Petitioner:

7. The Petitioner representative mentioned that a decision to only revise the prices of formulations where in cases the prices of the bulk drug had recently been revised upward is incorrect. An application under para 8(4) in Form III has to be decided on its own merits. The decision of NPPA to revise prices of formulations where there was an upward revision of the bulk drug prices after NPPP 2012 having been notified clearly demonstrates that the notification of NPPP 2012 did not act as a bar for adjudication of the pending applications and revision of the prices where they were required. Thus it is evident that NPPA has acted in a selective manner which is incorrect.

#### Governments' comments and recommendations:

8. The grievance of the Petitioner is that their application filed before NPPA for price fixation on 4.4.2012 pertaining to Histec EVT tablet and Form III application dt. 18.10.2012 for Fucibet cream 15 mg Aluminium tube the price of which was notified vide SO NO.1937(E) dt. 3.8.2009 should have been decided by the NPPA. As per para 8(4) of DPCO 1995, the price application for fixation or revision of the retail price of a formulation in Form III or Form IV is required to be fixed or revised within a period of 2 months from the date of receipt of the complete information. In the case of Histec it was decided by the Authority to ask the manufacturers to furnish detailed and specific justification for 100% MAPE (Maximum Allowable post manufacturing expenses) claim alongwith actual expenditure incurred by the company.

The Petitioner representative stated that they did not receive said letter from NPPA. NPPA representative has given a copy of the speed post despatch records from the office.

As per provisions contained in para 7 of DPCO 1995 MAPE ..... "shall not exceed 100%". It was therefore, an important information to be provided by the manufacturer which they did not provide. NPPA could not, therefore, fix the price of their formulation and the receipt of complete information cannot be said to be given to NPPA. The argument of the Petitioner to link this with IPCA case in para 5 above is not relevant as in the instant case information required was not provided by the company.

In respect of other application dated 18.10.2012 NPPA should have fixed or revised the price of the formulation. It may be mentioned that NPPA instead of closing application should have fixed the price of Fucibit cream irrespective of whether the Policy has been announced or not. Till such time the old DPCO is replaced by a new DPCO NPPA should have continued to perform the functions assigned to it under previous DPCO. The arguments of the NPPA that the Authority decided to only those cases of price fixation/revision of formulations where bulk drug prices were recently revised upwards by NPPA has no merit as neither DPCO 1995 nor pricing Policy 2012 authorised NPPA to do so. However, since the DPCO 1995 has already been repealed and saved by the provisions of DPCO 2013 what has been done or omitted to have been done can be saved. Any fixation by NPPA on the basis of information in Form III amounts to a new action. No new action can be taken under provisions of DPCO 1995 after it has been replaced by DPCO 2013. The case of Abott quoted by the Petitioner is different as in that case it was a review order on the notification already issued by NPPA. In the instant case the prices are yet to be fixed.

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

"The review application of the company merits no consideration and, therefore, may be rejected."

Issued on this date 3<sup>rd</sup> February, 2015

(Anil Jain)

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,  
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2. The Member Secretary,  
National Pharmaceutical Pricing Authority,  
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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. T.D. (NIC) for uploading order on Department's Website.