

No. 8/14/07-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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B Wing, 3rd Floor, Janpath Bhavan, New Delhi

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

Subject: Review application of M/s Pfizer Ltd. dated 28.09.2007 against the price fixation notified by NPPA vide S.O. No 1585(E) dated 21/9/2007 for their formulation "Benadryl Cough Syrup 100 ml". issued under Drugs (Prices Control) Order, 1995 (DPCO, 1995).

Ref. 1) Applicant Review application dated 28.09.2007
 2) NPPA notification under review S.O. No. 1585(E) dated 21/09/2007
 3) Record Note of discussions held in the personal hearing held in the matter on 11.07.2016

This is a petition under paragraph 22 of the Drugs (Prices Control) Order, 1995 (hereinafter called the DPCO) filed by M/s Pfizer Ltd. (hereinafter called the petitioner) against notification S.O. No.1585(E) dated 21.09.2007 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of "Benadryl Cough Syrup 100 ml".

2. Review Order was issued by this Department on 16.12.2010. The company had filed a writ petition No.2389 of 2011 before the Hon'ble Bombay High Court. The Hon'ble Court vide its Order dated 30.07.2013 had set aside the impugned Review order including the consequential order demanding payment with the directions that Review application under para 22 of DPCO, 1995 is heard afresh and after granting a personal hearing issue a fresh review order. Department had filed an SLP in the Supreme Court. However, Hon'ble Supreme Court vide its order dated 01.09.2015 did not interfere with the Order of Hon'ble High Court and dismissed the SLP.

3. A personal hearing was given to the company on 11.1.2016 by Shri R.K. Maggo, the then Director. However, in the light of Advice of Ministry of Law & Justice, it was decided to hear the matter once again by Shri M.K. Bhardwaj, Deputy Secretary, who joined in place of Shri R.K. Maggo, the then Director. Accordingly, a personal hearing was given to M/s Pfizer Ltd. on 11.7.2016.

4. The grievances of the Company raised in their review application dated 28.09.2007 were sent to NPPA and the comments of NPPA thereon were given to the Company through the Record Note of discussions held in the hearing on 11.07.2016. Record Note of discussion is made integral part of the review order. After considering the comments of NPPA the Company 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:

5. Point 1 :-

Company: The company representative mentioned that all the enquiries of NPPA pertain to Benadryl Syrup and not Benadryl cough syrup. In the notification dated 21.09.2007, the strength mentioned as under –

Diphenhydramine
Hydrochloride IP 14.08mg
Ammonium Chloride IP 0.138 g
Sodium Citrate IP 57.03mg,
Menthol IP 1.14mg,
Ethanol (95 per cent) IP 0.2625ml
Ethanol Content 5% v/v

The above ingredients are contained in their other formulation Benadryl cough formula.

NPPA comments:

NPPA representative mentioned that the company neither followed the notified prices nor they had applied to the NPPA for price revision under Form 3. Therefore, their review application is not maintainable as under proviso to para 22 no manufacturer, importer, distributor shall sell the formulation at a price exceeding the price fixed by the Government of which review has been applied for.

NPPA representative mentioned that they fixed the price in the public interest after getting it from whichever sources available as the company did not give any information despite reminders. Copies of such letters (Dated 13.02.2007 followed by reminders dated 27.02.2007, 25.05.2007, 23.07.2007 and 16.08.07) are enclosed.

In response to the NPPA letter dated 25.05.2007 the company rep mentioned that they had given the information on point (a), i.e. supplementary price list in Form V and also stated that the ORG IMS Data is incorrect. However, company rep confirmed that they did not give the control samples vide their letter dated 07.06.2007. They also did not give the purchase price of active ingredient during the past 3 years.

Company:

The company representative mentioned that Form V are reliable and ought to be taken into consideration as opposed to control sample. The company representative mentioned that they had given the control samples at the time of review application.

NPPA:

NPPA mentioned that on 23.07.2007 they had given a reminder followed by another reminder on 16.08.2007. NPPA rep mentioned that control samples were never given to them before the fixation of price by NPPA. NPPA purchased the samples from the market and copy of the purchase bill is enclosed with this Record Note of discussion.

