No. 31015/7/2013-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 22 OF DPCO, 1995

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

Ref. 1. Applicant's application dated 20.2.2013
2. Hon'ble High Court of Delhi order dated 15.10.2014 and 15.04.2015
3. 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
4. Record Note of discussions held in the personal hearing held in the matter on 25.11.2014 and 15.05.2015

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

2. 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.

3. In pursuance of the orders of Hon'ble Delhi High Court dated 15.10.2014 a review hearing was given to the petitioner on 25.11.2014. The orders passed by the Reviewing Authority on 03.02.15 are enclosed as Annexure I.

4. Subsequent to the passing of review order by the Reviewing Authority the petitioner challenged the review order in the Hon'ble Delhi High Court vide WPC 2640/2015 and CM No.4731/2015. The Hon'ble Delhi High Court vide its order dated 15.04.2015 set aside the impugned order and the matter was remanded to the Reviewing Authority to take a fresh decision in the matter. The Hon'ble Delhi High Court ordered as under:-

"The reviewing authority will issue notice to the petitioner fixing the date, time and venue for hearing its duly authorised representative. Upon hearing, the reviewing authority will pass a reasoned order, which will be communicated to the petitioner. This exercise will be conducted with expedition though, no later than twelve weeks from today.

Needless to say, the petitioner will supply all documents/details which it may be called upon to file by the reviewing authority, within the prescribed time. In adjudicating upon the petitioner's application due regard will be given to the directions contained in the order dated 15.10.2014, passed in the earlier round which, inter alia, provides that the petitioner's claim that it falls within the provision of paragraph 8(4) of the DPCO, 1995, will be examined by the reviewing authority."

5. A fresh hearing to the company was given on 15.05.2015. Record note of discussion, copies of which were given to the petitioner and NPPA are made integral part of the review order.

6. During the personal hearing the points raised by the petitioner, comments of NPPA and comments of the Reviewing Authority are as under:-

Petitioner:

7. The Petitioner representative mentioned that they had filed an application in form III for price fixation on 24.4.12 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.

8. 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.

9. 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.

10. 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.

11. 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.

12. 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

13. The NPPA representative stated that the case of Histac was considered in 126th 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 127th 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 128th meeting of the Authority held on 21.12.2012 and both cases were closed since NPPP 2012 was notified on 7.12.2012.

14. 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:

15. 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.

16. 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).

17. 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:

18. NPPA representative stated that in the 130th 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:

19. 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.

Petitioner

20. Company representative mentioned that company have informed the Hon'ble High Court of Delhi about the fixation of price included by NPPA in the agenda of 143rd Authority meeting on 13.2.2014 and it was put up for the approval of the Authority. As per the agenda No. 7 NPPA have proposed revised price of Histec EVT from Rs. 2.96 to Rs. 3.68 for pack of 2 tablets i.e. increase of 24.32% and in case of Fucibet cream from Rs. 30.52 to Rs. 46.22 for pack of 15 gm i.e. increase of 51.44%. However, surprisingly, as per the minutes of the Authority meeting it was stated as under:-

"The Authority discussed these cases in detail. It was deliberated that these cases were already closed by the NPPA and the company was informed accordingly. In view of this the Authority decided that DOP may also be informed with regard to their letter dated 19.11.2013 that there is no pending case of M/s Ranbaxy in the NPPA as their applications for price revision had earlier been closed consequent on announcement of NPPP 2012 and they have not requested for reopening of the same."

21. The company representative stated that as apparent in the previous para the injustice was done by NPPA as well as D/o Pharma in their order dt. 3.2.2015 and in the High Court also ASG have accepted that the order issued by DOP is contradictory in which they have accepted the error made by NPPA, still then, the review application was rejected by D/o Pharmaceuticals. So as an aggrieved party the company has again gone to the Court and Court has given relief that the Review Order may be set aside and fresh order should be issued. The company seeks justice and price approval from retrospective date with two years 10% increase for both the products. The company representative also mentioned that they have taken 10% annual increase on the previous price fixed under DPCO 1995.

NPPA

22. NPPA representative mentioned that minutes of 143rd Authority Meeting clearly states that the cases were closed earlier and there was no re-consideration.

