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

\+ **W.P.(C) 6740/2017 and CM No. 28067/2017**

ASSOCIATION OF CLINICAL BIOCHEMISTS
AND MICROBIOLOGISTS ACBM
(REGD) & ANR ..... Petitioners

Through: Mr K.P. Singh, Advocate with Mr K.K. Srivastava, Mr Ankur Sood, Mr Rishabh Singh, Mr Uday Bedi and Ms Romila Mandal, Advocates.

versus

UNION OF INDIA & ORS ..... Respondents

Through: Mr Srikant Misra, Advocate for (G.P.) UOI.
Mr Vikas Singh, Senior Advocate with Mr T. Singhdev, Ms Biakthan Sangi Das and Mr Tarun Verma, Advocates for R2/MCI.
Mr Sagar Shivam, Advocate with Mr Vikas Chopra, Advocate for R3 and R4.
Mr Rahul Gupta, Ms Ira Gupta, Applicant in CM No. 33996/2017, IMA.

CORAM:
HON'BLE MR. JUSTICE VIBHU BAKHRU

O R D E R

% 15.09.2017

VIBHU BAKHRU, J

1. The petitioner no.1 is an association of Clinical Biochemists and

Microbiologists and has filed the present petition, *inter alia,* impugning a letter dated 14.06.2017 (hereafter 'the impugned letter') ,issued by the Medical Council of India (hereafter 'MCI').

2. By the impugned letter, MCI has communicated the decision of its Executive Committee that "*all lab reports to be signed/countersigned by persons registered with MCI/State Medical Council.*"

3. It is the petitioner's case that the impugned communication is without jurisdiction and contrary to Section 15(2) of the Indian Medical Council Act, 1956 (hereafter 'IMC Act'). It is further contended that the impugned communication deprives members of the petitioner association of their valuable right to conduct their trade and profession.

4. The petitioners state that the members of the petitioner association are highly qualified persons and are engaged in the activity of laboratory testing. Since members of the petitioner association do not hold degree of MBBS and/or MD Degrees, they are not entered in the register maintained by the MCI or State Medical Councils. The petitioners state that the work of conducting laboratory test and submitting reports thereof is essentially a skilled task for which the members of the petitioner association are amply qualified and it is not necessary that the test report submitted by them be countersigned by a medical practitioner whose name is entered in the medical register. It is further stated that respondent no.3 (National Accreditation Board for Testing and Calibrating Laboratories) is competent to provide accreditation to pathology laboratories and no accreditation from MCI is required.

5. Mr Vikas Singh, learned Senior Counsel appearing for MCI had referred to the Clinical Establishments (Registration and Regulation) Act, 2010 and submitted that the said Act provides a comprehensive legal framework for registration of a clinical establishments. Section 3 of the said Act provides for establishment of a National Council which consists of representatives of various bodies including the Secretary General of Quality Council of India. The said National Council is *inter alia* charged with the function of prescribing the minimum standards of facilities and services; and (ii) minimum requirement of personnel, in a clinical establishment.

6. He submitted that the standard of qualification of personnel employed in clinical establishments would fall within the scope of the said Act. However, since the said act has not been adopted by the NCT of Delhi, the same is not applicable.

7. He fairly conceded that the IMC Act did not provide for any framework for prescribing the standards for technicians engaged in a pathology laboratory.

8. He drew the attention of this court to clause (c) of Section 15(2) IMC Act which expressly provides that no person other than a medical practitioner would be entitled to sign or authenticate a medical or fitness certificate or any other certificate required by law to be signed or authenticated by a duly qualified medical practitioner. He submitted that the members of the petitioner association were not entitled to sign any medical fitness certificate and a pathology report would fall within the scope of a medical certificate, if there is any expression of opinion and/or indicative

diagnosis. He submitted that it is in this context that MCI had issued the impugned communication insisting that a pathology report be countersigned by a medical practitioner.

9. At this stage, it is relevant to refer to clause (c) and Section 15(2) of the IMC Act, which reads as under:-

> "15(2)(c) shall be entitled to sign or authenticate a medical or fitness certificate or any other certificate required by any law to be signed or authenticated by a duly qualified medical practitioner:
>
> xxxx xxxx xxxx xxxx
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> 15(3) Any person who acts in contravention of any provision of sub-section (2) shall be punished with imprisonment for a term which may extend to one year or with fine which may extend to one thousand rupees, or with both;"

10. It is apparent from the above that no person other than a duly qualified medical practitioner is entitled to sign any medical report. Thus, members of petitioner association cannot sign a medical report or a medical certificate. However, the same does not preclude the members of the petitioner association to give a technical report as to the tests conducted by them. Plainly, such report can only be for consumption of medical practitioners and pathologists. The said report cannot be treated as diagnosis of any medical condition. Thus, there can be no objection if the technical report submitted by the qualified technicians indicates the result of their tests or the technical analysis of the samples, as long as the members of the petitioner association refrain from expressing any medical opinion or holding out the technical result of the medical tests conducted by

them as a diagnosis of any medical condition.

