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6 July 2006

Dr Hon KWOK Ka-ki Chairman Panel on Health Services Legislative Council Legislative Council Building 8 Jackson Road Central Hong Kong

Dear Dr Hon KWOK,

Regulation of Hydrophilic Polyacrylamide Gel (PAAG)

At the Health Services Panel special meeting of 27 April 2006, the Administration discussed with Members the abuse of PAAG for breast augmentation. The Administration undertook to tackle the problem by regulating the import of PAAG into Hong Kong through legislation. This letter seeks to update Members on the present position of the matter.

As PAAG is widely recognized for use as a dermal filler by plastic surgeons, the Administration considered that it is prudent to consult the medical profession before instituting any control on the import of PAAG, and hence sought the view of Hong Kong Medical Association (HKMA) after the Panel meeting. HKMA, in consultation

with the Hong Kong Society of Dermatology and Venereology and the Hong Kong Society of Plastic Reconstructive and Aesthetic Surgeons, wrote to the Department of Health (DH) regarding their position on 20 June 2006. HKMA holds that although intra-dermal injection of PAAG has been used for aesthetic and dermatological treatment, its continued use on human body should be discontinued in view of the reported irreversible side effects caused by abuse of the product.

After the meeting, DH also sought to ascertain further the landscape of PAAG use in Hong Kong, apart from its application in the medical field, in order to ensure any regulation introduced should not compromise the rightful use of the product in Hong Kong. It came to the Department's attention that PAAG is also used as a component in testing agents and therefore used by some laboratories.

In view of the above, the Administration considers that in regulating the import of PAAG for the protection of public health, safe and legitimate use of PAAG by laboratories should not be affected. As an interim measure, the Administration is inclined towards making legislative changes to require PAAG importer to obtain an import licence from DH. It is our intention that import licence would only be issued for PAAG <u>not</u> intended for use inside human body. In parallel, we would also expedite preparatory work in relation to the setting up of a regulatory framework for medical device including PAAG.

The Administration noted that this arrangement may have implications on relevant stakeholders including carriers, PAAG importers, traders or even users, in respect of their business operation. We will consult these stakeholders as soon as possible, with a view to introducing a regulatory regime which is both acceptable to the trade and conducive to the proper use of PAAG.

Yours sincerely,

(Jeff Leung) for Secretary for Health, Welfare and Food