

ITEM NO.37

COURT NO.9

SECTION X

S U P R E M E C O U R T O F I N D I A  
RECORD OF PROCEEDINGS

WRIT PETITION(S)(CIVIL) NO(S). 645/2022

INDIAN MEDICAL ASSOCIATION & ANR.

PETITIONER(S)

VERSUS

UNION OF INDIA & ORS.

RESPONDENT(S)

(1 MR. SHADAN FARASAT, LEARNED ADVOCATE WILL ASSIST THE COURT AS AN AMICUS CURIAE 2. MR. MURSALIN ASIJIT SHAIKH, APPLICANT-IN-PERSON WILL APPEAR IN I.A. D.NO. 95540 OF 2024 (APPLICATION FOR INTERVENTION)

IA No. 110039/2024 - APPLICATION FOR PERMISSION  
IA No. 132998/2024 - APPROPRIATE ORDERS/DIRECTIONS  
IA No. 139081/2024 - APPROPRIATE ORDERS/DIRECTIONS  
IA No. 110769/2024 - APPROPRIATE ORDERS/DIRECTIONS  
IA No. 133550/2024 - APPROPRIATE ORDERS/DIRECTIONS  
IA No. 110011/2024 - APPROPRIATE ORDERS/DIRECTIONS  
IA No. 140252/2024 - APPROPRIATE ORDERS/DIRECTIONS  
IA No. 130554/2022 - CLARIFICATION/DIRECTION  
IA No. 137201/2024 - CLARIFICATION/DIRECTION  
IA No. 117836/2024 - EXEMPTION FROM FILING O.T.  
IA No. 143229/2024 - EXEMPTION FROM FILING O.T.  
IA No. 142959/2024 - EXEMPTION FROM FILING O.T.  
IA No. 13659/2023 - INTERVENTION APPLICATION  
IA No. 139085/2024 - INTERVENTION APPLICATION  
IA No. 133899/2024 - INTERVENTION APPLICATION  
IA No. 110768/2024 - INTERVENTION APPLICATION  
IA No. 95540/2024 - INTERVENTION APPLICATION  
IA No. 132997/2024 - INTERVENTION/IMPLEADMENT  
IA No. 133673/2024 - INTERVENTION/IMPLEADMENT  
IA No. 133537/2024 - INTERVENTION/IMPLEADMENT  
IA No. 133534/2024 - INTERVENTION/IMPLEADMENT  
IA No. 139206/2024 - PERMISSION TO FILE APPLICATION FOR DIRECTION)

Date : 30-07-2024 These matters were called on for hearing today.

CORAM :

HON'BLE MS. JUSTICE HIMA KOHLI  
HON'BLE MR. JUSTICE SANDEEP MEHTA

Mr. Shadan Farasat, Amicus Curiae, AOR  
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Ms. Niharika Srivastava, Adv.

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Mr. Raji Gururaj, Adv.  
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Mr. Amarjeet Singh, AOR  
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Ms. Deveshi Chand, Adv.  
Mr. Dipanshu Krishan, Adv.

For Respondent(s)  
Union of India/  
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Food & Public Distribution,  
Min. of Info.& Broadcasting

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Mr. Vinayak Sharma, Adv.  
Mr. Rajat Nair, Adv.  
Mr. Kanu Agrawal, Adv.  
Mr. Shashank Bajpai, Adv.  
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Mr. Yajat Gulia, Adv.  
Mr. Rohit Gandhi, Adv.  
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Mr. Sarathraj B, Adv.  
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Ms. Vedika Rathore, Adv.  
Ms. Rithika Mathur, Adv.  
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Mr. Debmalya Banerjee, Adv.  
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Mr. Anmol, Adv.  
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Mr. Ayushman Arora, Adv.(NP)  
Mr. Aman Rana, Adv.(NP)

I.A.D.95540/2024 Mr. Mursalin Asijit Shaikh, Applicant-In-Person

UPON hearing the counsel the court made the following

**O R D E R**

1. An affidavit has been filed on behalf of the respondent No.5 stating *inter alia* that in the light of the suspension order dated 15<sup>th</sup> April, 2024, passed by the State of Uttarakhand, sale of 14 Ayurvedic medicines/formulations were stopped by the respondent No.5. It is submitted by learned counsel for the petitioner that on the last date of hearing, the impression sought to be given by the respondent No.5 was that the aforesaid products were not available for sale over the counter. However, the aforesaid 14 drugs are readily available in the market.

