No. 31015/61/2014-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 applications of M/s. Sanofi Ltd. against fixation/revision of ceiling prices of Frusemide 10 mg/ml injections, Phenarmine Maleate injection 22.75 mg/ml and Frusemide 40 mg tablet vide NPPA notification S.O. No. 2360(E) dated 15/9/2014 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013).

Ref. 1) Three Review applications dated 13.10.2014
2) NPPA notification under review S.O. No.2360(E) dated 15/9/2014
3) Record Note of discussions held in the personal hearing held in the matter on 7.11.2014

Whereas National Pharmaceutical Pricing Authority (NPPA), Government of India, vide price fixation Order S.O. No.2360(E) dated 15/9/2014 fixed/revised ceiling price of Frusemide 10 mg/ml injections, Phenarmine Maleate injection 22.75 mg/ml and Frusemide 40 mg tablet under DPCO, 2013.

2. And whereas aggrieved by the above notification, M/S Sanofi Ltd. (hereinafter referred to as the Petitioner) submitted review application dated 13.10.2014 under para.31 of DPCO, 2013 for the review of NPPA Price fixation Order S.O.No.2360 (E) Dated 15.9.2014 fixing Ceiling price of Frusemide 10 mg/ml injections, Phenarmine Maleate injection 22.75 mg/ml and Frusemide 40 mg tablet included in Schedule-I of the order (and also covered under DPCO, 1995).

3. The grievance of the Petitioner raised in their review application dated 13.10.2014 were sent to NPPA and the comments of NPPA thereon were given to the Petitioner through the record note of discussions held in the hearing on 7.11.2014. 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 Department's comments on the issue is recorded subsequently against each point:

(A) Frusemide (Lasix ampoule) 10 mg/2ml

The company representative mentioned that the formulation has been under price control since 1987 and the prices were fixed by PPA based on the cost of manufacturing and CC.PC.PL and PM norms, etc. In 1991 there were other companies namely M/s IDPL, Geno Pharma and J.B. Chemicals. All of them had stopped production of this formulation due to its non-remunerative prices . M/s Cyper Pharma Ltd. started producing the formulation in 1999 but discontinued subsequently as the prices fixed by NPPA were not viable. The above clearly suggests that prices as fixed by NPPA under DPCO 1995 were not remunerative and all other manufacturers have gradually gone out of the market. The price of the formulation under DPCO 2013 is going to further create a situation of poor access to this critical life saving drug. M/s Sanofi India Ltd. continued the manufacturing all through since 1987 and they are still continuing the production in public interest as the medicine is used for treating patients of fluid retention due to Cardiac and Renal failure which if not treated can be fatal. While fixing the ceiling prices vide Notification No. 2360(E) dt. 15.9.2014, NPPA has further reduced the prices of this formulation pack by 25.93% which will be

based on the average price reduction in relevant sub section. As per cost data for 2013 duly certified by the Cost Accountant the company incurs a loss of Rs. 19.55 million in this product. By this price reduction there will be an additional loss of Rs. 21 million. This will make the product commercially unviable.

Alternative medicines for this indication are more than twice expensive. The cost of treatment for a patient per day is less than Rs. 10 if it is considered 3 injection per day are required. Price reduction of this product whose price was fixed by NPPA itself under DPCO, 1995 by applying average reduction in the sub section leads to huge loss and continued marketing of this formulation pack may not be commercially viable. Hence we request the Deptt. of Pharma to give us relief which is available under para 19 of DPCO, 2013 which can be used in public interest as the product is life saving in nature and there are no other formulator of this product available in the market.

(B) Frusemide 40 mg Tablet

The company representative mentioned that the formulation has been under price control since 1987 and the prices were fixed by PPA based on the cost of manufacturing and CC.PC.PL and PM norms, etc. In 1991 there were other companies namely M/s IDPL, Geno Pharma and J.B. Chemicals. All of them had stopped production of this formulation due to its non-remunerative prices . M/s Cyper Pharma Ltd. started producing the formulation in 1991 but discontinued subsequently as the prices fixed by NPPA were not viable. The above clearly suggests that prices as fixed by NPPA under DPCO, 1995 were not remunerative and all other manufacturers have gradually gone out of the market. The price of the formulation under DPCO, 2013 is going further create a situation of poor access to this critical life saving drug. M/s Sanofi India Ltd. continued the manufacturing all through since 1987 and they are still continuing the production in public interest as the medicine is used for treating patients of fluid retention due to Cardiac and Renal failure which if not treated can be fatal. While fixing the ceiling prices vide Notification No. 2360(E) dt. 15.9.2014, NPPA has further reduced the prices of this formulation pack by 25.93% which will be based on the average price reduction in relevant sub section. By this price reduction, there will be a revenue loss of Rs. 26 million. This will make the product commercially unviable.

