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To:
Healthcare Planning and Development Office
Food and Health Bureau
19/F East Wing
Central Government Offices
2 Tim Mei Avenue, Tamar
Hong Kong

13 March 2015

Dear Sir,

RE: Concerns Upon the Regulation of Private Healthcare Facilities Consultation Document

We would like to express our concern over an issue raised in the Working Group on Regulation of Premises Processing Health Products for Advanced Therapies (WG3) of the Steering Committee on Review of Regulation of Private healthcare Facilities. One of the focuses of the Committee was in high risk medical procedures including stem cell manipulations.

In the consultation document Chapter 2.16, it mentioned about "introducing a new legislation with an overarching authority to regulate cells, tissues and health products for advanced therapies through a comprehensive set of regulatory controls including licensing requirements for premises, accreditation of premises, compliance with guidelines, adverse event reporting, designation of Person-in-charge, staffing requirement and training, import and export control, and registration of health products for advanced therapies."

Concerning the staffing requirement and training, it comes to our attention that laboratory testing plays an important role in the manipulation of some of the above procedures. The Supplementary Medical Professions Ordinance Chapter 359 (SMPO Cap 359), Section 32.1, states that a Medical Laboratory Technologist (MLT) is a " person trained in the practice of processing clinical, medical, legal, public health or veterinary specimens for the sole purpose of making and reporting on analysis or examination in vitro and the processing of all matters for human and animal consumption for the sole purpose of making and reporting on analysis or examination in vitro".

Therefore, we think that some procedures, such as processing of stem cell samples, fall into the above category and it is of utmost importance that qualified MLTs be required staff for the processing, testing and reporting of any tests or procedures that fall under the SMPO Cap 359.

In addition to the SMPO Cap 359, an additional set of subsidiary legislation (Cap 359 A-L) for medical laboratory technologists has been established to regulate the laboratory testing activities. It includes, the forming of a legitimate board, the schedule for registration & certification, registration examination, code of practice, proceedings preparatory to hearing etc.

This system of governance of medical testing professionals has been running for over 20 years and it is well respected by the related professions. The UGC funded BSc degree in Medical Laboratory Sciences, is established at the Hong Kong Polytechnic University, and specifically trains graduates for this profession. In short, Hong Kong has established regulations in place for medical laboratory

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testing and this has run successfully for over 20 years, and we should make good use of it. So, we sincerely hope when a new legislation on staffing and training is considered, the section for laboratory testing should be respected and applied appropriately.

MLT professionals feel very strongly that for stem cell and other medical processing and testing, Cap. 359 should not be derogated from any new Ordinances that are used to regulate the manner in which a person may practice a profession of medical processing and testing. We hope that the committee will use the existing Cap 359 ordinance to fulfill staffing needs for procedures and tests that fall under our category. It would not be practical to establish a new Ordinance for new professional requirements. Should you decide to establish a new professional ordinance this would certainly cause delays, and more problems than bringing benefit to the society.

Conclusion

Firstly, we insist that laboratory testing with human samples for the diagnosis, prevention or treatment of any disease in any part of the territory and in any laboratory setting for providing routine testing services to the public (not research and development activities) should be performed only by Registered MLTs with supplementary training provided by the laboratory for any specialized procedures.

Secondly, we are strongly against the formulation of another Ordinance to regulate other laboratory testing procedures on human samples, neither in stem cell manipulation nor in any other areas of medical procedures.

Thirdly, we support the regulation of such premises. However, we are against the idea of not utilizing the existing legislation framework for regulating the laboratory testing personnel involved.

Thank you for your kind attention.

Regards,

Eric Pang
President
Hong Kong Institute of Medical Laboratory Sciences