23. NPPA representative further stated that price of bulk drug Ranitidine(used in Histac tablets) was last revised on 11.10.2010 from Rs. 691 per kg to Rs. 660 per kg. Similarly the price of bulk drug of Betamethasone Valerate used in Fucibet cream 15 gm Aluminium tube was last revised on 12.6.2009 from Rs. 171 per gm to Rs. 160 per gm. It can be seen that in both cases the price of bulk drug were revised downwards but the company never approached NPPA for downward revision in their formulation price by applying in form III. Although, the ceiling price of Fucibet cream was revised by NPPA on suo-moto basis on 03.08.2009, the retail price of Histac remained unchanged. The company was asked to provide details of 100% MAPE for Histec tablet on 25.9.2012. The company stopped correspondence with NPPA after that and never enquired the status of price fixation Since the company was aware that 100% MAPE information is required then also it did not provide the information even for Fucibet cream which was applied later. Thus the company has not provided complete details in its form III application and the application remained incomplete. National Pharmaceutical Pricing Policy 2012 was issued on 7.12.2012 which states that data relating to May 2012 for working out ceiling price thereby indicating freezing of data with retrospective effect. The company had in fact taken benefit of downward revision of bulk drug price which is not in public interest.

Petitioner

24. The company representative mentioned that downward revision in the bulk drug price will not be necessarily resulting in downward price of formulation also as it is total of raw material, pacing material, conversion cost, packing charges and 100% MAPE prevailing as on the date of revision in the bulk drug price. In fact in case of Histec EVT even after downward revision in the bulk drug price i.e. Ranitidine HCL from Rs.691 perkg to Rs. 660 per kg, per tablet cost of raw material Ranitidine remains unchanged at Rs.0.10 per tablet. On the other hand there was enormous increase in packing material cost, conversion cost and packing charges, etc. Therefore, the allegation of NPPA that company has taken the benefit of downward revision is totally wrong, premature and misleading. Further, as in case of Fucibet cream 15 gm NPPA has revised the ceiling price on suo moto basis it could have also been done in case of Histec EVT tablet.

25. Further, none of the above reasons were mentioned by NPPA in their letter dated 10.1.2013 closing the price application file as per form III of DPCO 1995 as well as in the previous hearing dated 25.11.2014 nor it was reflected in DOP order 03.02.2015.

26. The company representative further mentioned that they denied having received any letter from NPPA dated 25.9.2012 nor any reminder regarding Histec EVT tablet. Also the proof of speed post provided by NPPA is not tenable because it does not confirm the letter quoted in it. In case of Fucibet cream NPPA had never sought any information from the company and still the company has not been given any price revision.

NPPA

27. The company's argument that downward revision in the bulk drug may not result in downward price revision of formulation is incorrect as same analogy can also be applied for upward revision.

28. The company did not provide complete information and this delay has resulted in non-consideration of their application and in the meantime NPPP 2012 was announced which does not permit retrospective price fixation. NPPA representative has mentioned that as stated earlier NPPA had sought information for 100% MAPE vide letter dated. 25.9.2012 and the proof of speed post through Govt. of India post has already been given. File number indicated in the speed post record makes it clear that the reference number is same as that mentioned in the letter. File No. 8(35)/2012/DP/Div.II/NPPA was mentioned in the letter dated 25.09.2012 and the same file number is appearing in the speed post record for s.no.566 to s.no.569. The company knowingly did not provide the sought information and incomplete application was given to NPPA. The company has never given representation regarding fixation of price after issue of letter dt. 25.9.2012 and started communication only after rejection on 21st December 2012 Authority Meeting.

29. Regarding previous downward revision of bulk drug, the company was mandatorily required to apply for revision within 30 days of bulk drug price revision but the company intentionally didn't apply for the same to take undue benefit.

Petitioner

30. The company representative mentioned that on the proof of speed post provided by NPPA no file no. could be traced therefore it should not be assumed a same letter was dispatched by NPPA and received by the company. The company representative also denied of not communicating with NPPA. In fact the company had submitted a letter dated 28th December 2012 requesting NPPA to process the price application before announcement of new DPCO as per new policy.

Our comments:

31. The points raised by the company regarding closure of their application and the reply of NPPA that in the 130th meeting of the Authority on 22.3.2013 it was decided to consider only those cases of price fixation/revision of formulations where the bulk drug price were recently revised upward by NPPA is already dealt with in our letter dated 27.8.2013 quoted above and the same is reproduced again.:-

"Action under DPCO 1995 cannot be suspended/kept in abeyance till such time a notification freezing the prices is issued or till such time new DPCO is notified. Fixation/revision of prices of bulk drugs and formulations which are to be considered by NPPA is based on the market changes which have already occurred and should be taken into account as the benefit to the companies or vice versa which has already accrued during DPCO 1995."

