



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

26 May 2015

Ms Joanne MAK
Clerk to Subcommittee on
Issues Relating to the Development of Chinese Medicine,
Legislative Council Panel on Health Services
Legislative Council Complex
1 Legislative Council Road
Central, Hong Kong

Dear Ms MAK,

Panel on Health Services

Subcommittee on Issues Relating to the Development of Chinese Medicine

**Administration's responses on issues raised at the meeting
held on 14 April 2015**

At the meeting of the Subcommittee on Issues Relating to the Development of Chinese Medicine held on 14 April 2015, Members requested for supplementary information on the development of proprietary Chinese medicines ("pCms"). The requested supplementary information is set out below.

I. Development of pCms

- (a) *Total amount of funding provided by the Innovation and Technology Commission ("ITC") on the research and development of Chinese medicines since 1999*

2. As at 31 March 2015, the Innovation and Technology Fund supported 104 Chinese medicine-related projects with a total committed funding amount of around HK\$191 million.

(b) Application of the Hong Kong Chinese Materia Medica Standards ("HKCMMS") in the use of Chinese medicine and pCm production

3. To safeguard public health and promote the development of Chinese medicine, the Government is committed to developing comprehensive reference standards for some commonly used Chinese herbal medicines. The Department of Health ("DH") launched the HKCMMS project in 2001 and set up an International Advisory Board comprised of local, Mainland and overseas renowned experts to give professional advice on the HKCMMS and examine the results of scientific research. The HKCMMS project aims to provide applicable and adoptable reference standards for the Chinese medicine industry, with a view to ensuring the safety and quality of Chinese herbal medicines and public health. So far, the research on 200 Chinese herbal medicines commonly used in Hong Kong has been completed, and six editions of HKCMMS covering standards for a total of 200 Chinese herbal medicines have been published.

4. The Chinese medicine industry may use the HKCMMS as reference standards. For instance, -

- (i) manufacturers of pCms may use the HKCMMS as the quality reference standards to control the quality for starting materials;
- (ii) Chinese herbal medicines traders may apply the HKCMMS in the procurement of Chinese material medica with good quality;
- (iii) in developing product specification for the purpose of pCm registration, the HKCMMS may be used for selecting markers for identification and assay;
- (iv) tests on Chinese herbal medicines conducted under the voluntary Hong Kong Certification Scheme for Chinese Materia Medica¹, implemented by the Hong Kong Productivity Council with the support of the Hong Kong Council of Testing and Certification, will also be performed on the basis of the HKCMMS;

¹ Under the voluntary Hong Kong Certification Scheme for Chinese Materia Medica, traders of Chinese herbal medicines in Hong Kong may seek certification from a third party (i.e. accredited certification body) to confirm their capacity for providing Chinese herbal medicines which are up to the standards.

- (v) the Hong Kong Accreditation Service has launched laboratory accreditation services with testing standards based on the HKCMMS;
- (vi) the Hospital Authority (“HA”) has made reference to the requirements set out in the HKCMMS in managing the risks of using Chinese medicines by conducting random checks.

5. We believe that the application of HKCMMS would help strengthen confidence of local and international buyers and consumers, thus facilitating trading of Chinese medicines in Hong Kong. To further develop the HKCMMS, the Government has also accepted the recommendation of the Chinese Medicine Development Committee (“CMDC”) which supports the continuation of the HKCMMS project to study and formulate standards for more Chinese herbal medicines; and the consideration of including study on the standard setting for Chinese medicines decoction pieces under the HKCMMS project, so that HKCMMS can be more widely adopted. The DH is now consulting experts in scientific research to actively explore the feasibility of implementing the recommendations. The future target for the HKCMMS is to develop standards for around 28 Chinese herbal medicines each year and include, as recommended by the CMDC, Chinese medicines decoction pieces in the scope of research.

(c) The application of HKCMMS by the HA

6. The use of Chinese medicines in the form of decoction pieces in the HA is in accordance with the standards set in the Chinese Pharmacopeia (“CP”). In general, for routine quality assurance of decoction pieces, the HA would follow the standards as recommended by the CP. However, for safety standards not covered by the CP or those peculiar to the local circumstances in Hong Kong, the HA will draw additional reference from the HKCMMS. Since the decoction pieces required by the HA are reviewed regularly, the HA does not maintain a list of Chinese medicines for which HKCMMS would be checked against.

(d) The expenditure involved for developing the HKCMMS

7. The DH has completed and published the reference standards of 200 Chinese Materia Medica as pledged in 2009-10 Policy Address. The expenditure involved for developing the HKCMMS is set out in the table below. Reference standards of another 33 CMM are expected to be published by end 2015.

| <i>Publication of HKCMMS</i> | <i>Number of Chinese Materia Medica included</i> | <i>Date of publication</i> | <i>Expenditure (HK\$ million)</i> |
|------------------------------|--|----------------------------|-----------------------------------|
| Volume 1 | 9 | July 2005 | 13.9 |
| Volume 2 | 24 | July 2008 | 10.0 |
| Volume 3 | 29 | February 2011 | 20.1 |
| Volume 4 | 36 | February 2012 | 25.1 |
| Volume 5 | 42 | December 2012 | 28.2 |
| Volume 6 | 60 | December 2013 | 43.3 |

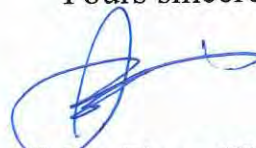
(e) The testing centre for Chinese medicines

8. The DH has, in collaboration with the Government Laboratory, started the preparatory work for setting up the testing centre for Chinese medicines, including the herbarium therein. The Government is conducting a site search and working out the implementation details, including the resources requirements and arrangements for the testing centre.

II. The arrangements for migration of pCms from transitional registration to formal registration

9. Currently there are over 8,500 pCm products issued with Notice of confirmation of transitional registration of pCm (i.e. "HKP"). In response to Member's enquiry, the Administration has approached the Chinese Medicines Board ("the Board") and has been advised by the Board that as of 7 May 2015 there were around 18% of pCm products carrying HKP status with outstanding quality specification and stability test reports.

Yours sincerely,



(Miss Fiona CHAU)
for Secretary for Food and Health