2024:DHC:5162

* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

Date of decision: 09th JULY, 2024

IN THE MATTER OF:

\+ **W.P.(C) 11217/2021**

DEEPAK SINHA ..... Petitioner

Through: Mr. Dhruv Surana and Mr. Arya Hardik, Advocates.

versus

MINISTRY OF HEALTH AND FAMILY WELFARE & ANR.
..... Respondents

Through: Ms. Monika Arora, CGSC with Mr. Subhrodeep Saha, Ms. Jyoti Tiwari and Ms. Radhika, Advocates for UoI.

CORAM:
HON'BLE MR. JUSTICE SUBRAMONIUM PRASAD

JUDGMENT

1. The Petitioner has approached this Court for a direction to Respondent No.2/Homeopathic Pharmacopoeia Laboratory, Ministry of Ayush to analyze the prescription/formulation of Krauss and Zimpel, as provided for in the German Homeopathic Pharmacopoeia to enable the Inter-Departmental Committee to give a reasonable conclusion *qua* the recognition of an alternative system of medicine.

2. The Petitioner claims to be a qualified electro-homeopath in the field of electro-homeopathy after obtaining a degree of B.M.E.H from DSM Medical College, Kanpur.

3. It is stated by the Petitioner that the Ministry of Health and Family Welfare through the Department of Health Research has set up an Inter-

Departmental Committee to look into the viability for recognition of a new/alternate medicine system including Electro Homeopathy.

4. Respondent No.2 is a Homeopathy Pharmacopoeia Laboratory set up as a national laboratory for laying down standards and testing for the identity, purity, and quality of homeopathic medicines. It is stated in the writ petition that under Rule 3A of the Drugs Rules, 1945 as framed under the Drugs and Cosmetics Act, 1940, Respondent No.2 functions as a Central Drug Laboratory for testing homeopathic medicines. It is stated in the writ petition that Electro Homeopathy is an alternative system of medicine that is purely herbal-oriented.

5. The Petitioner states that on 30.07.2011, he sought information from the Chief Public Information Officer (CPIO), Homeopathic Pharmacopoeia Laboratory, Ghaziabad regarding the legal status of German Homeopathic Pharmacopoeia in India and whether the same is recognized by the Indian Government. Information was also sought regarding the difference between the Indian and German Homeopathic Pharmacopoeia in the application filed under the RTI Act.

6. It is stated that the CPIO *vide* reply dated 24.08.20211 responded to the RTI application filed by the Petitioner stating that the German Homeopathic Pharmacopoeia is covered under the Second Schedule of the Drugs and Cosmetics Act and German Homeopathic Pharmacopoeia is recognized by the Indian Government.

7. Pursuant to the said information, the Petitioner filed another RTI application dated 15.02.2013 seeking information from Respondent No.1 regarding the date of incorporation of the formulation of Krauss and Zimpel in German Homeopathic pharmacopoeia and whether the department has

tried to find out about the efficacy of the medicines produced through those formulations. Material on record does not indicate that the said information as sought for by the Petitioner in the RTI application was revealed or not.

8. The Petitioner gave one more application on 05.06.2013 seeking the same information as sought in the earlier RTI application dated 15.02.2013. A reply was received from Respondent No.2 stating the Homeopathic Pharmacopoeia Laboratory never tried to find out about the efficacy of the medicine produced through the formulation of Krauss and Zimpel and stated that Respondent No.2 does not undertake analysis or efficacy reports from any private individuals.

9. Material on record also indicates that on 28.02.2017, a notice was issued by Respondent No.1/Ministry of Health and Family Welfare regarding the mechanism for consideration of proposals for recognition of new/alternative systems of medicine. Paragraph 6 of the said notice reads as under: -

> *"6. In view of the above, any person or body may forward proposals, seeking recognition to new, i.e., alternative systems of medicine, for examination by the said Inter-Departmental Committee. While doing so. they must invariably ensure the following requirements:*
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> *(a) Proposal should be quite detailed and complete in all respects in terms of para- 4(a) above.*
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> *(b) Two hard copies of the proposal may be forwarded to the Department of Health Research at the address, given below.*
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> *(c) In addition, soft copy of 6(b) above must invariably be forwarded simultaneously or immediately*

thereafter.

(d) It may be noted that the proposal will not be entertained in case both 6(b) & 6(c) above are not forwarded.

(e) The proposals thus received, and which are complete in all respects, will be placed before the said committee for their consideration in due course of time, in the manner indicated at para-5 above.

(f) The sender (s) of the proposal(s) are likely to be invited to the meeting of the committee, as and when the committee sits, to present their proposal before the committee. They may also be required to make power-point presentation and for any other demonstration before the committee, as may be required by the Committee. This will be intimated to the senders at the appropriate time. Further, they will be expected to provide all information / material to the committee, as may be asked for by the committee. In addition, in case there is more than one body / person forwarding proposals for the same system, they may be advised to interact with each other and send one consolidated proposal to facilitate administrative convenience and smooth processing of the proposal. In such a situation, representatives of all such bodies /persons may be invited to the meeting of the committee to plead their case.

