



Writ Petition No.18680 of 2014

IN THE HIGH COURT OF JUDICATURE AT MADRAS

Dated: 17/10/2022

C O R A M

THE HONOURABLE MR.JUSTICE N. SATHISH KUMAR

Writ Petition No.18680 of 2014

a n d

M.P.No.1 of 2014

Mediline Pharmaceuticals
rep. By its Managing Director
Plot Nos.2 & 3, I Main Road
E.V.P. Prabhu Avenue
Chinnakulothuvancherry
Chennai 602 101.

...

Petitioner

Vs

1. The Secretary
Ministry of Chemicals & Fertilisers
A Wing, Shastri Bhawan
Dr.Rajendra Prasad Road
New Delhi 110 001.
2. The Director
National Pharmaceutical Pricing Authority
Department of Pharmaceuticals
Ministry of Chemicals and Fertilisers
5/III Floor YMCA Cultural Centre Building
1 Jai Singh Road
New Delhi 110 001.



Writ Petition No.18680 of 2014

3. The Deputy Director
National Pharmaceutical Pricing Authority
Department of Pharmaceuticals
Ministry of Chemicals and Fertilisers
5/III Floor YMCA Cultural Centre Building
1 Jai Singh Road
New Delhi 110 001.

4. The Assistant Director
National Pharmaceutical Pricing Authority
Department of Pharmaceuticals
Ministry of Chemicals and Fertilisers
5/III Floor YMCA Cultural Centre Building
1 Jai Singh Road
New Delhi 110 001.

5. The Director of Drugs Controller
Office of the Director of Drugs Controller
No.359 D.M.S.Complex
Anna Salai
Chennai 600 006.

...

Respondents

PRAYER : Petition filed under Article 226 of the Constitution of India praying for the issuance of a writ of certiorari to call for the records and quash the impugned demand notice dated 2/7/2014 claiming a sum of Rs.4,56,927/- passed by the third respondent herein in Demand Notice F.No.21 (2139)/2011/Div.IV/NPPA-DPCO, 1995:Manufacturing/marketing of scheduled formulation “Ventisol” syrup 50 and 100 ml bottles without price approval.

For petitioner

... Mr.Kumararaja



WEB COPY



Writ Petition No.18680 of 2014

for Mr.Kumar and Baskar

For respondents

...

No appearance
for .R.1 to 4.

Mr.A.M.Ayyadurai
Government Advocate
for R.5.

ORDER

This writ petition has been filed to quash the impugned demand notice, dated 2/7/2014, claiming a sum of Rs.4,56,927/-, passed by the third respondent, in Demand Notice F.No.21 (2139)/2011/Div.IV/NPPA-DPCO, 1995:Manufacturing/marketing of scheduled formulation “Ventisol” syrup 50 and 100 ml bottles without price approval.

2. The case of the petitioner is that the petitioner has sold cough syrup known as “Ventisol” syrup. National Pharmaceutical Pricing Authority (in short NPPA), issued various notices to the petitioner, questioning why prior permission was not obtained for the product “Ventisol” as per NPPA. By way of reply to the notices, petitioner submitted that “Ventisol” syrup will not come under schedule formulation, as per G.O.Ms.No.448 (E) dated 29/3/2006, as the product composition was different from the Standard product. Suddenly, on



2/7/2014, notice was issued by the third respondent, claiming a sum of Rs.4,56,927/- to the petitioner Company which includes interest at the rate of 15% p.a., and asked the petitioner to pay the said sum, within a period of fifteen days, failing which the Revenue Recovery proceedings will be initiated.

3. Being aggrieved, the petitioner has come forward with the present writ petition praying for the relief as stated therein.

4. Heard Mr.Kumararaja, learned counsel for the petitioner and Mr.A.M.Ayyadurai, learned Government Advocate for the fifth respondent.

