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香港聽力學會
HONG KONG SOCIETY OF AUDIOLOGY

Views from the Executive Committee on the consultation paper "Regulation of medical devices"

To Whom It May Concern,

As an academic society representing audiologists (professionals who fit hearing aids) in Hong Kong, **our executive committee would like to express our support of placing hearing aids under Risk Class II provided that the registration procedures deem effective and necessary.**

At present, there is no pre-market control to assess the effectiveness and quality of the devices, and false advertisement on their effectiveness cannot be controlled. Hearing aids can be sold by any personnel without proper training. When untrained persons are fitting hearing aids, there may be a risk of over-amplification, causing further damage to hearing. In addition, fitting of custom aids requires taking an impression of the ear. Untrained personnel may subject the hearing aid candidate to risks such as pushing the impression material too far into the ear canal and causing damage to the eardrum and hearing. Hearing aids may also be sold to individuals who may not require them at all. Thus, **we suggest that regulations on the type of personnel eligible (i.e. audiologist or any personnel with proper training in Audiology) for fitting such devices be instituted.** When the devices are not fitted properly or when problems arise, a proper channel of handling adverse incident is non-existent presently.

As the hearing aid market in Hong Kong is relatively small, and manpower to verify device effectiveness, safety and quality of hearing aids is limited, we would like to suggest that the respective regulatory authority **accept clinical trial data and findings or approval of claims from overseas regulatory agencies,** such as the Food and Drugs Administration in the United States. **We also recommend that proof of prior registration at overseas regulatory agencies be considered as full or part evidence for registration approval or exemption.** This will expedite the process for new and effective products to be introduced into the local market, and reduce the effort required to verify device effectiveness, safety and quality. Members of our Society will be honored if we can provide further information regarding regulation of hearing aids.

Thank you for your attention.

Yours truly,

Lena L. N. Wong
Chairperson

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