(g) The proposals should be accompanied with full postal address (including 'Pin Code Number') and other contact details (telephone I mobile number, e-mail ID, etc.) of the sender(s).

(h) No canvassing in favour of their proposal(s) should be resorted to outside the scope of the meeting of the

committee. They will get ample opportunity to justify their case before the committee, when they are invited to attend the meeting.

(i) Normally, no representation against the decision of the Committee as well as that of the Government, regarding viability or otherwise of the proposal, will be entertained."

10. The Petitioner gave a representation for opinion/comments on electro-homeopathy. A reply was received by the Petitioner on the said representation on 28.11.2018. The Petitioner was advised to contact one Dr. Kuldip Tiwari, who had forwarded the combined proposal on Electro Homeopathy on behalf of a Joint Body which is a team of Electro Homeopathy Organizations.

11. The reply also states that the representation of the Petitioner was not received in time and it could not be taken up before the Inter-Departmental Committee to consider the proposal on electro-homeopathy that had been received from other bodies. The reply indicates that all the organizations were to submit a joint proposal based on their collective knowledge about the subject and no individual proposal was to be considered. The Petitioner was, therefore, advised to contact one Dr. Kuldip Tiwari, who had forwarded the combined proposal on behalf of the Joint Body, and details of Dr. Kuldip Tiwari were provided to the Petitioner herein in the said reply.

12. Material on record indicates that the Inter-Departmental Committee conducted the Fifth Meeting on 19.02.2021, to identify viable new systems of Medicine/therapy, and as regards electro-homeopathy, it was concluded that Electro Homeopathy as a system of medicine lacked detailed and authentic scientific data and Inter-Departmental Committee was unable to

properly access the viability of the system and progress further. The Inter-Departmental Committee was of the view that there ought to be properly compiled detailed clinical data to establish the efficacy/efficiency of the electro-homeopathy treatment, a common standard pharmacopoeia for the manufacture of medicines in the country and related activities, publications in reputed scientific national/international journals and well-analyzed monographs of clinical data from different clinical centres.

13. It is the case of the Petitioner that the Second Schedule of the Drugs and Cosmetics Act recognizes German Homeopathic Pharmacopoeia which consists of prescription/formulation of Krauss and Zimpel to manufacture electro homeopathic remedy and as per the Krauss and Zimpel prescriptions, it cannot produce tinctures used in homeopathy medium. The Petitioner states that the Homeopathic Pharmacopoeia Laboratory must analyze the prescriptions/formulations of Krauss and Zimpel and send it to the Inter-Departmental Committee which will analyze the proposal for new/alternative systems of medicine and give a reasonable conclusion for the recognition of an alternative system of medicine.

14. It is stated that Respondent No.2 has refused to accept the request of the Petitioner to analyze the formulations of Krauss and Zimpel. It is stated that the Petitioner has no other alternative but to approach this Court for issuance of a writ of *mandamus* directing the Respondents to analyze the formulations of Krauss and Zimpel since Respondent No.2/Homeopathic Pharmacopoeia Laboratory being the apex body recognized by the Government of India, it must analyze the formulations of Krauss and Zimpel which is used in electro homeopathy so that it may be sent to the Inter Departmental Committee for further consideration.

15. Notice was issued on 01.10.2021. Counter affidavits have been filed.

16. Learned Counsel for the Petitioner has more or less reiterated the averments made in the writ petition and has taken this Court to the Minutes of the Fifth Inter-Departmental Committee Meeting held on 19.02.2021 to substantiate his contention that the prescription/formulation of Krauss and Zimpel which is used in electro homeopathy would be a very important consideration by the Inter-Departmental Committee for recognizing electro homeopathy as a system of medicine.

17. It is stated that it is the duty of Respondent No.2 to analyze the tests so as to enable the Inter-Departmental Committee to consider whether electro-homeopathy can be recognized as an alternate form of medicine. He states that the Inter-Departmental Committee has only been for studying newer systems of medicine and does amount to failing in its duty if it does not recognize the tests.

18. *Per contra*, learned Counsel for the Respondents contends that Homeopathic Pharmacopoeia Laboratory, i.e., Respondent No.2 herein has merged with Pharmacopoeia Laboratory for Indian Medicine (PLIM) and re-established as Pharmacopoeia Commission for Indian Medicine and Homeopathy (PCIM &H) (subordinate office) under the Ministry of Ayush. Respondent No.2 is no more existent. It is further stated that the function of the Homeopathic Pharmacopoeia Laboratory with respect to homeopathic medicines has been laid down as per Rule 3A (7) of the Drugs and Cosmetics Rules, 1945 which has been framed under the Drugs and Cosmetics Act, 1940.