5. There is no representation on behalf of the respondents 1 to 4.

6. Despite several opportunities given to the respondents, only fifth respondent has filed counter.

7. Fifth respondent, in its counter has submitted that Mediline Pharmaceuticals (P) Ltd., has been granted licence of manufacture for sale of drug formulations in Form 25 bearing No.TN00002193, dated 2/5/2006 and



renewed upto 1/5/2021 under the provision of Drugs and Cosmetics Act, 1940 and Rules 1945. Initially, they had been permitted to manufacture for sale of “Ventisol” syrup with the following composition.

Each 5 ml contains
Theophylline IP 30 MG
Chlorpheniramine Maleate IP 1 mg
Salbutamol Sulphate IP eq. To Salbutamol 1 mg
Sodium Citrate IP 75 mg
Menthol IP 1 mg

8. It is further stated that the provisions related to mandatory price approval of Scheduled drug formulations under the Drugs (Prices Control) Order, 1995 read with Essential Commodities Act, 1955 are only enforced by National Pharmaceutical Pricing Authority, New Delhi. Hence, seeks for dismissal of the writ petition.

9. The learned counsel appearing for the petitioner submitted that the Guidelines would not be applied as the transaction had taken place between August 2006 and June 2007 and the Guidelines were issued only in the year 2012. Without assigning any reasons, the respondents are targetting the



petitioner for more than five years. Moreover, Clause 8 (6) of DPCO, 1995 would not apply to the product “Ventisol” syrup and they are manufacturing the same with the following composition:-

S.No.	Product/Composition/Pack Size/Batch No.	Company Price as reported to NPPA
1.	Ventisol MVT 102 M/D:01/07, E/D:12/08, dt 21/5/2007 Each 5 ml contains: Theophylline IP 30 mg, Cloropheneramine Malate IP 1 mg, Salbutamol Sulphate 1 mg, Sodium Citrate IP 75 mg, Menthol IP 1 mg	Rs.35.20 (100 ml glass bottle)

10. It is his further contention that S.O.325 (E) was issued on 23/1/2009, whereas the product of the petitioner was in the market only between 2007 – 2008. Hence, the show cause notice itself was bad and the same has to be rejected.

11. Mr.A.M.Ayyadurai, learned Government Advocate appearing for the fifth respondent submitted that the petitioner Company cannot manufacture/sell the product at exorbitant price to the public. The petitioner Company has not



applied for price approval of the product despite knowing the fact that at the time of commencement of manufacturing/marketing of the subject formulation, the product was under 'controlled price category" and there was no price fixed for the product and the same has been sold to public at higher price without prior price approval.

12. A cursory glance of Clause 10 of the Internal Guidelines No.2 of 2012, dated 9/10/2012, in F.No.20 (354)/2012/Div.IV/NPPA, NPP (Legal – 1 Division) would indicate that except for cases where show cause notice/demand notice has already been issued shall be processed, as per the revised guidelines.

13. A bare perusal of the G.O., dated 23/1/2009 would indicate that the third respondent had not applied their mind, as the product "Ventisol" was sold between January 2007 and December 2008. This itself clearly demonstrate that the respondents are sending the notice regularly only to harass the petitioner. Moreover, the product "Ventisol" was in the market between January 2007 and June 2008, whereas the Guidelines 2 of 2012 would apply only when the product was sold in the year 2012 and not between 2007 and 2008.



WEB COPY



Writ Petition No.18680 of 2014

N. SATHISH KUMAR, J

mvs.

14. Accordingly, this writ petition is allowed and demand notice dated 2/7/2014 claiming a sum of Rs.4,56,927/- passed by the third respondent in Demand Notice F.No.21 (2139)/2011/Div.IV/NPPA-DPCO, 1995:Manufacturing/marketing of scheduled formulation “Ventisol” syrup 50 and 100 ml bottles without price approval, is quashed. No costs. Consequently, the connected Miscellaneous Petition is closed.

17/10/2022

Index : Yes / No

Internet: Yes

Speaking/non speaking order

mvs.

To

1. The Director of Drugs Controller
Office of the Director of Drugs Controller
No.359 D.M.S.Complex
Anna Salai
Chennai 600 006.

W.P.No.18680 of 2014

Page No:8/8