# LCQ12: Regulation and development of Chinese medicine

Following is a question by the Hon Elizabeth Quat and a written reply by the Secretary for Food and Health, Professor Sophia Chan, in the Legislative Council today (January 20):

Question:

Regarding the regulation and development of Chinese medicine (CM), will the Government inform this Council:

(1) as a study has pointed out that there are minimal differences in the requirements to be met and the documents to be submitted for the respective registration of new proprietary Chinese medicines (pCms) in Hong Kong and on the Mainland, but due to the different registration systems for pCms in the two places, it takes about five years or more for Hong Kong-registered pCms to go through the Mainland's registration procedure afresh before they may be sold on the Mainland, and that the Government indicated last year that it would explore with the Mainland authorities matters on facilitating the use of Hong Kong-registered pCms on the Mainland, what progress has been made in the exploration;

(2) whether, in the long term, it will consider afresh exploring with the Mainland authorities the setting up of a mutual recognition system for pCm registration between the two places; if so, of the details and timetable; if not, whether it will consider taking the first step of jointly setting a common standard for registration of new pCms in the Guangdong-Hong Kong-Macao Greater Bay Area (Greater Bay Area);

(3) as the Mainland authorities announced in September last year that designated healthcare institutions operating in the nine Mainland cities of the Greater Bay Area would be allowed to use Hong Kong-registered drugs with urgent need clinically, subject to approval by the Guangdong provincial authorities, whether the Government will discuss with the Mainland authorities (i) the inclusion of Hong Kong-registered pCms in the relevant directory of drugs, and (ii) the designation as designated healthcare institutions of all high-quality hospitals in the Greater Bay Area, as well as those clinics of Hong Kong's Chinese medicine practitioners (CMPs) practicing in the Greater Bay Area and clinics run by funds from Hong Kong; if so, of the details and timetable; if not, the reasons for that;

(4) whether it will discuss with the authorities of Guangdong and Macao the collaboration in (i) establishing a clinical trial network for CM in the Greater Bay Area, (ii) drawing up a set of internationally recognised standards for clinical trials on CM, and (iii) establishing an international CM clinical research centre in the Greater Bay Area, so as to promote the research and development of CM in the Greater Bay Area; if so, of the details

and timetable; if not, the reasons for that;

(5) given that single CM granules supplied to CMPs for dispensing a prescription to replace any regular herbal medicines are exempted from registration, but in recent years some single CM granules have been tested and found by overseas authorities to contain toxic substances, and there have been cases in Hong Kong in which such medicines were found to have an aerobic count exceeding the prescribed limit and a wholesaler suspected of having made false claims on the production standard, whether the Government will consider amending the legislation to stipulate that (i) all single CM granules must be registered, or (ii) only those single CM granules produced by those manufacturers which conform to the specified production standards may be exempted from registration; and

(6) whether the Government will discuss with the competent authorities of CM in the Greater Bay Area and other Mainland cities (i) the collaboration in developing a mechanism for CM teleconsultation and treatment, as well as making complementary arrangements in aspects such as electronic medical records and modes for diagnoses and treatments, and (ii) the joint development of diagnostic and treatment plans or expert consensus in integrated Chinese and Western medicines that have greater efficacy, as well as the clinical collaboration modes (including the modes of inspection of patients, consultation and case conferences to be jointly undertaken by Chinese and Western medicine practitioners)?

Reply:

President,

In consultation with the Hospital Authority (HA), I provide a consolidated reply to the various parts of the question raised by the Hon Elizabeth Quat as follows:

(1) to (3) At present, the Mainland and Hong Kong have in place different registration regimes for the regulation of Chinese Medicine (CM) products. Applicants are required to submit applications for registration of proprietary CMs (pCms) pursuant to the respective registration requirements in the Mainland and Hong Kong and obtain approval, before such pCms can be sold in that particular place. With the support of the Central Government, the National Medical Products Administration promulgated the Work Plan for Regulatory Innovation and Development of Pharmaceutical and Medical Device in the Guangdong-Hong Kong-Macao Greater Bay Area (Work Plan) in November 2020, under which traditional pCm products for external use registered in Hong Kong will be allowed to be registered and sold in the Guangdong-Hong Kong-Macao Greater Bay Area (GBA) through a streamlined approval process. The Government is proactively following up with the Guangdong Medical Products Administration to implement the relevant arrangement, with a view to enhancing the business exchanges in respect of pCms with the Mainland and fostering the development of pCms in Hong Kong, thereby creating favourable conditions for CM drugs to "go global".

Furthermore, according to the Work Plan, designated healthcare institutions operating in the nine Mainland cities of the GBA may use Hong Kong-registered drugs with urgent clinical use, subject to the approval of Guangdong Province. The Government will implement the measure at the University of Hong Kong-Shenzhen Hospital on a trial basis. Preparatory work has been kick-started with the relevant Mainland authorities, which includes establishment of a collaborative platform and commencement of discussions with the relevant authorities to draw up the directory of drugs to be used in designated healthcare institutions in the GBA in accordance with the Work Plan, with the implementation details to be discussed. The Government will review the implementation in a timely manner to consider if the policy should be extended to cover CM drugs.