2. It is submitted by learned counsel for the respondent No. 5 that *vide* order dated 17<sup>th</sup> May, 2024, the State Government had put on hold the order of suspension passed on 15<sup>th</sup> April, 2024 and thereafter constituted a Committee to examine the matter. The Committee submitted its report to the State Government on 29<sup>th</sup> June, 2024. Based on the recommendations of the Committee, the State Government cancelled the suspension order on 01<sup>st</sup> July, 2024 and issued a fresh notice to show cause to the respondent No.5 on 08<sup>th</sup> July, 2024.

3. We are informed by learned counsel for the State of Uttarakhand that the respondent No.5 has responded to the aforesaid show cause notice on 19<sup>th</sup> July, 2024. She seeks a reasonable time to take a decision in the matter.

4. The State Government is directed to pass an order pursuant to its

show cause notice before the next date of hearing and communicate the same to the respondent No.5.

5. Coming to the next issue, Mr. K.M. Natraj, learned Additional Solicitor General submits that pursuant to the orders passed on the last date of hearing, a meeting with all the relevant stakeholders was conducted on 30<sup>th</sup> June, 2024. Around 40 parties had participated in the said meeting. Another meeting was conducted on 19<sup>th</sup> July, 2024. The Ministry seeks time to collate all the information and give its recommendations if granted two weeks' time.

6. Needful shall be done within two weeks with copies furnished to learned counsel for the concerned parties.

7. Learned *Amicus Curiae* informs the Court that 15 State Governments and Union Territories have not filed any affidavit so far, as directed by this Court. They include the following :

1. Andhra Pradesh
2. Arunachal Pradesh
3. Assam
4. Dadra & Nagar Haveli and Daman & Diu
5. Haryana
6. Jammu & Kashmir
7. Kerala
8. Ladakh
9. Lakshadweep
10. Meghalaya



11. Mizoram
12. Rajasthan
13. Sikkim
14. Tripura
15. Uttarakhand

8. None is present for the State Governments/Union Territories of Andhra Pradesh, Arunachal Pradesh, Dadra and Nagar Haveli, Haryana, Jammu & Kashmir, Kerala, Sikkim. Though learned counsel is present for the State of Uttarakhand, but affidavit has not been filed so far.

9. Issue notice of default to the Secretary Health of the above-mentioned States/Union Territories for non-compliance of the orders passed by this Court, with directions to make compliances within two weeks from today, failing which, Secretary, Health of all the defaulting States/Union Territories shall remain virtually present on the next date.

10. Coming to the remaining States in the list drawn up by the learned *Amicus Curiae*, learned counsel for the States of Meghalaya, Tripura and Rajasthan state that they have filed their affidavits only yesterday/this morning. Same be brought on record.

11. Learned *Amicus Curiae* has filed a Note for Hearing wherein he has summarized the comments and made some suggestions. One of the suggestions made by him relates to the substantive changes made in the prevailing mechanism of Ayush Drugs particularly in the context of Rule 158B II. (A) of the Drugs and Cosmetics Rules, 1945, which sets out a

table and specifies at Serial No.3 as follows:

"II.(A) For issue of license to the medicine with respect to Ayurveda, Siddha and Unani, the conditions relating to safety study and the experience or evidence of effectiveness shall be such as specified in columns (5) and (6) of The Table given below:-

Serial Number	Category	Ingredient(s)	Indication(s)	Safety study	Experience/ Evidence of Effectiveness	
(1)	(2)	(3)	(4)	(5)	(6)	
					Published Literature	Proof of Effectiveness
1.	(A) Ayurveda, Siddha and Unani drugs, given in 158B as referred in 3(a)	As per text	As per text	Not Required	Required	Not Required
2.	(B) Any change in dosage form of Ayurveda, Siddha and Unani drugs as described in Section 3(a) of the Drugs and Cosmetics Act, 1940	As per text	As per text	Not Required	Required	Not Required
3.	(C) Ayurveda, Siddha and Unani drugs referred in 3(a) to be used for new indication	As per text	New	Not Required	If Required	Required

12. Learned *Amicus Curiae* hands over a copy of the Notification dated 04<sup>th</sup> July, 2018, issued by the Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy (Ayush), Government of India, which watered down the aforesaid Rule and dispensed with clinical trials with new indications and on the aspect of effectiveness and suggested that proof of effectiveness in the form of a Pilot Study may be required for the drugs in question.

13. It is submitted that the aforesaid Notification has diluted the Rules without any amendment thereto, which is impermissible in law. The Notification dated 04<sup>th</sup> July, 2018 is taken on record and the UOI is directed to respond to the above.

14. Coming to the effective use of the existing penalty mechanism

under law, learned *Amicus Curiae* refers to his note at page 74 and submits that he has drawn out a chart to indicate the limited extent of penal action taken by States and Union Territories under the DMR Act, 1954, The DC Act, 1940 and the CPA Act, 2019. In fact, he states that the affidavits filed by the concerned State Governments shows that in most cases, the penalties imposed are NIL and similarly, the action taken is very poor. Despite the statutes being in place, the State Governments and Union Territories have been taking these provisions quite lightly.

