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

\+ W.P.(C) 5120/2024

JACOB VADAKKANCHERY ..... Petitioner

Through: Mr. Prashant Bhushan and Mr. Anurag Tiwary, Advocates

versus

UNION OF INDIA AND ANR. ..... Respondent

Through: Mr. Ravi Prakash, CGSC, UOI with Ms. Astu Khandelwal, Mr. Taha Yasin, Mr. Yasharth Shukla, Mr. Ali Khan and Mr. Ayushman, Advocates
Mr. Uzair Ullah Khan, GP, UOI
Mr. T. Singhdev, Mr. Aabhaas Sukhramani, Mr. Abhijit Chakravarty, Mr. Bhanu Gulati, Mr. Tanishq Srivastava, Mr. Anum Hussain, Mr. Sourabh Kumar and Ms. Ramanpreet Kaur, Advocates for R-2/NMC

% Date of Decision: 15th May, 2024

CORAM:
HON'BLE THE ACTING CHIEF JUSTICE
HON'BLE MS. JUSTICE MANMEET PRITAM SINGH ARORA

JUDGMENT

MANMOHAN, ACJ: (ORAL)

1. Present writ petition has been filed as a Public Interest Litigation ('PIL') seeking a direction to the Respondents to mandate all medical professionals practicing in the country to specify to a patient (in the form of additional slip in the regional language) along with the prescription, all

kinds of possible risks and side effects associated with a drug or a pharmaceutical product being prescribed.

2. Learned counsel for the Petitioner states that prescription medications come with side effects, which have potential to do much harm. He states that the patient has a right to make an informed choice and therefore, it should be mandatory for the doctor prescribing the drug to explain the side effects attached to consuming such a drug to the patient. He states that upon being made aware of the side effect of the drug being prescribed by the doctor, the patient will be able to make an informed choice, whether to consume it or not.

2.1. He states that in the existing regime, the obligation to communicate the potential risks and side effects exist on the manufacturer under Clause 6.2 of Schedule D(II) of the Drugs and Cosmetics Act, 1945 ('Act of 1945') and on the pharmacists under Regulation 9.11 of Chapter 4 of the Pharmacy Practice Regulations, 2015 ('Regulations of 2015'). He states that however, these stipulations in the law are not sufficient. He states that it is the medical practitioner prescribing the drug, who should be made responsible for handing out the information about the potential risk to the patient in the regional language.

2.2. He states that prescribing a drug without specifying the possible side effects does not amount to obtaining valid consent of the patient. He states that the emphasis in law to inform the patient must shift from the manufacturer and pharmacist to the medical practitioner.

2.3. He concludes by stating that the medical practitioner should be the individual handing out the insert provided by manufacturers to the patient

while prescribing the drug as it would highlight the significance of the declarations made in the insert to the patient. He states that patients do not tend to take serious note of the insert when it is provided by the manufacturer and/or the pharmacist.

3. In reply, learned counsel for Respondent No. 1 states that the petition acknowledges that there exists sufficient legislation to ensure that the patient is aware about the potential risks and possible side effects of the drugs. He states that the existing provisions in the Act of 1945 and the Regulations 2015, ensure that the risk is duly communicated to the patient. He states that the direction sought by the writ Petitioner is unworkable considering how overworked medical practitioners are and would hinder rather than facilitate medical advice to the patients.

4. Learned counsel for the Respondent No. 2 states that in addition to what has been submitted by Respondent No. 1, the direction sought by the Petitioner that the information be handed over in regional languages is unworkable. He states that doctors work on all India basis and are posted in different States and they may not be conversant with the regional language and therefore, unable to comply with the directions sought herein. He states that a medical practitioner is required to exercise the standard of care and skill, which was explained by the Supreme Court in ***Jacob Mathew v. State of Punjab and Anr.***[1]. He states that a medical practitioner has to act in accordance with the general and approved practice and so long as he/she does the same he/she is not liable for the tort of negligence. He states that there are inherent and acknowledged risks, when Schedule D drugs are

[1] (2005) 6 SCC 1 (paras 24 and 25)

prescribed and sometimes the anticipated side effects become known and evident in future after the data accumulates. He states that if the obligation to apprise the patient of the possible side effects is transferred to the medical practitioner, it will expose the doctor to allegations of negligence in future even though the factum of the side effect becoming a possibility was uncertain at the time of prescription.

5. We have heard the learned counsel for the parties and perused the record.

6. The Petitioner admits that there exist legislative safeguards with respect to the apprising the patient about the possible side effects of the prescribed drugs. Schedule D(II) of the Act of 1945 obliges the manufacturer or his agent importing the drug to provide a package insert which shall duly disclose the side effects of the drugs to the consumer. In addition, Regulation 9.11 of Chapter 4 of the Regulations 2015 imposes a duty on the registered pharmacist to apprise the patient/carer about the possible side effects, etc.

7. The Petitioner does not dispute with respect to the sufficiency of the information supplied by the manufacturer through the insert provided with the drug at the time of sale by the registered pharmacist. The Petitioner however, contends that if the same insert is provided by the doctor along with the prescription, it can be presumed that the patient/carer would be able to make an informed choice with valid consent.

8. Since the legislature in its wisdom has elected to impose this duty on the manufacturer and the pharmacist, we do not find any ground for issuing a direction as prayed for in this PIL as it would amount to judicial

legislation. In this regard, it would be apposite to refer to the observations of the Supreme Court in ***Dr. Ashwani Kumar v. Union of India and Anr.***[2], which reads as under:

> "31. In V.K. Naswa v. Union of India [V.K. Naswa v. Union of India, (2012) 2 SCC 542 : (2012) 1 SCC (Cri) 914] , this Court in clear and categoric terms had observed that we do not issue directions to the legislature directly or indirectly and any such directions if issued would be improper. It is outside the power of judicial review to issue directions to the legislature to enact a law in a particular manner, for the Constitution does not permit the courts to direct and advise the executive in matters of policy. Parliament, as the legislature, exercises this power to enact a law and no outside authority can issue a particular piece of legislation. It is only in exceptional cases where there is a vacuum and non-existing position that the judiciary, in exercise of its constitutional power, steps in and provides a solution till the legislature comes forward to perform its role."

9. However, since, in the present PIL it is admitted that there is no vacuum, the directions prayed for cannot be issued.

10. Accordingly, the present PIL along with applications is dismissed.

ACTING CHIEF JUSTICE

MANMEET PRITAM SINGH ARORA, J

MAY 15, 2024/hp/aa

[2] (2020) 13 SCC 585