

HKAML BOARD: May 12, 2004

Chairman:  
Marianne Leung  
Director  
PathLab Medical Lab Ltd

The Hon. Michael Mak Kwok Fung  
Chairman, Panel on Health Services  
Legislative Council, HKSAR  
Hong Kong

Vice Chairman:  
Li Wai Chun, Alex  
Director  
Bright Growth Medical Lab Ltd

Dear Sir,

**Responses to the Consultative Paper on Regulation of Medical Devices**

Hon. Secretary:  
Chu Lai Chun, Vicky  
Director  
Asian Medical Lab

The Hong Kong Association of Medical Laboratories (HKAML) is a local association of private medical laboratory companies, with about 40 well-established private labs as members. The HKAML's strategic vision is threefold: Professional Improvement, Allied Health Collaboration & Public Education.

Hon. Treasurer:  
Li Tak Man, Adrian  
Director  
Uni-Lab Ltd

We thank you for this opportunity to participate in the discussions on the proposed Regulation of Medical Devices. Although the committee has been in discussion for almost 2 years without any representation from the medical laboratory sector, we hope that we can still provide some helpful input to the consultation process.

Council Members:  
Lam Chak Hang, Jason  
Director  
Chan & Hau Medical Lab Ltd

Please find our views on the proposed legislation:

**1. Principles of Regulation of Medical Devices**

In principle, HKAML does not object to the categorization of medical devices according to Classes 1 to 4 (Low Risk to High Risk), or to the product registration proposals of 4.26 for local manufacturers, local distributors or importers.

Yeh Yuk Ying, Emily  
Director  
The Giant Medical Lab & X-Ray  
Services Ltd

**2. Pre- and Post-Market Control**

We have no objections to your pre-market and post-market controls. However, we foresee that the regulatory body will have a huge task, to register products, manufacturers and importers. Also, the burden of the program lies mainly with the importers of the medical devices and not with the retailers. There is no mention of charges for registration of each product. We feel these should be kept as low as possible, to reduce the burden on local importers, particularly the smaller ones.

Ng Chiu Hung, Jacky  
Director  
Health-Tech Medical Lab Ltd

**3. Control on the use and operation of medical device**

We have no objections to your proposals on the operation of high-risk medical devices. However, licensing bodies already regulate many health professionals. The medical device regulations should make clear reference to specific devices that require trained or licensed persons to operate them, e.g. X-Ray machines. The task force should also be careful to review existing legislation, to ensure that if there is double regulation, it is consistent in both ordinances.

Cheung Wing Hing, Winnie  
Director  
Exact Medical Lab & X-Ray  
Services

**4. Representatives of Medical / Dental / Nursing / Supplementary Medical Professions / other regulated professions should all be invited to be on the Assessment Body for product assessment.**

The definition of a medical device, (C 4.6, page 11), is very broad. It is confusing, in a healthcare setting, to know which pieces of equipment need to be categorized and which do not.

Hon. Advisor:  
Thomas Yeung  
Director  
Thomas Medical Laboratory

HKAML BOARD:

Chairman:  
Marianne Leung  
Director  
PathLab Medical Lab Ltd

Vice Chairman:  
Li Wai Chun, Alex  
Director  
Bright Growth Medical Lab Ltd

Hon. Secretary:  
Chu Lai Chun, Vicky  
Director  
Asian Medical Lab

Hon. Treasurer:  
Li Tak Man, Adrian  
Director  
Uni-Lab Ltd

Council Members:  
Lam Chak Hang, Jason  
Director  
Chan & Hau Medical Lab Ltd

Yeh Yuk Ying, Emily  
Director  
The Giant Medical Lab & X-Ray  
Services Ltd

Ng Chiu Hung, Jacky  
Director  
Health-Tech Medical Lab Ltd

Cheung Wing Hing, Winnie  
Director  
Exact Medical Lab & X-Ray  
Services

Hon. Advisor:  
Thomas Yeung  
Director  
Thomas Medical Laboratory

There are many, many instruments in each of the medically related professions, ranging from weight balances, pipettes and dental lab equipment to large laboratory analyzers. How these instruments need to be classified, (that they are not used on human beings and carry no physical risk to any human being), probably depends on the Assessment Body. Therefore we hope that you will invite persons in each of the regulated professions to consult, review and to draw up a list of devices unique to their own profession. HKAML will be pleased to offer our services in reviewing medical laboratory devices.

5. **Regulatory laws govern professions other than just doctors and dentists.**

There are many references in the consultation paper to Ordinances regulating doctors and dentists. However, there are other medically related professions that are also regulated by Ordinances, Boards and Councils. Nurses, Medical Technologists, Radiographers, Optometrists, Occupational Therapists, Physiotherapists and Chiropractors are just a few examples. We hope that you will be fair to all professions by also including references to them in your next consultation document.

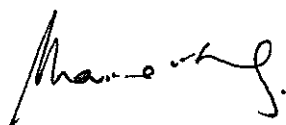
6. **Regulation of selected medical devices, such as lasers and intense pulsed light devices.**

It is apparent that most of the debate has been centered on whether non-doctors (versus doctors and dentists only) may use these two types of devices. The decision will be difficult as the task force weighs the pros and cons of consumer safety, social demands and economic factors.

HKAML supports a compromised route, which will improve the standards and safety of the consumer much more than the present system. We believe that it is necessary to regulate persons operating such beauty devices. They should have appropriate knowledge for the safe use of this equipment. This should involve training, followed by certification and possibly, licensing by a new authority. A survey of suitable training courses in Hong Kong and overseas should be conducted prior to the licensing. Educational institutions should be encouraged to introduce courses to meet the demand. This new authority should have a code of practice guiding and advising licensed persons of their responsibilities. They should be encouraged to work together in harmony with medical doctors as supervisors, consultants or advisors.

We believe all registered doctors and dentists should be exempt from licensing when they themselves use the two types of devices in their practice.

Yours sincerely,



Marianne S.T. Leung  
Part 1 Reg. MLT  
BS, MT (ASCP)(USA),  
AIMBS (UK), AHKMTA(HK)  
Chairman