(4) and (6) In response to the Construction Plan for the Chinese Medicine Highlands in the Guangdong-Hong Kong-Macao Greater Bay Area (2020-2025) promulgated by the National Administration of Traditional Chinese Medicine in November 2020, the Government, through the Chinese Medicine Development Fund, will further encourage local academies, research institutions and the CM trade to co-operate with their counterparts in the GBA to carry out more research on the basic theories, clinical aspects and standards development of CM.

The Government is planning the development of the first Chinese medicine hospital (CMH) in Hong Kong. The types of clinical services to be provided include pure CM services, services with CM playing the predominant role and integrated Chinese-Western medicine (ICWM) services. ICWM services will be provided as regards specific patient types or diseases where CM and western medicine (WM) would be integrated (with CM playing the predominant role) into the care protocols based on the respective strengths of both treatment types to achieve the desired patient outcome.

The CMH will be equipped with teleconsultation facilities for joint consultations with local, Mainland or overseas partnering institutions and experts, and a clinical trial and research centre for Phases I and II clinical trials. This will help promote training and research development of the local CM and CM drugs (including pCms) sector, and foster multilateral collaboration. The CMH will collaborate with local universities (including the three universities with Schools of CM) as well as local, Mainland or overseas institutions to promote and conduct evidence-based clinical scientific research (CM and ICWM), in-depth studies on CM theories, and research on the clinical application of pCms.

Furthermore, the HA was commissioned by the Government to launch the ICWM Pilot Programme (the Programme) in September 2014 to develop clinical protocols for three selected disease areas, namely stroke care, musculoskeletal pain management and cancer palliative care, with a view to gathering experiences in the operation of ICWM and CM in-patient services. Currently, ICWM in-patient services and CM out-patient follow-up services for in-patients of the above disease areas in seven hospitals of the HA are provided to make use of the advantages of ICWM to provide appropriate medical treatment for local patients. Given that the Programme is still in its pilot

stage, the HA will continue to explore the development of ICWM services and examine the feasibility of expanding the Programme in a timely manner in response to and in line with the Government's planning and operational model of the CMH.

(5) "Single CM granules for prescription" are made from condensed extracts of single CM decoction pieces. "Single CM granules for prescription" sold by wholesalers of Chinese herbal medicines (Chms) are regulated and monitored under the existing regime. "Single CM granules for prescription", when only supplied to CM practitioners for dispensing a prescription to replace common CM decoction pieces, fall into the category of Chms specified in Schedule 1 or 2 to the Chinese Medicine Ordinance (CMO), and are subject to the licensing regime for CM traders under the CMO.

At present, the Chinese Medicines Board (CMB) of the Chinese Medicine Council of Hong Kong (CMCHK) and the Department of Health (DH) have in place a stringent regulatory regime for the issue and renewal of licences as well as inspections in regard to four types of CM drug traders (namely retailers of Chms, wholesalers of Chms, wholesalers of pCms and manufacturers of pCms). The scope of inspection includes environmental hygiene of the premises, contamination risks, labelling and storage conditions of the CM drugs, transaction documents and records as well as test reports. The CMB has also compiled practising guidelines for the trade stipulating requirements (such as safety standards) to be observed by Chm wholesalers in the sale of "single CM granules for prescription" (Note 1). If there is any violation of the CMO or the practising guidelines, the DH will initiate criminal prosecution or refer the case to the CMB of the CMCHK for disciplinary inquiries.

The DH has also in place a market surveillance system to ensure the safety of CM drug products, including all registered pCms and the Chms listed in Schedules 1 and 2. Apart from conducting investigations and tests proactively, the DH also takes samples of Chms and pCms (including CM granules) from wholesalers and retailers for testing.

Note 1: The following should be observed:

- Ensure that the "single CM granules for prescription" being sold complies with the three safety requirements prescribed for registration of pCms (i.e. limits of heavy metals or toxic elements, pesticides residue limits and microbial limits);

- Supply "single CM granules for prescription" only to CM practitioners, licensed retailers or wholesalers of Chms. If the "single CM granules for prescription" contain any Schedule 1 medicine, the said granules should be supplied only to registered CM practitioners, licensed retailers or wholesalers of Chms in respect of Schedule 1 medicines;

- Ensure that the label on the container or package of "single CM granules for prescription" includes the following particulars:

(i) name of the "single CM granules for prescription";
(ii) weight equivalence i.e. the amount of original processed herbal medicine that is equivalent to one gram of the granules;
(iii) a statement containing the following Chinese text: "åª›ä¸-é†«™•æ—¹é…ç™¼ä½¿ç”¨";
(iv) packing specification of the "single CM granules for prescription";
(v) normal dosage or maximum dosage of the "single CM granules for prescription";
(vi) name of the manufacturer or distributor of the "single CM granules for prescription"; and
(vii) expiry date of the "single CM granules for prescription"; and

- Ensure that the relevant particulars in respect of every transaction whereby a "single CM granules for prescription" containing Schedule 1 medicine, is acquired, received, sold or distributed are recorded.