With regard to point (1), NPPA mentioned that they had written a letter dated 30.12.2015, which, inter alia, mentioned as under:-

“That the NPPA has fixed MRP of Benadryl Formulation in price notification dated 21.09.2007 in public interest under para 10(b) of DPCO’ 1995. The said price fixation was carried on the basis of formulation pack as available in the market as it was necessary to do so to protect consumer against unjustified price increase and avoid unreasonable burden. The company has failed to substantiate their claim in respect of price increase with proper justification and control samples despite reminders from this office. The said price notification has been fixed under para 10(b) & 11 of the DPCO’ 1995 and ‘notes’ mentioned therein clearly obligates the concerned company to comply with the MRP fixed therein. In case the company desired any price revision, it is required to approach the NPPA to seek price approval. It is not open to the company to defy the aforesaid price order/notification dated 21.09.2007 on the pretext that initial inquiries were in r/o Benadryl 12.5ml or on slight change in nomenclature as Cough Syrup instead of Cough formula. Composition of formulation mentioned in aforesaid price order dated 21.09.2007 is identical to the composition of Benadryl Cough Formula 100ml marketed by the company. The aforesaid price order has been issued under the DPCO, 1995 promulgated under section 3 of EC Act, 1955. As per section 6 of EC Act, 1955 said orders issued under section 3 are mandatory to be complied with. The aforesaid price order is fully applicable to Benadryl Cough Formula 100ml and the company cannot be allowed to escape from its responsibility on flimsy pretexts to earn unjust enrichment at the cost of consumers. The company is liable to deposit overcharged amount with interest thereon for charging higher price than the price fixed for such formulation under the provision of DPCO, 1995 read with EC Act, 1955.”

6. Point No.2

Company : The company representative also mentioned that at no point of time their price was increased by more than 20% as at that time the limit for annual increase in the price of non scheduled formulations was 20% per annum. In fact, the company’s price increase was slightly more than 10%.

NPPA comments: NPPA representative denied the submission of the company as mentioned in point 2 above and stated that company did not give control samples to prove that they have not increased the prices above 20%. Further, they did not give any details despite asking for purchase price of API for the last 3 years as per letter dated 25.05.2007 along with control samples which was not provided by both the companies.

7. Point No.3

Company : The company representative mentioned that NPPA had taken ORG-IMS price of Rs.25.78 while as per the Form V the price was Rs.28.47. Therefore, the annual price increase is around 10 % and not 20%.

NPPA comments: The contention of the company is totally unacceptable and denied. We have fixed the price in public interest under para 10 (b) and 11 on the basis of available information after taking all the relevant facts into consideration.

8. Point No.4

Company: The company representative mentioned that NPPA had taken ORG-IMS data and subsequently ORG-IMS has certified that the prices of the formulation during period November, 2005 were incorrect instead of Rs.25.78 they were Rs.28.47 and copy of the letter from ORG IMS was enclosed by the company with their original review application dated 28.09.2007.

NPPA comments: NPPA representative mentioned due to the non-submission of the tangible information by the company, NPPA collected the samples from the market and fixed the price of Rs.38.61 in public interest under para 10 (b) and 11 of DPCO, 1995.

9. Point No.5

Company: The company representative mentioned that NPPA vide letter dated 17.12.2015 have clearly admitted that they have notified the price of Benadryl cough syrup instead of Benadryl syrup 12.5 mg/100 ml. The company representative drew attention of NPPA's letter dated 17.12.2015 wherein NPPA has clearly mentioned that they have taken the price of Benadryl syrup 12.5 mg/100ml as shown in ORG IMS data into account while fixing the price of said formulation under para 10 (b), which is a different formulation, i.e. Benadryl cough syrup.

NPPA comments: NPPA has mentioned that their contention is misleading and their assumption is totally wrong, as a matter of fact NPPA has fixed the price for the Benadryl syrup active ingredient (bulk drug). It was obligatory on the part of the company to follow the notified price. In case they desired any price revision it was open to them to apply in Form III. This notification is/was fully applicable to the aforesaid formulations. It is also noted once the price is notified that remains valid till it is revised by specific notification. In this connection refer to the judgements delivered by the Hon'ble High Court of Delhi in the case of M/s Glaxo Smithkline, Tristar (260/2009 WA) Madras High Court in price formulations. Accordingly, the price notification once issued under DPCO, 1995 are mandatorily to be complied with.

