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For information

Legislative Council Panel on Health Services
Subcommittee on Issues Relating to the Development of Chinese Medicine
Development of Proprietary Chinese Medicines

The use of traditional medicine is increasingly popular around the world. Committed to the development of traditional Chinese medicine, the Government attaches much importance to the quality and safety of Chinese medicines in particular. This paper introduces the Government's efforts in promoting the development of proprietary Chinese medicines (pCms).

(I) Regulation of Chinese Medicines

2. To ensure and enhance the quality of Chinese medicines and their safe use by the public, the Chinese Medicine Ordinance (Cap. 549) (CMO) provides for the comprehensive regulation of Chinese medicines traders, pCms, and the import and export of Chinese medicines.

Registration of Chinese Medicines Traders

3. In accordance with the CMO, any persons engaged in any of the four types of Chinese medicines trade, namely retail of Chinese herbal medicines, wholesale of Chinese herbal medicines, manufacture of pCm and wholesale of pCm, are required to apply to the Chinese Medicines Board (CMB) under the Chinese Medicine Council of Hong Kong for the respective Chinese medicines trader licence. The applicants for such licences must fulfil the requirements of the CMO on premises, sanitation, storage, facilities and knowledge and experience of responsible persons, and the requirements as stipulated in other relevant legislation in Hong Kong. Licences will be issued by the CMB upon

payment of the relevant fees by the applicants. The licence for a Chinese medicines trader is valid for two years. A licensed Chinese medicines trader may apply to the CMB for renewal of the licence not less than six months before its expiry. The CMB introduced in April 2003 the licensing of Chinese medicines traders as a regulatory measure. The mandatory licensing of Chinese medicines traders became fully effective on 11 January 2008. As at end of March 2015, the number of holders of the four types of Chinese medicines trader licences is as follows:

- Retailer licence in Chinese herbal medicines – 4 634
- Wholesaler licence in Chinese herbal medicines – 886
- Manufacturer licence in pCms – 279
- Wholesaler licence in pCms – 1 047

Registration system of pCms

4. Proprietary Chinese medicines in Hong Kong are regulated under the CMO. The CMB started to accept applications for pCm registration on 19 December 2003. On the whole, to have its registration application approved, a pCm must meet the registration requirements regarding safety, quality and efficacy prescribed by the CMB. To guarantee the quality and efficacy of pCms, their safe consumption and public health, the CMO requires that starting from 3 December 2010, all products falling within the definition of pCms must be registered before they can be imported, manufactured or sold in Hong Kong.

5. The CMB is responsible for formulating registration requirements and processing registration applications of pCms in Hong Kong. The Department of Health (DH) provides professional and administrative support for the CMB. To ensure the safe use of medicines, applicants for pCm registration should submit four types of information documents, on the general, safety, efficacy, and quality aspects. For registration requirements, please refer to **Annex**.

6. In addition to the requirements stipulated in the CMO, applicants for pCm registration must ensure that their products fulfil the requirements of other legislation, such as the Undesirable Medical Advertisements Ordinance (Cap. 231), the Public Health and Municipal Services Ordinance (Cap. 132) and the Trade Descriptions Ordinance (Cap. 362). Besides, applicants for pCm registration must also ensure that their products comply with the requirements of the Trade Marks Ordinance (Cap. 559).

(II) Development Trend of Proprietary Chinese Medicines

7. The registration system for pCms aims to regulate the manufacture and sale of pCms so as to ensure the quality, safety and efficacy of pCms, their safe consumption and public health. The registration system has gained recognition and support of the trade and the community.

8. Pursuant to section 129 of the CMO, the CMB may issue a certificate for clinical trial and medicinal test for the purpose of facilitating clinical tests conducted by any persons including local universities, hospitals and pCm research and development(R&D) enterprises to test the safety and efficacy of pCms. The CMB has also developed the Good Clinical Practice for Proprietary Chinese Medicines to set out the proper process of clinical tests to guarantee the scientific reliability of test results and safeguard the interests and safety of the subjects.

Implementing Good Manufacturing Practice for pCms

9. At present, the Good Manufacturing Practice (GMP) requirement in respect of pCms in Hong Kong is not mandatory. According to the CMO, a licensed pCm manufacturer may apply to the CMB for a GMP Certificate for Manufacturer (GMP Certificate), which certifies the manufacturer's compliance with good practice in the manufacture and quality control of pCms. There are currently 279 licensed pCm manufacturers in Hong Kong. Most of them are

small and medium enterprises (SMEs) (i.e. with less than 100 employees). To date, 14 local pCm manufacturers have been awarded the GMP Certificate. For information about the introduction of the GMP requirement to pCms and the corresponding support measures provided by the Government, please refer to the paper summited to the Subcommittee on Issues Relating to the Development of Chinese Medicine under the Legislative Council Panel on Health Services by the Government on 25 November 2014 (LC Paper No. CB(2)322/14-15(03)).

