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Government of India
Directorate General of Health Services

Nirman Bhawan, New Delhi.
Dated: 08th November, 2017

MINUTES OF MEETING

The minutes of the meeting to finalize the draft notification in respect of Medical Diagnostic Laboratories including signatory authority / Technical head of Medical Diagnostic laboratory of the sub-committee held under the Chairmanship of Dr. B.D. Athani, Spl. DG on 1st November, 2017 at Nirman Bhawan, New Delhi are enclosed for information and necessary action.



(Dr. Anil Kumar)
Addl. DDG (AK)

Member Secretary of Subcommittee

To

All Participants

Copy for information to:

- 1 PPS to DGHS /PPS to Special DG(BDA)/ PPS to AS and DG
- 2 PPS to JS (SK)/ PA to Addl. DDG (SG)/PA to Addl.DDG(AK)
- 3 PA to Director (Bindu Tiwari)/US(MS division)
- 4 SO MS Division
- 5 National Council Secretariat

Minutes of the Meeting

The meeting of Subcommittee to finalize the draft notification in respect of minimum standards of Medical Diagnostic Laboratories including signatory authority/technical head of medical diagnostic laboratory held under the chairmanship of Dr. B D Athani, Spl. DGHS on 01-11-2017 at Nirman Bhawan, New Delhi.

List of Participants is at Annexure 1

The following three documents were circulated in advance to all participants:

1. Draft Notification of minimum standards of Medical Diagnostic Laboratories,
2. Letter indicating the view of MCI in response to queries of NABL and
3. Copy of Delhi High Court order of judgement for the case WP(C) 6740/2017 and CM No- 28067/2017 dated 15-9-2017

Dr. B D Athani, Spl. DGHS, the Chairman of the Subcommittee welcomed the participants. After introduction, the chairman stated that the main agenda of the meeting is the issue of signatory authority of medical diagnostic laboratory reports or technical head for running of medical diagnostic laboratory. He stated that the views of both medical and MSc / Phd in Biochemistry/Microbiology and other Laboratory professionals are being sought.

Dr. Anil Kumar, Addl.DDG(AK) informed that as per the decision taken in 10th meeting of National Council, this subcommittee was constituted to deliberate on this very issue under consideration and give its recommendation for consideration of National Council.

Initially the views of the following representatives of MSc/PhD/Lab. Technologists were sought

- a. Dr Ajay Soni, National Coordinator, Association of Clinical Microbiologists and Biochemists(ACMB)
- b. Shri Arjun Maitra, General Secretary, National M.Sc Medical Teachers' Association (NMMTA)
- c. Shri Kaptan Singh Sehrawat, President, Indian Confederation of Medical Laboratory Science ICMLS
- d. Dr Malkit Singh, Executive Member, Indian Confederation of Medical Laboratory Science ICMLS
- e. Dr Pankaj Kaul, General Secretary Indian Confederation of Medical Laboratory Science ICMLS
- f. Dr Siva Adarsh, Executive Member ACBM
- g. Shri Rishabh Rajput, Joint Secretary, ACBM-DC

Views of representative of MSc/PhD Laboratory Professionals as mentioned above:

- a. Many institutions are running clinical biochemistry course where students are exposed to clinical work. The committee was also informed that presently there is no council, no regulatory authority for running various degree courses. It was agreed that information like universities where these courses can be conducted as well as comparison of degrees awarded currently by them and competency level of the

- people holding these degrees etc. is not available.
- b. These qualified laboratory professionals just give results of investigation for the convenience of medical professionals treating the patients. There is no trespassing or encroachment in professional area of doctors.
 - c. As per the ethics, laboratory professionals have to write whatever they are observing in the given sample. They were also of the view that when they have been recognized for teaching in medical colleges, then why there is now objection to allow them being a signatory authority on medical reports. The view was also expressed that they are having desired qualification and experience of working in laboratory for a number of years and nothing against their name, qualified laboratory professional having MSc/MSc, PhD qualification should be allowed to sign lab reports.
 - d. Contribution of laboratory professional in management of diseases is enormous, at par with medical professionals. It is the basic science which is being applied to medical science. However the boundaries are becoming bigger.
 - e. It was agreed that the competency of such Lab. Professionals should be there but competency may be introduced in a phased manner.