10. Point No.6

Company: The company representative mentioned that NPPA has not shown any basis for fixation of price of Benadryl cough syrup. As per their own statement quoted in letter dated 17.12.2015 under para 17 and para 22 NPPA has stated that price Benadryl syrup 12.5mg/100ml as shown in ORG IMS was taken into account while fixing the price of the said formulation.

NPPA comments: NPPA representative mentioned that their contention is totally wrong and misleading. In fact the company should give the cost details of the products they are referring to.

11. Point No.7

Company: The company representative mentioned that NPPA has incorrectly noted the price of Benadryl syrup and projected it as Benadryl cough syrup

NPPA comments: The contents of the point 7 are strongly denied by the NPPA representative.

12. Point No.8

Company : The company representative mentioned that NPPA has not made any enquiry on Benadryl cough syrup while fixing its price, therefore, the fixing of price of Benadryl cough syrup was not in order.

NPPA comments: NPPA representative mentioned that their contention is wrong and misleading because it was the company who deliberately and willfully did not submit the requisite details, i.e, control samples and purchase price of their API for the last 3 years with the sole intention to continue charge higher price from the consumers since NPPA was required to carry out mandatorily to fix the reasonable price for the consumers. Price fixation was carried out by purchasing samples from the market as sold to the consumers in the market. Once the price notification was done it was obligatory for the company to follow the notified price from the date of notification. In case they desired any price revision they should have sent the control samples in Form III. The company representative wanted to confirm the copies of the bill produced by NPPA and company was asked to confirm it and sent us written comments by 13th evening failing which the hearing record recorded today will be treated as final.

13. The company repeats and reiterates its entire submissions as contained in the letters dated 23.12.2015 and January 11, 2016. The company denies all oral submissions as conversed by NPPA. The submissions of NPPA are not relevant and germane to the issue at hand and raised only with a view to create confusion and red-herring. In the face of clear admissions the exercise of power of NPPA is without jurisdiction and the impugned notification is wholly misconceived, not maintainable and ought to be set aside.

14. Company vide its letter dated 13.01.2016 has stated that at the further outset, as regards the bill produced by NPPA is concerned, it is submitted that batch No.620-2831 as mentioned in the invoice is that of 'Benadryl Cough Formula 100ml' and not 'Benadryl Syrup' as mentioned on the invoice and sought to be contended by NPPA. It is for this reason that NPPA has conveniently only sought to produce the invoice, without the actual formulation. If the actual formulation was to be made available, then the position would be made amply clear that the formulation as sought to be purchased was 'Benadryl Cough Formula 100 ml'.

15. The above and other submissions made by NPPA in their communication as well as during the oral submissions amply makes it clear that –

- a) Though NPPA sought to conduct enquiry for 'Benadryl Syrup 12.5 mg (100ml)' it has instead vide the impugned Notification sought to notify price for 'Benadryl Cough Syrup 100ml' (which according to NPPA is same as 'Benadryl Cough Formula 100ml');
- b) The alleged ORG IMS price which was taken into consideration by NPPA for 'Benadryl Syrup 12.5 mg(100ml)' was applied to 'Benadryl Cough Syrup 100 ml' (which according to NPPA is same as 'Benadryl Cough Formula 100ml') under the impugned Notification; and
- c) That no enquiry was ever conducted by NPPA for 'Benadryl Cough Syrup 100ml' (which according to NPPA is same as 'Benadryl Cough Formula 100 ml') and that there is no material and/or record available with NPPA for any purported price increase for the formulation 'Benadryl Cough Syrup 100 ml' (which according to NPPA is same as 'Benadryl Cough Formula 100ml'), which would warrant or justify invocation of exercise of powers under para 10 (b) of DPCO, 1995.

16. **Examination:**

There are distinctly two stages one before issue of notification 1585(E) dated 21.09.2007 and two after issue of notification and following price notification dated 21.09.2007.