Alternative medicines for this indication are more than twice expensive. Daily cost of treatment to patient is less than Rs.2 per day. Price reduction of this product whose price was fixed by NPPA itself under DPCO, 1995 by applying average reduction in the sub section we leads to huge loss and continued marketing of this formulation pack may not be commercially viable. Hence we request the Deptt. of Pharmaceuticals to give us relief which is available under para 19 of DPCO, 2013 which can be used in public interest as the product is of life saving in nature and there are no other formulator of this product available in the market.

(C) Pheniramine Maleate 22.75 mg/ml injection

The company representative mentioned that the formulation has been under price control since 1987 and the prices were fixed by PPA based on the cost of manufacturing and CC.PC.PL and PM norms, etc. The price of the formulation under DPCO, 2013 is going to create a situation of poor access to this critical life saving drug. M/s Sanofi India Ltd. continued the manufacturing all through since 1987 and they are still continuing the production in public interest as the medicine is used for treating patients of symptomatic relief of acute allergic conditions in skin. While fixing the ceiling prices vide Notification No. 2360(E) dt. 15.9.2014, NPPA has further reduced the prices of this formulation pack by 32.90% which will be based on the average price reduction in relevant sub section. Currently, the company is incurring loss of Rs.3.13 million and by this price reduction, there will be an additional loss of Rs. 40 million. This will make the product commercially unviable.

Alternative medicines for this indication are more than twice expensive. Daily cost of treatment to patient is less than Rs.12 per day. Price reduction of this product whose price was fixed by NPPA itself under DPCO, 1995 by applying average reduction in the sub section we leads to huge loss and continue market of this formulation pack may not be commercially viable. Hence we request the Deptt. of Pharmaceuticals to give us relief which is available under para 19 of DPCO, 2013 which can be used in public interest as the product is of life saving in nature and there are no other formulator of this product available in the market.

4. NPPA comments in PH for all three formulations:

NPPA representative mentioned that there are only two methods of pricing under DPCO, 2013 – one is averaging and another is monopoly method. Since M/s Sanofi was the only manufacturer having more than 1% MAT value, the case was considered as a monopoly item and price was fixed in line with provisions of DPCO, 2013.

5. Department's comments :

The formulations covered in all the three petitions are those which were under price control under DPCO, 1995 and they continue to be under price control under DPCO, 2013. NPPA has noted that the company is the only formulator and, therefore, they have applied the monopoly condition and fixed the price as per DPCO provisions. It may be mentioned that pricing of formulations covered under DPCO, 1995 and also DPCO, 2013 are to be fixed under para 10 of the DPCO, 2013. As per para 10 (1) and 10(2) the price fixed and notified under the provisions of DPCO,1995 will remain effective for one year. Manufacturers may revise the prices of such formulations as per annual WPI for the previous calendar year and thereafter the formula as per sub-paragraph 1 of paragraph 4 of this DPCO,2013 shall be applied for fixing the ceiling price of such formulations.

Further under para 6(1) it is mentioned that where the average price to retailer of a scheduled formulation, arrived at as per the formula specified in sub-paragraph (1) of paragraph 4, has the effect of ,-

a) no reduction in average price to retailer with respect to the prices to retailer of the schedule formulation; and
b) there are less than five manufacturers for that formulation having one percent or more market share.

The ceiling price calculation is given in subsequent sub-paras using monopoly condition.

Since these drugs were already covered under price control under DPCO, 1995 in most of the cases no reduction was expected. The framers of DPCO, 2013 had, therefore, made a conscious exception under para 6(2) of DPCO, 2013 as under –

> "6(2) Notwithstanding anything contained in this paragraph, where the price has been fixed and notified by the Government under the Drugs(Price Control) Order, 1995 the provisions of sub-paragraph (1) shall not apply".

The prices of these drugs were not to be fixed under paragraph 6 i.e no reduction in prices due to absence of competition. NPPA has erred in fixing the prices under section 6 of DPCO, 2013.

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

"NPPA may be directed to fix the price under para 4(1) of DPCO, 2013 and not under para 6."

Issued on this date 6th 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. Sanofi Ltd.,
   D-2, 4th Floor, Southern Park,
   Saket District Centre,
   Saket, New Delhi-110017

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. Technical Director, NIC with the request to upload the review order on the Department's website