19. As per the said Rule 3A (7) of the Drugs and Cosmetics Rules 1945, the function of the Homeopathic Pharmacopoeia Laboratory is to analyze or

test such samples of drugs as may be sent to it under sub-Section 2 of Section 11 or sub-Section 4 of Section 25 of the Drugs and Cosmetics Act, which reads as under: -

> *"**11.(2)** Without prejudice to the provisions of sub-section (1), the [Commissioner of Customs] or any officer of the Government authorized by the Central Government in this behalf, may detain any imported package which he suspects to contain any drug [or cosmetic] the import of which is prohibited under this Chapter and shall forthwith report such detention to the Drugs Controller, India, and, if necessary, forward the package or sample of any suspected drug [or cosmetic] found therein to the Central Drugs Laboratory.*
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> *xxx*
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> ***25.(4)** Unless the sample has already been tested or analysed in the Central Drugs Laboratory, where a person has under sub-section (3) notified his intention of adducing evidence in controversion of a Government Analyst's report, the Court may, of its own motion or in its discretion at the request either of the complainant or the accused, cause the sample of the drug [or cosmetic] produced before the Magistrate under sub-section (4) of Section 23 to be sent for test or analysis to the said Laboratory, which shall make the test or analysis and report in writing signed by, or under the authority of, the Director of the Central Drugs Laboratory the result thereof, and such report shall be conclusive evidence of the facts stated therein."*

20. It is also stated that since Electro Homeopathy is not a recognized form of medicine, the analysis of Electro Homeopathy does not fall within the jurisdictional purview of Respondent No.2 and they are duty bound to

analyze or test such samples of drugs as may be sent to it under sub-Section 2 of Section 11 or sub-Section 4 of Section 25 of the Drugs and Cosmetics Act.

21. In the opinion of this Court, the entire claim of the Petitioner is completely unfounded. Whether to recognize a new/alternate system of medicine is purely a matter of policy. Courts do not interfere with policy and do not lay down policies. The Apex Court in Academy of Nutrition Improvement & Ors. v. Union of India, **2011 (8) SCC 274** has held that the Courts must be reluctant to interfere in matters relating to public health. The Apex Court has held as under: -

> *"**35**. This Court in a series of decisions has reiterated that courts should not rush in where even scientists and medical experts are careful to tread. The rule of prudence is that courts will be reluctant to interfere with policy decisions taken by the Government, in matters of public health, after collecting and analysing inputs from surveys and research. Nor will courts attempt to substitute their own views as to what is wise, safe, prudent or proper, in relation to technical issues relating to public health in preference of those formulated by persons said to possess technical expertise and rich experience.*
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> ***36**. This Court in Directorate of Film Festivals v. Gaurav Ashwin Jain [(2007) 4 SCC 737] , pointed out: (SCC p. 746, para 16)*
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> > *"16. The scope of judicial review of governmental policy is now well defined. Courts do not and cannot act as appellate authorities examining the correctness, suitability and appropriateness of a policy, nor are courts advisors to the executive on matters of policy which the executive is entitled to*

formulate. The scope of judicial review when examining a policy of the Government is to check whether it violates the fundamental rights of the citizens or is opposed to the provisions of the Constitution, or opposed to any statutory provision or manifestly arbitrary. Courts cannot interfere with policy either on the ground that it is erroneous or on the ground that a better, fairer or wiser alternative is available. Legality of the policy, and not the wisdom or soundness of the policy, is the subject of judicial review…."

xxx

***38**. In our considered opinion the petitioners' challenge to the constitutionality of the impugned amendment is bound to fail. Courts are not equipped to decide the medical issue relating to public health, as to whether compulsory iodisation should be replaced by voluntary iodisation as has been done in some developed countries, so that both common salt and iodised salt are available in the market and only those 10% who are deficient in iodine can opt for iodised salt. The Government of India has taken note of scientific and medical inputs, research results and survey data to conclude that compulsory iodisation is the most effective and accepted method for elimination of iodine deficiency disorders and that consumption of iodised salt by persons not suffering from iodine deficiency will not adversely affect them."*

22. The Inter-Departmental Committee is considering as to whether Electro Homeopathy should be considered as a new/alternate system of medicine is awaiting further analysis from various groups which are working in the field. In any event, the stand of Respondent No.2 that since Electro Homeopathy is not covered in Rule 2(dd) and Second Schedule of

the Drugs and Cosmetics Act and the Homeopathic Pharmacopoeia, the analysis of the electro-homeopathic medicines will not fall within the purview of Respondent No.2 and does not require any interference. Respondent No.2 is only obliged to carry out the functions as mentioned under the Drugs and Cosmetics Act and the Rules framed thereunder. Clinical studies are not covered under the purview of Respondent No.2 and the stand of the Inter-Departmental Committee that it will not accept the application from an individual does not warrant any interference. It is for the Petitioner to get in touch with the other organizations which are trying to make out their case of recognizing Electro Homeopathy as a new/alternate form of medicine.

23. The writ petition is thoroughly misconceived. The petition is dismissed along with pending application(s), if any.

SUBRAMONIUM PRASAD, J

JULY 09, 2024
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