First Stage:

It may be seen from that NPPA, before fixing the price under para 10(b) of DPCO, 1995 had made enquiries from the company on 25.05.2007 and they requested the company, inter alia, seeking the control samples indicating MRP for the months of November, 2005 and November, 2006. NPPA also requested the company to provide purchase price of the active ingredients (bulk drug) during the last 3 years. In its reply dated 07.06.2007, the company stated that ORG-IMS data is erroneous and the data filed by them in Form V is more reliable. NPPA further issued letters to the company on 23.07.2007 and 16.08.2007, in which NPPA requested the company to submit control samples of the formulation to substantiate their claim. The company, however, did not submit control samples to substantiate their claim. "Benadryl Syrup" or "Benadryl Cough Syrup" are the brand names and are similarly sounding. The company by not giving the control samples of its formulations has disabled NPPA to fix the prices in public interest. NPPA, not only depended upon IMS-ORG data but had purchased the samples from one M/s. Pradeep Medicos, Janak Puri, New Delhi who had sold the formulations in the name of Benadryl syrup at Rs. 48.08/-. During the hearing the company representative has referred to their formulations as Benadryl syrup allegedly not conforming to the ingredients mentioned in the notification and the formulations Benadryl cough formula which, as per the company contained the same ingredients, i.e.

Diphenhydramine
Hydrochloride IP 14.08mg
Ammonium Chloride IP 0.138 g

Sodium Citrate IP 57.03mg,
Menthol IP 1.14mg,
Ethanol (95 per cent) IP 0.2625ml
Ethanol Content 5% v/v

as in the notification.

Company further in their letter dated 13.01.2016 states that the batch No. mentioned in the bill pertains to "Benadryl Cough Formula" and the above ingredients are contained therein.

17. Instead of depending upon the outside information, i.e. ORG the company should have provided the internal documents, i.e. control samples and bulk drug prices to enable NPPA to fix the price. Form V does not include control samples and bulk drugs prices. Had the company given information in time and all relevant information, perhaps, the grievance should not have been there. The action of NPPA in fixing the price of formulation is based on data from whatever source could be available in the public interest. Either Benadryl Syrup or "Benadryl cough formula" are brand names and not to be confused with the ingredients contained in the drug.

18. Company representative stated that NPPA admitted having notified the price of Benadryl cough syrup instead of Benadryl syrup. It is important to note that the ingredients notified by NPPA in the notification dated 21.09.2007 are contained in one of the formulations of the company. We have to be guided by the ingredients and not by the Brands.

19. In regard to point that NPPA has not shown any basis for fixation of price of Benadryl cough syrup it may be mentioned that the data used by NPPA is supported by the bill of M/s. Pradeep Medicos, Janak Puri, New Delhi. If the company does not co-operate by providing complete information NPPA is within its rights to fix the prices as per the available information.

20. It is, therefore, concluded that the company did not facilitate NPPA by giving authentic information with control samples and bulk drug prices with the intent to evade price fixation. Government cannot wait indefinitely when the companies do not cooperate due to their commercial benefits.

Second Stage after the notification is issued:

21. Once the notification fixing the price of a formulation is issued it is for the manufacturers/distributors etc. to follow the price notified. The price Notification pertains to drug ingredients i.e.

Diphenhydramine
Hydrochloride IP 14.08mg
Ammonium Chloride IP 0.138 g
Sodium Citrate IP 57.03mg,
Menthol IP 1.14mg,
Ethanol (95 per cent) IP 0.2625ml
Ethanol Content 5% v/v

Therefore, even if the ingredients are contained in their formulation 'Benadryl Cough Formula' the company was supposed to follow the price notified by NPPA. However, NPPA has to issue overcharging notices for the formulation which contains the same ingredients, i.e. "Benadryl Cough Formula".

22. It is, therefore, concluded that the company did not facilitate NPPA by giving authentic information with control samples with the intent to evade price fixation. Government cannot wait indefinitely when the companies do not cooperate due to their commercial benefits. Any overcharging by the company from the public with respect to the formulation which contains same ingredients has to be recovered as per the provisions of Essential Commodities Act.

Government Order:

23. **In view of the above facts, the review application of the company is rejected having no merits. NPPA while deciding overcharging may, however, calculate the overcharging with reference to the formulations which contains the same ingredients as notified by NPPA vide notification dated 21.9.2007.**

Issued on this date, the 19th day of September, 2016.

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

To

1. M/s Pfizer Ltd.
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2. The Member Secretary,
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YMCA Cultural Centre Building, New Delhi-110001

Copy to :

1. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.
2. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
3. Technical Director, NIC with the request to upload the review order on the Department's website