Testing and certification of Chinese medicines

10. Hong Kong is a major international trading hub of Chinese medicines. Testing and certification is one of the important measures to ensure product quality. Testing and certification of Chinese medicines can help users differentiate the genuine products, and reduce the chance of their buying of fake, misprocessed (such as bleached), adulterated or contaminated products. For Chinese medicines manufacturers and traders, testing and certification would help enhance customer confidence and satisfaction, and reduce the risk of recall of products which fail to meet legal requirements and subsequent lawsuits. It can also ensure that the medicinal herbs in the prescriptions adopted by Chinese medicine practitioners are genuine and of good quality. In the long run, the development of testing and certification of Chinese medicines can reinforce the position of Hong Kong as a testing and certification hub in this area. In line with the development of Chinese medicine and the testing and certification industry, the Hong Kong Productivity Council, with the support of the Hong Kong Council for Testing and Certification, is tasked with developing and promoting a voluntary Hong Kong Certification Scheme for Chinese Materia Medica. Under the scheme, 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.

The Hong Kong Chinese Materia Medica Standards Project

11. 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 DH launched the Hong Kong Chinese Materia Medica Standards (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.

12. 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. In addition, the formulation of the HKCMMS allows Hong Kong to align with international standards, facilitates trading of Chinese herbal medicines and enhances the quality of the raw materials for manufacturing pCms, thereby creating more business opportunities. The HKCMMS cover the sources, properties and various identification indicators for verifying the authenticity of Chinese herbal medicines. Indicators relating to the safety and quality of Chinese herbal medicines, such as contents of heavy metals, pesticide residues and aflatoxin, which have attracted international concern, are also included.

13. At present, research relating to the HKCMMS is conducted by six local universities (including the University of Hong Kong, the Chinese University of Hong Kong, City University of Hong Kong, Hong Kong University of Science and Technology, Hong Kong Baptist University and the Hong Kong Polytechnic University), the China Medical University of Taiwan and the National Institutes for Food and Drug Control under the China Food and Drug Administration (CFDA). The CFDA and the State Administration of Traditional Chinese Medicine provide advice and support for the project. 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. The future target for the HKCMMS is to develop standards for some 30 Chinese herbal medicines each year and include, on the recommendation of the Chinese Medicine Development Committee, Chinese medicines decoction pieces in the scope of research (see paragraph 22 below).

Application of the HKCMMS

14. The Chinese medicine industry may use the HKCMMS as reference standards. For instance, manufacturers of pCms may use the HKCMMS as the quality reference standards for starting materials. Chinese herbal medicines traders may consult the HKCMMS in setting the quality standards for incoming herbal medicines. The Hospital Authority also refers to the requirements set out in the HKCMMS in purchasing Chinese herbal medicines and carrying out random checks. Tests on Chinese herbal medicines conducted under the Hong Kong Certification Scheme for Chinese Materia Medica mentioned in paragraph 10 above will also be performed on the basis of the HKCMMS.

15. In addition, the Hong Kong Accreditation Service has launched laboratory accreditation services with testing standards based on the HKCMMS. The services include:

(i) identifying the authenticity of Chinese herbal medicines by means of microscopic examination, physiochemical analysis and chromatographic analysis; and
(ii) conducting chemical tests other than those mentioned in (i) but set out in the HKCMMS.

(III) Research and Development of Chinese Medicines

Infrastructure

16. As for infrastructure, the Hong Kong Science Park (Science Park) under Hong Kong Science and Technology Parks Corporation provides enterprises with research infrastructure, including the two biotechnology buildings established in Science Park Phase 2 as well as laboratory facilities for companies in the Park. Phase 3 is under construction as scheduled. Its first three buildings were completed in March 2014 and officially opened in September 2014, while the remaining two buildings will be completed in 2016. Upon completion of Phase 3, it is expected that more space will be available for the R&D of the biotechnology industry (including Chinese medicines and western pharmaceuticals).

Innovation and Technology Fund

17. Managed by the Innovation and Technology Commission, the Innovation and Technology Fund (ITF) has been supporting universities, research institutions and enterprises in their applied R&D since its establishment in 1999. R&D of Chinese medicines is within the scope of the ITF. The key funding programmes under the ITF are as follows:

(1) *Innovation and Technology Support Programme*

This programme supports midstream/downstream R&D projects undertaken mainly by universities, R&D centres, industry support organisations, professional bodies and trade and industry associations. Supported projects are categorised into platform and collaborative projects. Platform projects require 10% contribution from the industry as sponsorship and 90% from the ITF. The intellectual property rights generated from the projects will be owned by the main applicant. For collaborative projects, the ITF will contribute not more than 50% of the funding and the industry at least

50%. The intellectual property rights generated from the projects will be owned by the industry if its contribution is higher than 50%.

