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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
12th March, 2015

Dear Sir,

RE: The Regulation of Private Healthcare Facilities Consultation Document

I am writing on behalf of the association and our members are medical laboratory scientists (MLT) who practicing laboratory tests in HK both in public and private sectors. The above consultation document has brought to our attention and we would like to express our concern over an issue raised in the Working Group on the Regulation of Premises Processing Health Products for Advanced Therapies (WG3) of the Steering Committee on Review of Regulation of Private healthcare Facilities.

The discussion in the committee about the stem cell manipulations is our major concern. It is no doubt that the manipulations of stem cells would include various laboratory tests such as the enumeration of stem cell count, checking the cell viability, the characterization of stem cells as well as the tight control procedures for the aseptic storage of the stem cells. It is very clear that these are the laboratory functions that should be carried by registrated MLT personnel under Cap359. 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." As mentioned before, we think the Supplementary Medical Professions Ordinance (Cap.359) has already defined the functions of MLTs in performing laboratory tests within Hong Kong. Thus we cannot agree to setup a new legislation for the MLT to perform the specific laboratory tests for stem cells. The current regulation under Cap.359 is adequate for the laboratory tests of stem cells. We hope if a new legislation on the stem cell manipulation is introduced, the section for the regulations of MLT for the performing tests of stem cells should be unchanged.

To summarize, we believe a registrated MLT personnel under Cap.359 is enough to perform laboratory tests for stem cells. There should not be any new regulations that are specific and related to laboratory tests of stem cells.

Regards,

Chau Kong WONG
Chairman
Hong Kong Biomedical Scientists Association