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Clerk to Panel on Health Services
Legislative Council
Legislative Council Building
8 Jackson Road
Central
Hong Kong

Dear Miss So,

**Meeting of Legislative Council Panel on Health Services on 12 November 2007
Commencement of Sections of the Chinese Medicine Ordinance
and Chinese Medicines Regulation**

At the meeting of the Legislative Council Panel on Health Services on 12 November 2007, we briefed Members on the Government's plan to commence on 11 January 2008 the provisions in the Chinese Medicine Ordinance and Chinese Medicines Regulation, which govern the control over the possession, sale, import and export of Chinese herbal medicines and over the manufacture, sale by way of wholesale, import and export of proprietary Chinese medicines, in order to fully effect the licensing regime of Chinese medicines traders and the import and export control of Chinese medicines. Members supported our proposal and requested us to provide relevant information on the publicity and educational work, staffing arrangements to carry out the enforcement work, and the timetable for implementing the Undesirable Medical Advertisements (Amendment) Ordinance 2005. We hereby provide the relevant information as per Members' request.

Publicity and Education

In order to familiarise the Chinese medicines trade with and prepare them for the proposed commencement of the legislative provisions, the Chinese Medicines Board (CMB) under the Chinese Medicine Council of Hong Kong (CMCHK) has launched a series of publicity and educational activities, including mounting posters at the shopping centres and markets of the Food and Environmental Hygiene Department, Housing Department and The Link; issuing circular memoranda to individual Chinese medicines traders and relevant organisations; conducting seminars and visiting business operators. Prior to the commencement of the relevant legislative provisions, the CMB will make announcements in newspapers, CMCHK website and telephone hotline of the Department of Health (DH), organise press conferences, issue press releases and send circular memoranda to Chinese medicines traders and Chinese medicine practitioners to remind them to apply for a licence and comply with the legislation and practising guidelines.

Staffing arrangements for enforcement work

The DH provides administrative support to the CMCHK and its underlying Chinese Medicine Practitioners Board, CMB, as well as various committees. With regard to the regulation of Chinese medicines, the DH is also responsible for implementing the legislative provisions on the practice of Chinese medicine in the Chinese Medicine Ordinance and its subsidiary legislation. The main enforcement actions include -

- (i) conducting investigation and assisting in prosecution against offences specified in the Chinese Medicine Ordinance and its subsidiary legislation;
- (ii) providing evidence to the Court for offences specified in the Chinese Medicine Ordinance and its subsidiary legislation; and
- (iii) issuing import and export licences for 31 types of Schedule 1 Chinese herbal medicines and five types of Schedule 2 Chinese herbal medicines specified in the Chinese Medicine Ordinance.

Under section 146 of the Chinese Medicine Ordinance, the Director of Health has authorised 31 DH officers (including nine Pharmacists/registered Pharmacists and four Chinese Medicine Assistants) as inspectors for the purpose of enforcing the Chinese Medicine Ordinance and its subsidiary

legislation. The existing enforcement officers have all received internal training on investigation, evidence collection and prosecution proceedings, as well as enforcement training provided by the Customs and Excise Department (C&ED), the Department of Justice, and The Academy of Experts in the United Kingdom. The inspectors conduct regular and ad hoc inspections of the business premises of Chinese medicines traders to ensure that they comply with the practicing requirements specified in the legislation and practising guidelines. They also provide expert advice to Chinese medicines traders on the use, quality control and processing of proprietary Chinese medicines and Chinese herbal medicines and the manufacture of proprietary Chinese medicines. In addition, each year the DH will sample-check the heavy metal and toxic elements contained in 2 400 proprietary Chinese medicines and 400 Chinese herbal medicines sold in the market. If such elements are found to have exceeded the permitted levels, the DH will take appropriate actions, such as demanding the Chinese medicines traders to stop selling and recall the products with problems. Upon receiving complaints about the breach of practicing requirements by Chinese medicines traders, the DH will conduct investigations and where necessary, refer the case to the CMB for consideration of disciplinary actions, including revocation or suspension of licence, variation of licensing conditions or issue of warnings.

At present, the issue of import and export licences for proprietary Chinese medicines is carried out pursuant to the Pharmacy and Poisons Ordinance. With the commencement of the provisions as proposed, such import and export licences can be issued in accordance with the definition of proprietary Chinese medicines under the Chinese Medicine Ordinance. The DH has now maintained all import and export information on proprietary Chinese medicines products in order to monitor their sources and movement, so that in the event of a medical incident, the DH can take such corresponding actions as stopping the sale and ordering a recall of the products. After import and export control has been imposed on the 36 types of Chinese herbal medicines, the same arrangements will be applicable to monitoring their sources and movement.

To ensure the smooth implementation of the relevant legislative provisions, the DH and Government Laboratory plan to increase their manpower in the 2008-09 financial year to strengthen the inspection of Chinese medicines traders, investigation of non-compliant cases and testing of Chinese herbal medicines. The DH will also coordinate and align its efforts with other Government departments. When the relevant legislative provisions come into operation, C&ED officers may enforce the import and export control of the 31 types of Schedule 1 Chinese herbal medicines and five types of Schedule 2 Chinese herbal medicines under the Chinese Medicine Ordinance in accordance

with the Customs and Excise Service Ordinance and Import and Export (General) Regulations. Pursuant to the Import and Export Ordinance, the Director-General of Trade and Industry has also authorised DH officers to issue import and export licences to regulated Chinese herbal medicines. Moreover, the DH has provided training to C&ED officers for the identification of the above-mentioned 36 types of Chinese herbal medicines, and has made other corresponding arrangements.

Implementation timetable for the Undesirable Medical Advertisements (Amendment) Ordinance 2005

The Undesirable Medical Advertisements (Amendment) Ordinance 2005 shall come into force on a date specified by the Secretary for Food and Health. Under the new Schedule 4, if a product is not registered under either the Pharmacy and Poisons Ordinance or the Chinese Medicine Ordinance, its advertisement must clearly include a disclaimer, before the claims of regulation of body sugar or glucose and/or alteration of the functions of the pancreas, regulation of blood pressure and regulation of blood lipids or cholesterol (Items 4 to 6 of Schedule 4) are allowed. Therefore, the Administration will endeavour to implement the registration system for proprietary Chinese medicines as soon as possible so that the Undesirable Medical Advertisements (Amendment) Ordinance 2005 can commence at an early date.

Yours sincerely,

(Patrick SIU)
for Secretary for Food and Health

c.c. Director of Health (Attn : Dr Amy CHIU
Dr Henry NG)