(2) University-Industry Collaboration Programme

This programme aims to encourage more private sector R&D through leveraging the knowledge and resources of universities. The emphasis is to enhance collaboration between private companies and universities in Hong Kong. The industry and the ITF will each contribute 50% for the supported projects. All intellectual property rights will be owned by the industry.

(3) General Support Programme

The programme aims to provide funding support for non-R&D projects that contributed to the upgrading and development of our industries as well as fostering an innovation and technology culture in Hong Kong. Projects under the programme may include conferences, exhibitions, seminars, workshops, promotional events, studies and surveys.

(4) Small Entrepreneur Research Assistance Programme

The programme provides funding under the ITF on a matching basis to support small local enterprises in carrying out their own applied R&D projects. The funding is granted on a dollar-for-dollar matching basis. At present, the amount of funding is capped at $6 million per project. The recipient company will own all intellectual property rights generated from the project.

18. Since its establishment, the ITF has supported over 80 Chinese medicine-related projects with a total funding of about $200 million. These projects involve R&D of new Chinese medicines, technologies related to manufacturing, analysis, testing and quality control of Chinese medicines, pre-clinical and

clinical testing of Chinese medicines, as well as research on integrative Chinese and Western medicine. Through these projects, the ITF also assisted in the establishment of many R&D facilities for local universities and research institutions to provide high-standard service and support of high standards to the Chinese medicine industry.

Research and Development Cash Rebate Scheme

19. Besides, the Innovation and Technology Commission also runs the Research and Development Cash Rebate Scheme. The scheme aims to reinforce the research culture among private companies and encourage them to establish stronger partnership with designated local public research institutions. Under the scheme, a company will receive a cash rebate equivalent to 30% of its expenditure on two types of applied R&D projects:

(1) projects supported by the ITF; and

(2) projects funded entirely by the company and conducted in collaboration with designated local public research institutions.

Committee on Research and Development of Chinese Medicines

20. To orchestrate efforts of the Government and the industry, academic and research sectors in promoting the development of R&D and testing of Chinese medicines, the Government set up the Committee on Research and Development of Chinese Medicines in December 2011. Appointed by the Secretary for Commerce and Economic Development and chaired by the Commissioner for Innovation and Technology, the main duties of the committee include: acting as a platform to gauge views from various stakeholders on the R&D of Chinese medicines in Hong Kong; identifying the direction for promoting the R&D of Chinese medicines in Hong Kong, monitoring work progress and recommending improvement measures; and facilitating the sharing of R&D outcome and collaboration among parties concerned to create synergy in the R&D of Chinese medicines.

(VI) Development of the Chinese Medicine Industry

21. The Chief Executive established the Chinese Medicine Development Committee in February 2013 to focus on the study of four major areas, namely personnel training and professional development, the development of Chinese medicine services, scientific research and industry development (including testing of Chinese medicines). Chaired by the Secretary for Food and Health, the committee comprises of representatives of various sectors including Chinese medicine practice, Chinese medicines, academia, scientific research, testing and healthcare services, as well as lay members. The Chinese Medicine Practice Sub-committee and the Chinese Medicines Industry Sub-committee (CMIS) have been set up under the committee to have more focused discussion on various subjects.

22. For the development of Chinese medicines, the CMIS discussed the progress of developing the HKCMMS project. After discussing in detail the development of the HKCMMS and taking into account the results of the studies on decoction pieces carried out by universities and the application of the HKCMMS to certification, the Chinese Medicine Development Committee submitted the recommendations of the CMIS on the further development of the HKCMMS for consideration by the Government. The recommendations are as follows:

- Support the continuation of the HKCMMS project to study and formulate standards for more Chinese herbal medicines; and
- Launch a study on the standard for Chinese medicines decoction pieces under the HKCMMS project. During the course of the study, apart from consulting the International Advisory Board and the Scientific Committee about the scientific research, views of the Chinese medicine industry will also be sought.

23. The Government accepted the recommendations of the CMIS mentioned in paragraph 22 above. The DH will continue with the HKCMMS project. The "Hong Kong Chinese Materia Medica Standards Volume VII" covering the reference standards for about 30 Chinese herbal medicines is expected to be published this year and the research on another 28 Chinese herbal medicines is underway.

