F. No. 31023/09/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS
……..

A Wing, Shastri Bhawan,
New Delhi 110 001

Order

By this order, the review application dated 29/08/2007 filed by M/s Cadila Pharmaceuticals Pvt. Ltd. (hereinafter called the company/applicant) against notification S.O. No. 1295(E) and 1296(E) dated 30/07/2007 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of their formulations Envas 2.5 mg and Envas 5 mg is being disposed of. Earlier this review application was dismissed by Department of Pharmaceuticals (DoP) on 16/04/2008 being time barred. The company had filed writ petition CWP No. 6417 and 6050 of 2008 before Hon'ble High Court of Gujarat. The Hon'ble Court had ordered on 12/10/2017 that DoP shall hear the matter on merits on the review application.

Brief facts of case are as under:-

2. NPPA, vide its notifications dated S.O. No. 1295(E) and 1296(E) dated 30/07/2007 had fixed the prices of Envas 2.5 mg and Envas 5 mg respectively. Being aggrieved, the company had filed review application dated 29/08/2007 under para 22 of DPCO, 1995. This review application was not filed within 15 days of notification, (as per extant provisions under para 22 of DPCO, 1995), hence DoP rejected the application being time barred. However, the company did not comply with the price notifications and NPPA issued demand notice to the company on 17/03/2008 for Rs. 92,91,159/- in respect of Envas 5 mg and another demand notice dated 02/04/2008 for Rs. 49,51,687/- in respect of Envas 2.5 mg tablet. Thereafter, the company filed two writ petitions (Special Civil Application No. 6417 and 6050 of 2008) in Hon'ble High Court of Gujarat.

3. The Hon'ble High Court of Gujarat, vide its order dated 12/10/2017 has, inter-alia, ordered as under:-

"…..The decision of the Department, reflected in communication dated 16/04/2008 in not entertaining the Review Applications of the petitioner dated 29/08/2007 is hereby set aside. Delay in filing Review Application under Para/Rule 22 of DPCO, 1995 is hereby condoned, with a direction to the competent authority to hear and decide the Review Application of the petitioner in accordance with law and on merits within a period of eight weeks from the date of receipt of the present order…… It is further directed that until the Review Applications are decided, the demand notice issued in both the cases by the respondent shall not be enforced and shall be subject to the outcome of the decision in Review."

4. In accordance with order of Hon'ble High Court matter was listed for hearing on 02/01/2018. Both the company and NPPA were heard. The company/applicant has contended as under:

(i) In April 2005, Envas 2.5 mg was available in strip of 10 tablets at Rs. 14.28/- per strip and Envas 5.0 mg was available in strip of 10 tablets at Rs. 23.30/- per Strip.

(ii) This packing of 2.5 mg continued till April, 2006 in 10 tablets Strip with revised price at Rs. 15.95 /- per strip and packaging of 5 mg at revised price of Rs. 25.95/- per strip (10 tablets per strip).

(iii) Therefore, the price increase was only 11.9% during April, 2005 to April, 2006 which was within the stipulated limit of 20% during the year. In the same month, the packaging of 2.5 mg and 5 mg were changed from 10 tablets strip to 15 tablets strip at Rs. 23.93/- and Rs. 38.93/- respectively per strip.

(iv) This price of Rs. 23.93/- per strip (Strip of 15 pack) and price of Rs. 38.93/- per strip (Strip of 15 pack) was fixed on pro-rata basis and therefore, there was no increase in actual per tablet price.

(v) Therefore, the observation made by NPPA regarding the price increase of more than 20% is totally wrong and NPPA had, without affording opportunity to being heard to applicant herein and without parting natural justice, decided the matter on its own and erroneously or inadvertently notified the MRP under para 10(b) of DPCO, 1995 and issued demand order thereon.

(vi) It is common law and cardinal principle of natural justice and even interpretation of law that, once the matter become subjudice on certain point before the adjudicating authority, the time and period of such adjudication process or finality or deciding matter, should be excluded and not to be reckoned while issuing any demand notices dated 17/03/2008 and dated 02/04/2008 for such period which may cause grave hardships and not rendering justice.

5. In view of the above, the company stated that when no contravention took place while converting the drug strip from 10 tablet to 15 tablet and made applicable pro-rata charges on it i.e. same price per tablet and not in excess, the impugned orders passed on 17/03/2008 and dated 02/04/2008 and demand so made there under by the Authority may be recalled or set aside the aforesaid order and demand made thereupon.