Views of the Sub-committee members:

- a. As there is no council/regulatory body presently in India for laboratory professionals like MSc/PhD/ Laboratory technologist, they do not have indemnity insurance, no liability falls upon them if any miss-happening occurs due to wrong reporting of investigations.
- b. There is a Delhi Court judgement on this issue in respect of the case WP(C) 6740/2017 and CM No- 28067/2017. If same is to be contested, then appeal can be preferred against this judgement.
- c. It was agreed that some newer branches like molecular genetics require laboratory professionals having MSc/PhD qualification. However, now many newer branches of lab investigations viz. Immunology, molecular biology, and genetics cannot be equated with routine laboratory investigations. Presently Doctors completing MD Pathology have due exposure in this segment and are well qualified to give their opinion.
- d. Laboratory professionals and doctors are supplementary and complementary to each other and they should work in same spirit.
- e. Due to more and more use of auto analyzers, Artificial intelligence (AI), role of professional in laboratories are getting reduced in processing samples for various investigations and reporting.
- f. Grey areas exist between reporting on specimen and making final diagnosis. To remove this fallacy, regulatory commission, structured courses and evaluation of competence is required.
- g. Today medical science, like any other branch of the science, is the matrix science and all participants in this matrix are equally important and it will not be fair to leave or compare importance of any member in the matrix.
- h. Dr Vandana Jain, Director, NABL opined that all lab investigation reports by Laboratory professionals like MSc/PhD should be without diagnosis and with a disclaimer that “this report is only for their reference to the medical doctor for arriving final diagnosis”. This is as per the Delhi High Court judgement.
- i. Dr Parul Goel, Deputy Secretary, MCI was of the opinion “all lab reports to be signed/counter signed by persons registered with MCI/State Medical Council”. She informed that clause 15 (2) (b), 15 (2) (c), of Indian Medical Council Act 1956 and

1.1.3 of MCI Code of Ethics, the Laboratory reports can be signed only by doctors registered with MCI. Further MCI has no regulatory power to take action against Laboratory professionals like MSc / PhD / Lab.Technologists.

It was noted that there is no consensus and conflicting views were emerging in the sub-committee regarding procedure, authority and mode of testing competency level and final individual signatory authority on the lab reports. The chair observed that further deliberations may be required on the subject. Chairman asked the member of sub-committee to forward their detailed views so that final consensus can be arrived on the subject. However no new views have been received till the issue of these minutes.

After discussions and deliberations, the following points were recommended:

1. There is a Court order that cannot be overruled and has to be followed. Non-medical Laboratory professionals cannot trespass into diagnostic area. As per the Court Order, the interpretation of the Lab. Report cannot be done by MSc / PhD / Technologists Laboratory Professionals; However the Hon'ble High Court has not taken cognizance of following issues:

- (i). Data related to registration status and competency levels of MSc/PhD/technologists is not available
- (ii). MSc/PhD/technologists are currently not regulated by any council. A vast number of such personnel are available who should not be functioning without regulation.
- (iii). As per Medical Institutions Regulations, 1998 (Amended upto 8-6-2017) of MCI, in the departments of Anatomy, Physiology, Biochemistry, Pharmacology and Microbiology, non-medical teachers may be appointed to the extent of 30% of the total number of posts in the department.
- (iv). The Indian Medical Council Act empowers only the medical professionals (Doctors) to sign the Laboratory Report. The draft notification for medical diagnostic laboratories issued under Clinical Establishments Act also requires the Laboratory Report to be signed by atleast an MBBS doctor.
- (v). Accountability in terms of Consumer laws and medico legal applications will also need to be settled in case of non-medical laboratory personals.
- (vi). The order of Hon'ble High Court has made provision for the Laboratory test results to be signed by MSc/Phd Laboratory Professionals. There is distinct difference between Indian Medical Council Act and order of High Court.

2. Regarding signing of Laboratory Reports by those holding MDS qualification in Oral pathology and radiology, it may be allowed as per Dental Council Act.

3. Ministry will have to consider regulating Laboratory professionals belonging to various branches like Biochemistry, Microbiology and Genetics etc. by a separate Council. Consultation with Ministry of Law will be necessary for further decision in this regard.

The meeting ended with a vote of thanks to the Chair.

Annexure 1

LIST OF MEMBERS OF NATIONAL COUNCIL FOR CLINICAL ESTABLISHMENTS AND OTHER PARTICIPANTS

The first meeting of Subcommittee to finalise the draft notification in respect of Medical Diagnostic Laboratories including signatory authority/technical head of medical diagnostic laboratory

| S.No | Name with Designation | Address | Telephone No./Mobile No./Fax No. | E-mail |
|---|---|---|----------------------------------|------------------------------|
| Chairman and Members who attended the meeting. | | | | |
| 1 | Dr B.D. Athani, Spl.DGHS and Chairman of Subcommittee | Dte.GHS, Nirman Bhawan, | | |
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