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W.P.No.26484 of 2023

IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED: 29.07.2024

CORAM :

THE HONOURABLE DR.JUSTICE ANITA SUMANTH

W.P.No.26484 of 2023

Dr.B.Mukesh

.. Petitioner

vs

1.Ministry of Health and Family Welfare,
Government of India,
Nirman Bhavan, New Delhi,
Rep. By its Under Secretary.

2.Indian Council of Medical Research,
Department of Health Research,
V.Ramalingaswami Bhawan, Ansari Nagar,
New Delhi – 110 029.

3.Dr.V.Mohan
Chairman,
Madras Diabetes Research Foundation,
4, Conron Smith Rd, Gopalapuram,
Chennai, Tamil Nadu – 600 086.

.. Respondents

Petition filed under Article 226 of the Constitution of India praying to issue a writ of mandamus directing 1st and 2nd respondent to initiate appropriate and necessary action against the 3rd respondent based on the recommendations of the 1st respondent vide communication in 1340015/2019/Drug Regulation in File No.X-11035/272/2016-DFQC, dated 14.05.2019 and based on the representation of the petitioner dated 05.06.2023, sent by the petitioner to the 2nd respondent, within the time frame fixed by this Court.



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For Petitioner : Mr.T.Mohan, Senior Counsel
for Mr.Abhinav Parthasarathy

For Respondents : Mr.Krishna Ravindran, for R3
No appearance for R1, R2

ORDER

The petitioner is a medical doctor and seeks a mandamus directing R1 and R2, being the Ministry of Health and Family Welfare, Government of India / R1 and Indian Council of Medical Research (ICMR/R2), to initiate appropriate action as against R3, who is also a medical Doctor and Chairman of the Madras Diabetics Research Foundation, based on recommendations of R1 vide communication dated 14.05.2019.

2. The crux of the matter relates to whether the use of 'Pioglitazone' (drug), including its Fixed Dose Combinations, is appropriate or otherwise, for medical use. According to petitioner, the use of the drug is perfectly in order, but an opinion has been given by R3 to the effect that the use of drug has detrimental effects such as bladder cancer.

3. Based on the above opinions, which the petitioner believes are incorrect, the drug has been withdrawn / banned from medical use. The petitioner has written to R1 as early as on 03.03.2016 bringing to its notice what he terms as a '*criminal conspiracy/false propaganda*' with regard to the drug. The petitioner has also written to the Central Vigilance Commission in this regard.

4. On 14.05.2019, R1 writes back to the petitioner relating to



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the enquiry caused by the CVC and the communication reads thus:-

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'. . . .

Subject – Complaint alleging conspiracy propaganda regarding Diabetic Drug Pioglita : one by Dr.V.Mohan, Chennai – Reg.

Sir,

I am directed to refer to your complaint No.nil dated 01.11.2017 received through Central Vigilance Commission's letter No.89036/2017/Vigilance-6/365859 dated 22.12.2017 on the above subject. It is informed that the complaint has been examined in Drugs Regulation Division and it is intimated that the role of Dr.G.N.Singh, the then DCG(I), had been examined earlier and it was found that it was part of the DCG (I)'s responsibilities to ensure safety of patients and the fact that pioglitazone was actually banned in France and Germany could not have been ignored. Against this backdrop, the DCG (I)'s action was on the side of caution and it was found that no blame attaches to him for the action taken by him in this regard. This conclusion had been approved by the Competent Authority in this Ministry. Hence, no action lies against Dr.G.N.Singh on this matter."

5. While thus justifying their decision to withdraw the drug from public use, R1 has also, on the same date, referred the complaint filed by the petitioner to the attention of ICMR, and requested R2 to take necessary action in that regard. The matter now rests with R2, to decide as to whether the drug is safe for medical use or not.

6. The role of R2 in this matter is purely to collate empirical and scientific data on the veracity or otherwise of the drug, and after hearing the views of the petitioner as well as R3, and other voices from the scientific/medical community, take a view on the resumption or otherwise



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of the use of the drug 'Pioglitazone' in India. To be noted that such a matter should not be approached in an adversarial fashion, as it concerns public interest. Since the matter has been referred to the attention of ICMR, it is incumbent on R2 to do the needful, expeditiously.

7. There is hence a direction to R2 to hear the petitioner, R3, as well as any others deemed appropriate, after issuing notices to them, look into the use of 'Pioglitazone' in the treatment of diabetics and pass appropriate orders on the representation of the petitioner. Since it is a matter concerning public health, let this exercise be completed within a period of twelve weeks from date of receipt of this order.

8. This writ petition stands disposed in terms of this order. No costs.

29.07.2024

Index:Yes/No
Neutral Citation:Yes
ssm

To

- 1.The Under Secretary,
Ministry of Health and Family Welfare,
Government of India,
Nirman Bhavan, New Delhi,
- 2.Indian Council of Medical Research,
Department of Health Research,
V.Ramalingaswami Bhawan, Ansari Nagar,
New Delhi – 110 029.
- 3.The Chairman,
Madras Diabetes Research Foundation,
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DR. ANITA SUMANTH,J.

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