6. <u>Comments of NPPA:</u>

(i) NPPA was established, inter alia, to fix/ revise the prices of controlled bulk drugs and formulations and to enforce the prices and availability of the medicines in the country, under the Drugs (Prices Control) Order, 1995 (DPCO, 1995). NPPA is also entrusted the task regarding monitoring the prices of non-scheduled formulations in accordance with the provisions of DPCO, 1995 and internal guideline approved by the Ministry of Chemical and Fertilizers from time to time. Companies are short listed where there is an increase in prices of a non-scheduled formulations by more than 20% in one year and the annual turnover of any formulation pack exceeds Rs. 1 crore vide Internal Guideline No. 2/2007 dated 19.02.2007. Subsequently, the limit of increase in price was revised to 10% vide Guideline No.

3/2007 dated 16.03.2007, which came into existence prior to the fixation of price for these two formulations. The Ministry has also informed the status of price fixation of non-scheduled formulations under the provisions of Para 10(b) of DPCO, 1995 vide these Guidelines from time to time. The prices of non-scheduled formulations packs are to be monitored on the basis of data on prices available in ORG-IMS on regular basis.

(ii) It has been noted that the company increased the MRP of Envas 2.5 mg and Envas 5 mg by more than the permissible limit. In order to ensure that the prices of important drugs / medicines are not increased unreasonably, NPPA had decided to examine the reasons for increase in the price. In view of the above fact, the company was asked to submit the requisite information including **control sample**, vide letter dated 08.02.2007 and 16.06.2007. However, reply submitted by the company was not acceptable as it is not supported by control samples of these two formulations. The samples are obligatory for the examination of increase in MRP by the company. Since company has not submitted the **control samples**, MRP of the formulations was fixed in the 95th Meeting of the Authority held on 24.07 2007 as follows:

Particulars	Envas 2.5 mg	Envas 5 mg
(a) Price as per ORG/Company as on April 2005	11.73	19.13
(b) Add 20% Trade Margins on ORG Price	2.35	3.83
(c) Sub Total	14.08	22.96
(d) Add 20% for increase in price, as per guidelines	2.82	4.59
(e) Net Retail Price	16.89	27.55
(f) Add Sales Tax/Vat 4%	0.68	1.10
. (g) Maximum Retail Price for 10 Tab(incl. E.D. + VAT)	17.57	28.65
(h) Maximum Retail Price for 15 Tab(incl. E.D. + VAT)	26.35	42.97
(i) Price as per sample purchased	28.34	46.07
(j) Difference	1.99	3.10

(iii) Company is required to implement the notified price within 15 days from the receipt of the communication/ notification. However, the company did not comply with the notified price in accordance with the notifications S.O. No. 1295 (E) and 1296 (E) dated 30.07.2007 for these two formulations. This fact of non-compliance was further established on the basis of samples purchased by the NPPA. These samples are manufactured subsequent to the date of notification, it was seen that the company has not complied with the maximum retail price notified.

(iv) Paragraph 22 (proviso) of the DPCO, 1995 explicitly requires implementation of price fixation notifications against which a review has been applied for. However the concerned company neither filed the review petition within the stipulated time i.e. 15 days nor did they comply with the price notifications. Therefore, demand notices were issued to them by NPPA in full compliance with the provisions of DPCO, 1995. Further, the company, vide Letter dated 28.01.2008, categorically admitted in para 4 that the petitioner has not implemented the notified price which is explicitly against

the provisions of DPCO, 1995.

(v) According to Para 22 of DPCO 1995, "Provided that pending a decision by the government on the application submitted under the above paragraph, no manufacturer, importer or distributer, as the case may be shall sell a bulk drug or formulation, as the case may be, at a price exceeding the price fixed by the government of which a review has been applied for". The company has not implemented the notified prices despite several communications in this matter. The petitioner company willfully and knowingly did not implement notified price for the above said formulation within 15 days with the intention to earn unauthorized amount at the cost of the consumer. The petitioner has deliberately violated the provisions of DPCO, 1995. Accordingly, the submission of samples by the company after the personal hearing cannot be accepted at this stage as it contains new submission.