32. The NPPA representative has raised a point that price of bulk drug Ranitidine (used in Histac tablets) was last revised on 11.10.2010 from Rs. 691 per kg to Rs. 660 per kg. Similarly the price of bulk drug of Betamethasone Valerate used in Fucibet cream 15 gm Aluminium tube was last revised on 12.6.2009 from Rs. 171 per gm to Rs. 160 per gm. While the price of bulk drug was revised downwards, the company never approached NPPA for downward revision in their formulation price by applying in form III.

33. Para 8(2) of DPCO 1995 states if the Government fixes or revises the price of any bulk drug under the provisions of this Order and a manufacturer uitlises such bulk drug in his scheduled formulations he shall, within 30 days of such fixation or revision, make an application to the Government, in form III for price revision of all such formulations and the Government may, if it considers necessary, fix or revise the price of such formulation.

34. In the case of Histec EVT tablet the bulk drug price of Ranitidine was revised downward by NPPA on 11.10.2010 from Rs. 691 to 660. It was incumbent upon the company to file an application in form III under para 8(2) of DPCO 1995. But the company did not do that. The argument of the company that the packing material, etc. had gone up is not an answer to why the company did not file a price revision application under para 8(2) whether there was an increase in packing material or not it was for the company to file an application which they did not.

35. Further in the case of Histec EVT tablet NPPA representative has provided speed post proof vide which the company was asked to provide justification for 100% MAPE information. Since the company did not provide complete details to NPPA regarding claim of 100% MAPE it cannot be said that the conditions of "receipt of complete information" as mentioned in para 8(4) of DPCO 1995" have been met with. Para 7 of DPCO 1995 allows MAPE not exceeding 100%. NPPA was, therefore, within its right to seek information to decide MAPE. It is immaterial whether after considering the information, NPPA/Govt. provides 100% MAPE or less.

36. The claim of the company that query of the NPPA regarding justification for grant of 100% MAPE is incorrect as the same is contrary to the order dated 27.11.2013 passed by the reviewing authority in a review application filed by IPCA. It may be stated that the review order issued in the case of IPCA was issued on 27.11.2013 while the information from the company on 100% MAPE was asked by NPPA on 25.9.2012. It was not possible for anybody to anticipate a Government decision much earlier than it was taken. It may, therefore, be concluded in the case of Histec tablet that the company did not file price revision under para 8(2) of DPCO 1995 while it was incumbent upon them to file such an application. Further the

company did not provide the information sought by NPPA and, therefore, it can be presumed that NPPA was not facilitated by the company to fix the price on the application filed by them.

37. However in the case of Fucibet cream 15 gm aluminium tube cost of bulk drug Bethamethasone Valerate was revised by NPPA on 12.6.2009 from Rs.171 per gm to Rs.160 per gm. However, the ceiling price of Fucibet cream was revised by NPPA on 3.8.2009. NPPA representative could not show any letter seeking details of 100% MAPE in the case of Fucibet cream. The claim of NPPA representative that the company should have provided information pertaining to 100% MAPE in the case of Fucibet cream also has no merit as neither NPPA sought breakup under form III application nor was the company mandated to provide the same. Therefore, the company is entitled for price fixation on their application for Fucibet cream filed on 18.10.2012.

Recommendation

In respect of Histec EVT tablet the company did not provide the information to NPPA. NPPA may seek relevant information pertaining to form III from the company within 3 weeks from the issue of Order and the company will provide necessary details within another 3 weeks from the date of receipt of order. After receipt of complete information from the company NPPA will revise the prices as per provisions of DPCO, 1995.

In the case of Fucibet cream 15 mg Aluminium tube, NPPA to consider the information filed by the company in form III and fix the price within 45 days from the date of issue of this order. In respect of revision of Ranitidine downward by NPPA on 11.10.2010 from Rs.691 to Rs.660/- NPPA may take action as per extant rules and procedures.

Issued on this date 07th October, 2015.

(R.K. Maggo)
Director/07.10.2015

To

1. M/s Ranbaxy Laboratories Limited
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   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. T.D. (NIC) for uploading order on Department's Website.