中華人民共和國香港特別行政區政府總部食物及衞生局
Food and Health Bureau, Government Secretariat
The Government of the Hong Kong Special Administrative Region
The People's Republic of China

Our Ref : FHB/H/24/2
Your Ref : CB2/PL/HS

Tel : 3509 8956
Fax : 2840 0467

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Ms Maisie LAM
Clerk to Panel
Legislative Council Panel on Health Services
Legislative Council Complex
1 Legislative Council Road
Hong Kong
(Fax : 2185 7845)

Dear Ms LAM,

Legislative Council Panel on Health Services
Issues relating to "Regulation of Chinese herbal medicines"

I refer to the letter from Dr. Hon. Helena WONG Pik-wan to the Legislative Council Panel on Health Services on 10 March 2017 requesting the Administration to provide information on the regulation of Chinese herbal medicines, our detailed response is as follows.

Regulation of Chinese Herbal Medicines

The Chinese Medicine Council of Hong Kong (CMCHK) is an independent statutory body established in 1999 under the Chinese Medicine Ordinance (Cap. 549) (CMO). Under the CMCHK, the Chinese Medicines Board (CMB) is responsible for formulating and implementing the regulatory measures for Chinese medicines (CM) according to the CMO. The Department of Health (DH) is responsible for providing professional support to the CMCHK in implementing regulatory measures for CM.

Currently, we have put in place a stringent regime for the regulation of Chinese herbal medicines (Chm) and CM traders. For Chm, since there are

different varieties of CM, they have been classified into different categories for regulatory control according to their toxicity and degree of popularity in Hong Kong. Having regard to the need of regulatory control, 605 types of Chm have been listed as 31 types of Schedule 1 Chm and 574 types of Schedule 2 Chm respectively under the CMO. Schedules 1 and 2 have clearly stated the origin of each Chm such as the information of the scientific name of plant or animal origin (including family, genus and species) and the medicinal parts for identification. The Chm specified in Schedules 1 and 2 shall apply to the dried or processed form of such medicines and the following regulatory controls have been imposed –

Regulation on import and export of Chm

According to the Import and Export (General) Regulations (Cap. 60A), all Schedule 1 Chm and five types of Schedule 2 Chm (namely Radix Clematidis, Flos Campsis, processed Radix Aconiti, processed Radix Aconiti Kusnezoffii and Radix Gentianae) are subject to licensing control. Importation/exportation of these Chm must be covered by an import/export licence.

Regulation on sale of Chm

(i) Licensed retailers or licensed wholesalers of Chm can only carry on their business related to the 605 types of Chm listed (including 31 types of Schedule 1 Chm and 574 types of Schedule 2 Chm) in the CMO at the premises specified in their licences ;

(ii) Control for the 31 types of Chm listed in Schedule 1 is more stringent as they are toxic and regulatory controls are set out as follows –
   (a) Chm listed in Schedule 1 must be dispensed in accordance with a prescription given by a registered Chinese medicine practitioner and cannot be sold by retail;
   (b) No medicine traders shall possess, wholesale or dispense the Chm listed in Schedule 1 unless specified in their licences; and
   (c) To fulfil the requirements on recording Chm listed in Schedule 1, licensed retailers of Chm have to keep dispensing record and licensed wholesalers of Chm have to keep the related purchase and sales record.

<u>Regulation on CM traders</u>

Regarding the regulation of Chinese medicine traders, any person who is engaged in the business of the retail and wholesale of Chm must obtain a relevant licence from the CMB and comply with the relevant practising

guidelines which include purchasing Chm only from reputable suppliers, ensuring the quality of Chm and their proper use, and keeping related transaction documents and records (for a period of not less than 2 years from the date of the transaction) to enable tracing of the source and distribution network of Chm suspected to have problems whenever necessary.

Most of the Chm currently sold in Hong Kong are imported as decoction pieces from the Mainland, and any business engaged in the production of decoction pieces in the Mainland must meet the requirements of the "Good Manufacturing Practice for Pharmaceutical Products" and accredited by the provincial Food and Drug Administration under the China Food and Drug Administration. In addition, responsible personnel engaged in retail and wholesale business of Chm in Hong Kong should have basic knowledge of authentication of Chm to determine the authenticity and quality of Chm so as to ensure the safety of Chm used by public.

The DH often conducts inspections to the premises of licensed retailers and wholesalers of Chm to ensure their compliance with the requirements of the law and the practising guidelines. As at 17 March 2017, the CMCHK has issued licences to 4 690 retailers and 935 wholesalers of Chm.

Testing of Chm

At present, the DH adopts a two-pronged strategy to testing Chm. Firstly, the DH draws samples of around 45 Chm every month from the market for testing in order to monitor the quality and safety of the Chm regulated under the CMO. The regular testing items include pesticides residues (including 20 testing parameters of Organochlorine pesticides and 17 testing parameters of Organophosphate pesticides), heavy metals content (including Arsenic, Cadmium, Lead and Mercury) and morphological identification to ensure that the Chm sold in the market are in compliance with the requirements on the safety as set out by the CMB and the origin and the medicinal parts of the Chm stipulated in the CMO. Secondly, the DH conducts targeted testings, that is, samples of specific Chm will be obtained for testing in response to information collected from other channels, including adverse drug reaction reporting system, public complaints and referrals from other government departments.

The testing of pesticide residues and heavy metals in Chm is carried out by the Government Laboratory and consists of 2 stages. The first stage involves tests on the Chm samples in their raw state before decoction to check whether they contain the 37 pesticides and 4 heavy metals and the respective residue levels/contents. The second stage test is conducted to assess the

quantity of pesticide residues or heavy metals in the decoction of the Chm concerned. Testing for pesticide residues and heavy metals in the decoction of Chm is considered to be a closer simulation of condition during human consumption which is more appropriate for human risk assessment. The procedures and scope of tests are recognised by both the CMB and the international expert group of the Scientific Committee set up under the Hong Kong Chinese Materia Medica Standards project.

If any sub-standard Chm are found, the DH may request the Chinese medicine traders concerned to recall the products and refer the case to the CMCHK for follow-up actions. Press statements will also be issued. Moreover, the DH will continue to maintain close liaison with the relevant Mainland regulatory authorities for timely exchange of information on quality and safety of CM according to the established mechanism, to safeguard public health.

Management of CM by the Hospital Authority

The Hospital Authority (HA) has established policy for the centralized procurement of CM products. All CM products supplied to the HA must comply with the regulatory policy for CM in Hong Kong including the CMO, the Protection of Endangered Species of Animals and Plants Ordinance (Cap. 586), Import and Export Ordinance (Cap. 60) and Food Safety Ordinance (Cap. 132), etc. In addition, the manufacturing process of CM products supplied to the HA must meet the Good Manufacturing Practice standards. All CM products must also meet the HA's product specifications on quality and safety.

We thank Members of the Panel on Health Services for expressing concerns about this matter.

Yours sincerely,

(Mr James LAM)
for Secretary for Food and Health

c.c. Director of Health
(Attn: Assistant Director (Traditional Chinese Medicine))