(vi) The mandate of the DPCO, 1995 is absolutely clear and unambiguous as regards to implementation of price by the manufacturer or importer. It is an obligation/duty of every manufacturer or importer to implement the price fixed by the Central Government within 15 days from the date of the concerned notification. There is absolutely no ambiguity with regard to the mandatory and binding applicability of this provision on all manufacturers. The compliance of NPPA's notifications/S.O.s is to be done by the company irrespective of any right / wrong review application filed by it or not.

(vii) It is further stated that as per para 22 of DPCO, 1995, even for the review, implementation of price fixed / notified is prerequisite and mandatory requirement, which has to be adhered to by the manufacturer. Acceptance of control sample submitted by the company at this stage not only dilutes provisions of DPCO, 1995 but is also against the principles of natural justice.

7. Examination:

The matter under review is to adjudicate the validity of the two price notifications dated 30th July, 2007 fixing the prices of two tablet formulations based upon Enalapril Maleate in the strengths of 2.5 mg and 5 mg being sold by M/s Cadila Pharmaceuticals Ltd. under brand names Envas 2.5 mg and Envas 5 mg respectively.

(ii) M/s Cadila Pharmaceuticals Ltd., were obliged to revise its prices within 15 days of the date of notification in line with the provisions of DPCO 1995. Even if the company was aggrieved with notified prices, they could approach the Reviewing Authority under the Department of Chemicals & Petrochemicals, within a period of 15 days from the date of notification, but only after implementing the notified prices. However, without implementing the notified prices, the company approached the Reviewing Authority that too after expiry of 15 days. In line with the relevant provisions of the prevailing DPCO 1995, the Reviewing Authority did not entertain the Review Application being time barred as well as failure of the company to implement the notified prices.

(iii) The company approached the Hon'ble High Court of Gujarat at Ahmedabad challenging the NPPA notifications dated 30th July 2007 and the decision of the

Reviewing Authority about not entertaining their Review Application. The matter remained subjudice for more than a decade and vide its Order dated 12th October, 2017, the Hon'ble Court set aside the communication dated 16th April 2008 about not entertaining the Review Application, dated 29th August, 2008 preferred by the company. The Court further directed the Reviewing Authority to hear and decide the above referred Review Application within in a period of 8 weeks from the date of receipt of the Order.

(iv) In compliance to the directions of the Hon'ble High Court of Gujarat, the Reviewing Authority in the DoP has examined the application and heard the applicant company on 2nd January 2018.

(v) As per averments of NPPA, the company/applicant did not submit the Control Samples during the process of examination of their matter and the impugned price notification dated 30th July 2007 was issued taking this fact into consideration. The NPPA's Guidelines dated 19th February 2007 and 16th March 2007, clearly provide that the monitoring of prices of non-scheduled formulations will continue to be worked out on the basis of regular data from ORG IMS. The entire calculations carried out by NPPA were based upon ORG data in absence of the Control Samples preferred by the applicant. The agenda note of 95th meeting of NPPA held on 24/07/2007 about various overcharging matters, clearly indicate that the Control Samples were not submitted by the Company. The letter written by NPPA to the applicant on 8th February 2007, also refers and establishes that the Control Samples were not submitted despite reminders. Furthermore, non-implementation of the notified prices within 15 days, was another ground for not entertaining the review request at that time, in terms of the provisions of prevailing at that time i.e. DPCO, 1995.

(vi) The prayer of the company/applicant that the demand notice may not be issued /takes effect once the review petition is patently wrong and devoid of merit. Any exclusion of period is made only for the limitation of filing an appeal or application under Limitation Act, 1965. No exemption from demand can be granted to the company which violated/ not complied with S.O. which was mandatory as per provisions of DPCO, 1995.

(vii) After hearing the applicant company and going through the response of NPPA, it is felt that the Review Application is devoid of merits and the process of recovery of overcharged amounts as per NPPA's demand notices dated 17th March 2008 for Rs. 92,91,159/- in respect of Envas 5 mg tablets and another notice dated 2nd April 2008 for Rs. 49,51,687/- in respect of Envas 2.5 mg tablets, need to be pursued further in line with the relevant provisions of the DPCOs 1995 and 2013. The power to take action in regard to demand notices comes under purview of NPPA.

8. Decision:

"Review application of the company is devoid of merit and is hereby rejected. NPPA may proceed with the recovery of the amount against the relevant demand notices as per law."

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

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

To

1. Cadila Pharmaceuticals Pvt. Limited, Cadila Corporate Campus, Sarkhej Dholka Road, Bhat, Ahmedabad – 382210.

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.