11. In ***Manohar R. Jadhav and Ors. v. The State of Maharashtra & Ors.: Contempt Petition No. 119 of 2009, decided on 15.12.2010***, the Bombay High Court had considered the allegation that certain persons holding Diploma in Medical Laboratory Technology (who were members of the Association of Clinical Laboratory Analysis and Practitioners) had violated the interim order and had been practicing as pathologists. The Bombay High Court had after considering the sample reports submitted by the technicians observed as under:-

> "6 I have given careful consideration to the submissions. It must be noted here that the Contemnors are not parties to the Public Interest Litigation in which interim order has been passed. Clause (4) of the interim order directs that if the persons holding DMLT or other equivalent qualifications are running a pathological laboratory, they should appoint a qualified pathologist as recognized by the Medical Council to certify their reports. The Division Bench observed that if they do not appoint a qualified pathologist, they cannot be permitted to practice as such. Perusal of the documents forming part of Exhibit – C show that there are various disclaimers printed on the reports allegedly issued by the Contemnors. The disclaimers are to the effect "Above readings are to be certified by the pathologist", "strictly for the use of Medical Practitioners & Pathologists", "these are not medical diagnostic results", etc. Some reports clearly record that the same contain readings based on technical analysis and no opinion is indicated. What is recorded in those reports are readings recorded during technical analysis of blood or other samples. The reports are not issued by the Contemnors as practicing pathologists. In fact, some of

> the said reports record that the readings are to be certified by the pathologists. The reports record the technical results on analysis of samples. The said reports do not record any conclusion or any opinion of whatsoever of nature. The technicians are not authorized to record any opinion and/or to diagnose anything. They cannot issue reports containing opinions and if they want to do so, they will have to appoint a qualified pathologist, who will be able to record an opinion on the basis of the readings of the technical analysis and who will be able to record diagnosis on the basis of the results of the analysis. The order of the Division Bench does not prevent the persons holding qualifications as DMLT or equivalent from analyzing the samples of blood or urine and from recording the results of the technical analysis."

12. This Court is also of the view that although members of the petitioner association are not precluded from acting as a laboratory technicians and submitting the result of tests conducted by them, adequate safeguard must be maintained to ensure that the reports submitted by them are not mistaken as medical certificates or diagnostic reports as that would, concededly, violate Section 15(2)(d) of the IMC Act, 1956. Thus, it would be apposite that all test reports must necessarily bear a disclaimer to the effect that the report are strictly for the use of medical practitioners and pathologists and the reports are not medical diagnostic results. Any pathological report which purports to record any opinion or to indicate any diagnosis must necessarily be co-signed by a qualified medical practitioner.

13. At this stage, it would be necessary to refer to the impugned communication, the contents of which are set out below:-

"Sub:- **Letter/e-mail dated 12.06.2016 received from National Accreditation Board for Testing & Calibration Laboratories.**

Sir,

Kindly refer to your e-mail letter dated 08.10.2014 along with letter dated 12.08.2014 to finalize the following information:-

1) Whether the M.Sc with Ph D candidates who as a matter of fact are not registered with MCI are eligible to sign medical laboratory reports?

2) Can persons holding MBBS degree registered with MCI/State Medical Council sign the medical test reports?

3) Can PhD (Medical Microbiology, Medical Biochemistry, Life Sciences, Applied Biology, Cytogenetics, Biotechnology) in relevant discipline be allowed to sign medical test reports? If not, can the same be allowed if they are co-authorised with a person registered with MCI/State Medical Council?

The above matter was considered by the Ethics Committee at its several meetings & lastly on 6th & 7th February, 2017. The decision of the Ethics Committee was placed before the Executive Committee for approval on 11.04.2017.

It was decided by the Executive Committee that "All lab reports to be signed/countersigned by persons registered with MCI/State Medical Council."

You are therefore requested to kindly abide the above said decision of the Council and widely publicise the above decision to all the concerned."

14. The decision of the Executive Committee that all reports are to be signed/countersigned by persons registered with MCI/State Medical Council must be read which in the context of the three questions set out in the impugned communication. The said decision of the Executive answers question nos.2 and 3 in the affirmative and there can be no dispute that MCI's decision in this regard is in conformity with the provisions of Section 15(2)(d) of the IMC Act and cannot be faulted.

15. Insofar as the first question is concerned - that is, whether M.Sc/PHD candidates, who are not registered with MCI, are eligible to sign medical laboratory reports - the same must be answered in the negative as has been done by MCI. However, MCI decision in this regard must be read in the context. The expression "medical laboratory reports" as used in the first question cannot be misunderstood to mean test reports which merely indicate the result of tests and/or the manner in which the tests are conducted.

16. The expression "medical laboratory reports" must in the context of the impugned communication, be understood to mean reports that contain medical diagnostic results and/or an opinion with regard to the tests results. A technical report stating test results and indicating the analysis of samples without recording any opinion thereon, would not fall within the scope of medical laboratory reports as contemplated under the impugned communication.

17. The impugned communication, thus, cannot be understood in a wider sense as urged by the petitioner and must be read in the restrictive manner

as indicated above.

18. The petitioners can have no grievance if the impugned communication is read in the manner as indicated above and, therefore, no further orders are required to be passed in this petition.

19. The petition and the pending application are disposed of with the aforesaid observations.

VIBHU BAKHRU, J

SEPTEMBER 15, 2017
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