15. All the State Governments/Union Territories are directed to explain their inaction/indolence in imposing penalties and deterrents for compliances of the statutes, wherever required.

16. Further, except for the States of Jharkhand, Goa, NCT of Delhi, Odisha and West Bengal, none of the other States are following the practice of granting prior approval of the advertisements before issuance of licence so as to ensure that there is proper labeling and no mismatch. All the State Governments/Union Territories, except those mentioned above, shall respond to the aforesaid aspect highlighted by the learned *Amicus Curiae* within two weeks.

17. Learned *Amicus Curiae* points out that there is a strong need for centralized lifting of complaints. Earlier, the Ministry of Consumer Affairs, UOI had entered into an MOU with Advertising Standard Council of India (ASCI) to monitor misleading advertisements through the misleading

advertisements portal (GAMMA), but the said MOU came to an end in April, 2020. During the years 2018 to 2022, 2573 complaints related to the health sector were registered, out of which 2505 were resolved. The partnership between the Ministry of Consumer Affairs and ASCI helped in increasing the number of complaints in view of the positive response received from the Department.

18. We have been informed that now the Ministry of Consumer Affairs has set up a National Consumer Helpline Portal and the GAMMA Portal has been integrated with the aforesaid Portal. The affidavit filed by the Ministry of Consumer Affairs reflects that in a period of two years, from April, 2022 to May, 2024, only 132 complaints in the health sector were received, out of which 116 complaints have been disposed. The number of complaints received itself is abysmally low, what to speak of the disposal. Fact of the matter is that the complaints which were over 2500 between April, 2018 and 2022, have dwindled to 132. This itself speaks volumes about the manner in which the Ministry has been operating the website bringing the aforesaid website to the notice of the public at large for them to utilize the services offered.

19. It is stated by learned *Amicus Curiae* that unlike ASCI that used to voluntarily undertake due diligence and take action on noticing any non-compliance, the website of the Ministry only focusses on the complaints received and does not take any initiative on its own to identify the

problems faced by the consumers and tackle the misleading advertisements, issued by various parties, which is why the number of complaints received are so very poor.

20. The aforesaid aspect needs to be seriously examined by the Ministry of Consumer Affairs. A specific response shall be furnished within two weeks.

21. As for the need for effective inter-state coordination, highlighted by the learned *Amicus Curiae*, we find that there is merit in the aforesaid submission particularly, in the light of the data furnished by such of the States Governments/Union Territories, who have filed their affidavits. It appears from the said data collated by learned *Amicus Curiae* that in some states, i.e., in the case of State of Chhattisgarh, Gujarat, NCT of Delhi and West Bengal, a large number of complaints were forwarded to other States for the reason that the manufacturing units in respect of which complaints were received, were operating within the concerned State/Union Territories. But no data has been furnished by the receiving States of the complaints as to the action taken on the complaints received. This leaves the consumer feeling helpless and completely in the dark regarding the action taken on the reports in response to the complaints forwarded to the receiving States.

22. We are of the opinion that the Ministry of Ayush, UOI must set up a dashboard for all the States to furnish details of the complaints received

by them and referred to another State Licensing Authority for appropriate action and the action taken by the concerned State Licensing Authority so that the data comes in public domain and can be accessed by the consumers. The aforesaid dashboard would also help in dealing with prosecutions under the DC Act in as much as lack of information on the action taken is a big deterrent for prosecution purposes and needs to be addressed on priority. Creation of a dashboard would help in addressing the aforesaid aspect as well.

23. The aforesaid issue shall be addressed by all the concerned State Governments/Union Territories and the Central Government and fresh affidavits shall be filed within two weeks.

24. Mr. K.M. Nataraj, Learned Additional Solicitor General submits that several applications for intervention have been filed in the present case. Having perused the same, it is his submission that IA Nos. 110768/2024 and 110769/2024 are extraneous to the issues raised before this Court and may not be entertained.

25. As none is present on behalf of the applicants in the aforesaid applications, appropriate orders shall be passed on the next date.

26. As for the remaining applications, learned counsel for the petitioner has furnished a consolidated list of the applications along with the prayers made. The same are taken on record. Orders on these applications are deferred for the Central Government to file an affidavit

placing on record the recommendations made pursuant to the joint meeting conducted with various stakeholders.

27. List on 27<sup>th</sup> August, 2024, on top of the Board.

**(Nand Kishor)**  
**Court Master (NSH)**

**(Pooja Sharma)**  
**Court Master(SH)**

**(Geeta Ahuja)**  
**Assistant Registrar-cum-PS**