

## LCQ5: Development of the Chinese medicine industry

Following is a question by Dr the Hon Elizabeth Quat and a written reply by the Secretary for Food and Health, Professor Sophia Chan, in the Legislative Council today (May 15):

Question:

To promote the development of the Chinese medicine (CM), the Government has allocated \$500 million to establish a dedicated Chinese Medicine Development Fund. One of the aims of the Fund is to assist local CM traders in the production and registration of Chinese proprietary medicines. The Government also plans to amend the definition of "proprietary Chinese medicine" in the Chinese Medicine Ordinance (Cap. 549). Regarding the development of the CM industry, will the Government inform this Council:

(1) whether it will amend Cap. 549 to require single CM granules that are supplied to CM practitioners for dispensing a prescription to undergo proprietary CM registration, so as to align the requirements for them with those for compound CM granules and other single CM granules that are sold publicly; if so, of the details; if not, the reasons for that;

(2) given that some CM practitioners have pointed out that as various CMs in a herbal formula, upon being boiled together, may produce new ingredients with therapeutic effects, single CM granules prescribed for the same formulae may not necessarily have the same therapeutic effects, whether the Government knows the reasons why the 18 Chinese Medicine Centres for Training and Research under the Hospital Authority have ceased to prescribe compound CM granules for patients since April 1 last year;

(3) given that the registration requirements of new CM involve prolonged and costly clinical trials and medicinal tests, and the Hong Kong market is of a small scale, whether the Government will consider discussing with the Mainland authorities the setting up of a mutual recognition system of CM registration between the two places; if so, of the details; if not, the reasons for that; and

(4) whether it will consider conducting clinical medicinal tests in the CM hospital upon its commissioning in future, with a view to promoting the development of the CM industry in Hong Kong; if so, of the details; if not, the reasons for that?

Reply:

President,

My reply to the four parts of the question is as follows:

(1) Currently, products that fall within the definition of proprietary Chinese medicine (pCm) in the Chinese Medicine Ordinance (Cap. 549) (CMO) must be registered with the Chinese Medicines Board established under the Chinese Medicine Council of Hong Kong (CMCHK) before they can be imported, locally manufactured and sold. pCm means any proprietary product –

- (a) composed solely of the following as active ingredients:
  - (i) any Chinese herbal medicines (Chms); or
  - (ii) any materials of herbal, animal or mineral origin customarily used by the Chinese; or
  - (iii) any medicines and materials referred to in subparagraphs (i) and (ii) respectively;
- (b) formulated in a finished dose form; and
- (c) known or claimed to be used for the diagnosis, treatment, prevention or alleviation of any disease or any symptom of a disease in human beings, or for the regulation of the functional states of the human body.

In general, Chinese medicine (CM) granules must be registered with the Chinese Medicines Board before they can be imported, locally manufactured and sold. However, the CMO and its subsidiary legislation also exempt some pCms from registration, such as pCms compounded by CM practitioners (CMPs) for individual patients and pCms manufactured by local manufacturers entrusted by CMPs. CMPs must fulfill their professional responsibility to ensure the safety, quality and efficacy of the compound pCms concerned. On the other hand, single CM granules, when supplied to CMPs for dispensing a prescription to replace any medicinal decoction pieces, fall into the category of Chms specified in Schedule 1 or 2 of the CMO, and are subject to the licensing system for CM traders under the CMO.

The Department of Health (DH) has put in place a stringent regulatory system for Chms and pCms. All registered pCms and the Chms listed in the Schedules to the CMO are within the scope of the DH's market surveillance system. The DH conducts regular inspections on licensed CM traders, takes samples of registered pCms (including CM granules) and Chms from wholesalers and retailers for testing as well as investigations and tests proactively. Therefore, pCms that CMPs purchased from pCm wholesalers/manufacturers and Chms that CMPs purchased from Chm wholesalers are regulated and monitored under the existing system.

To provide safe and efficacious CMs for patients, CMPs should source supply from reputable licensed Chms wholesalers, and should not purchase Chms of unknown composition or source. If a CMP has conducted himself in a way which has fallen short of the reasonable standards of conduct expected among his professional colleagues in the course of operating business, it may constitute a professional misconduct, and will be dealt with seriously by the CMPs Board and the Disciplinary Committee of CMPs established under the CMCHK.

(2) The Hospital Authority (HA) has established an open and transparent tendering mechanism to procure CM products that meet the statutory

requirements and the relevant quality standards from the market for patients' use. The HA will accept tenders for CM products and consider their tender prices on the conditions that the tenderers concerned as well as their products meet the statutory, safety and quality requirements as stated in the invitation to tender.

In addition, CMPs are required to conform with the CM theories and clinical situations of the patients concerned in prescribing suitable CM products. At present, processed Chms and CM granules are available in the 18 CM Centres for Training and Research for CMPs to facilitate their provision of appropriate CM services for patients.

As far as the tendering of CM granules for prescription is concerned, both single CM granules and compound CM granules are among the tender items. The former is a mandatory supply item whereas the latter is optional. Regarding the contract mentioned in the question that has been effective since April 1, 2018, the tenderer selected by the HA under the above-mentioned tendering mechanism has met the requirements specified in the tender. Compound granular products that are not provided by the successful tenderer are optional supply items.

The HA will review tenders for CM products on a regular basis, and will make timely adjustments in response to the market development and clinical service needs.

(3) Hong Kong and the Mainland implement different registration systems for regulating CM products under their respective legal and statutory regulatory framework. Currently, there is no direct mutual recognition arrangement for product registration between the two places. To further promote and encourage CM development in Hong Kong, the Government will explore with the Mainland on how to facilitate the use of Hong Kong registered pCms in the Mainland. The Government will also encourage, fund and support research, registration and development of CM in Hong Kong through the \$500 million CM Development Fund.

(4) Leading and promoting scientific research and development of CM (including pCms) in Hong Kong is one of the main objectives of the future CM Hospital (CMH). The CMH will collaborate with the local universities (including the three universities with Schools of CM) and also local or educational institutions in other places to promote and conduct evidence-based clinical scientific research (CM and Integrated Chinese-Western Medicine), in-depth studies on CM theories and research on the clinical application of pCms. Facilities including a clinical trial and research centre will be set up in the planned CMH for conducting clinical trials at different stages. Supported by clinical services as well as CM and scientific research talent of the CMH, the centre will serve as a development platform for research on new pCms and enhancing the treatment efficacy of registered pCms.