24. Moreover, the Government stated in 2013 Policy Address that Hong Kong enjoyed a clear advantage and had good development potential in the testing and certification industry, which had a good foundation based on a robust accreditation system, high professional standards and an excellent reputation. Having examined the current Chinese medicine testing services in Hong Kong, the CMIS agrees that testing services would help ensure the quality of products and strengthen consumer confidence, and that the development of testing standards and related business could also enhance Hong Kong's position as an international Chinese medicine testing and certification hub. After thorough deliberation, the CMIS suggested that the Government should seize the advantage and set up a testing centre for Chinese medicine specialising in the testing of and scientific research on Chinese medicine, with a view to establishing reference standards and testing methods and promoting them as authoritative international benchmarks. This will enhance the testing standards in Hong Kong, thereby improving the quality of Chinese medicines and paving the way for the internationalisation of the Chinese medicine industry. The CMIS also recognises that the role of the Government should be to formulate policies, set directions and provide appropriate legislative framework. Hence the testing centre should be responsible for establishing rigorous reference standards and testing methods for Chinese medicines while the testing services should be provided by the practitioners/organisations in the industry to facilitate the development of the testing industry in Hong Kong. The Chinese Medicine Development Committee has accepted the recommendations of the CMIS and submitted them to the Government for consideration.

25. In the 2015 Policy Address, the Government announced that it has accepted the recommendation of the Chinese Medicine Development Committee to set up a testing centre for Chinese medicines to be managed by the DH. The testing centre will specialise in the testing of and scientific research on Chinese medicines, with a view to setting reference standards for the safety, quality and testing methods of Chinese medicines. Apart from continuing to study and formulate more HKCMMS, the testing centre will also embark on relevant hi-tech research to strengthen the capability for the quality control and identification of Chinese medicines. A herbarium on Chinese medicines of international standard will be set up. Through various platforms and close collaboration with the relevant international and Mainland organisations, the testing centre will help promote the HKCMMS and the reference standards for testing Chinese medicines as authoritative international benchmarks to pave the way for the internationalisation of Hong Kong's Chinese medicine industry. The DH has started the preparatory work for setting up the testing centre.

(V) Registration system of pCms in Mainland China

26. Hong Kong and the Mainland run two independent systems on the registration of pCms. A brief account of the pCm registration system in the Mainland and a comparison with the Hong Kong system are provided in our submission of 15 December 2014 to the Subcommittee on Issues Relating to the Development of Chinese Medicine under the Legislative Council Panel on Health Services (LC Paper No. CB(2)453/14-15(02)).

Food and Health Bureau

Department of Health

Innovation and Technology Commission

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Annex

Registration System of Proprietary Chinese Medicine in Hong Kong

Item	Description
Ordinance	Chinese Medicine Ordinance (Cap. 549)
Conditions of registration	The registration requirements specified by the Chinese Medicines Board (CMB) in respect of the safety, quality and efficacy of the proprietary Chinese medicines (pCms) concerned must be met.
Classification category	Proprietary Chinese medicines can be classified into the following categories: (i) Established medicines (ii) Non-established medicines (including health-preserving medicines) (iii) New medicines (such as pCms containing newly discovered Chinese herb or new medicinal part of a Chinese herb, preparation of a new Chinese medicine prescription, and pCms with altered route of administration.）
Requirements for manufacturer	The manufacturer must hold a valid manufacturer licence.
Requirements for testing organisation	The testing reports must be issued by laboratories that meet the requirements of the CMB, such as laboratories fulfilling the requirements set by the International Organisation for Standardisation (ISO) (i.e. ISO 17025), the Good Laboratories Practice (GLP), the Good Clinical Practice for Proprietary Chinese Medicines (GCP), or municipal Institutes for Drug Control／clinical trial centres in the Mainland that are recognised by both the China Food and Drug Administration and the CMB.

Assessment and approval procedures	The CMB is responsible for the assessment and approval of the applications for registration of pCms.
Registration requirements: General documents	
Details of applicant	• Personal information of the person-in-charge of the applicant company
Details of manufacturer	• Certified copy of manufacturing authorisation issued by the country of origin (if applicable)
Sale documentation	• Certified copy of sale documentation issued by the country of origin (if applicable) • Copy of documentary proof of manufacture or sales history of the product in Hong Kong (if applicable)
Product information	• Label • Package insert • Prototype sales pack • Product sample • Master formula provided by the manufacturer
Registration requirements: Product safety documents	
	• Heavy metal and toxic element test report • Pesticide residue test report • Microbial limit test report • Acute toxicity test report • Long-term toxicity test report • Local toxicity test report (for external preparation) • Mutagenicity test report • Carcinogenicity test report • Reproductive and development toxicity test report • Summary report on product safety documents

Registration requirements: Information on efficacy	
	• Interpretation and principle of formulating the prescription • Reference materials on product efficacy • Principal pharmacodynamic study report • General pharmacological study report • Clinical trial protocol and summary report • Summary report on product efficacy documents
Registration requirements: Information on quality	
	• Manufacturing method provided by the manufacturer • Product specifications set by the manufacturer or laboratory • Method of analysis of the specifications • Certificate of analysis of the specifications • Stability test report • Physiochemical properties of crude drugs