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For information

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

Policy and direction of supporting development of proprietary Chinese medicines ("pCms")

Purpose

The use of traditional medicine is increasingly popular. Committed to the development of Chinese medicine, the Government attaches much importance to the quality and safety of Chinese medicines in particular. This paper introduces the policy and direction of supporting the development of the proprietary Chinese medicines ("pCms").

Background

2. In order to ensure the quality, safety and efficacy of the pCms and their safe consumption by members of the public, as well as to safeguard public health, the Chinese Medicine Ordinance (Cap. 549) ("CMO") provides for regulation of, among others, the manufacture and sale of pCms with a view to giving confidence to the general public that the pCms registered under the CMO are safe for consumption.

3. Any person who engages in manufacturing of pCms and wholesaling of pCms is required to apply to the Chinese Medicines Board ("CMB") under the Chinese Medicine Council of Hong Kong established in accordance with the CMO 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 the responsible persons, as well as 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 has

implemented since April 2003 the regulatory measures for the licensing of Chinese medicines traders. The mandatory licensing of Chinese medicines traders became fully effective on 11 January 2008.

4. To implement the regulation of pCms under the CMO, the CMB started to accept applications for pCm registration on 19 December 2003. In order to be registered, a pCm must meet the registration requirements regarding safety, quality and efficacy prescribed by the CMB. To guarantee the quality and efficacy of pCms as well as their safe consumption by the members of the public and to safeguard public health, the CMO requires that starting from 3 December 2010, all products falling within the definition of pCms under the CMO 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 documents containing the general information as well as information on the safety, efficacy, and quality of the pCms concerned.

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).

Policies of Supporting the Development of pCms

Formal registration of pCms

7. For the measures to facilite the formal registration of pCms, 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 ("the Subcommittee") by the Government on 25 November 2014 (LC Paper No. CB(2)322/14-15(01)).

Good Manufacturing Practice ("GMP") for pCms

8. At present, the GMP requirement in respect of pCms in Hong Kong is not mandatory. The Government is still in the process of consulting various stakeholders of the pCm sector on how to implementation of GMP, and there is still no timetable for implementing the GMP. According to the CMO, a licensed pCm manufacturer may apply to the CMB for a Certificate for Manufacturer ("GMP Certificate"), which certifies the manufacturer's compliance with good practices in the manufacture and quality control of pCms. There are currently 278 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 in respect of pCms, please refer to the paper summited to the Subcommittee by the Government on 25 November 2014 (LC Paper No. CB(2)322/14-15(03)).

The Hong Kong Chinese Materia Medica Standards ("HKCMMS")

9. 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 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. 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 covers 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.

10. 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 236 Chinese herbal medicines commonly used in Hong Kong has been completed, and seven editions of HKCMMS have been published.

11. 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.

Funds and training for technologies

12. Currently, the trade could apply for various funding programmes under the Innovation and Technology Fund ("ITF") as well as the SME Funding Schemes under the Trade and Industry Department to cater the diversified business needs of enterprises. The ITF has supported over 80 Chinese medicine-related projects with a total funding of about $200 million since its establishment. These projects involve research and development ("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 medicines. 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. For details of the various funding schemes, please refer to the paper summited to the Subcommittee by the Government on 15 December 2014 (Annex IV of LC Paper No. CB(2)453/14-15(02)).

13. Besides, in response to the concerns of the trade and to assist manufacturers in adopting GMP to the production of pCm, the DH has invited relevant experts [including the representatives from the Hong Kong Institute of Biotechnology Limited ("HKIB"), Hong Kong Productivity Council, SGS Hong Kong Limited and International Society

for Pharmaceutical Engineering] and collaborate with the relevant government agencies [including the Hong Kong Science & Technology Parks Corporation ("HKSTPC") and the Innovation and Technology Commission and Employees Retraining Board] to brief the Chinese medicines traders on the requirements of hardware and software for GMP, training and consultancy service in relation to GMP and support measures provided by the Government. Licensed pCm manufacturers who have been awarded the GMP Certificate would also be invited to share their experiences in the implementation of GMP. Meanwhile, the DH also provides information on GMP for all licensed Chinese medicines traders through the Chinese Medicines Traders Newsletter. All relevant information is made available online (www.cmd.gov.hk) for traders' reference. Besides, the DH would meet with pCm manufacturers who are interested in the implementation of GMP and already have preliminary designs of their premises, and explain to them current GMP guidelines as well as discuss with them on various issues including the premises setup, facilities and manpower, in order to assist them to implement GMP.

Directions of Supporting the Development of pCms

14. The Chief Executive set up the Chinese Medicine Development Committee ("CMDC") in February 2013 to focus on the study of four major areas of Chinese medicine, namely personnel training and professional development, development of Chinese medicine services, research and development, as well as development of the Chinese medicines industry (including the testing of Chinese medicines). Chaired by the Secretary for Food and Health, the committee comprises 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 ("CMISC") were formed under the CMDC to focus deliberation on respective areas.

Testing and certification

15. Having examined the current Chinese medicine testing services in Hong Kong, the CMISC under the CMDC agreed that Chinese medicines testing would help ensure the quality and safety of pCm products. After thorough deliberation, the CMISC suggested that the

Government should seize the advantage of Hong Kong in Chinese medicines testing and set up a testing centre for Chinese medicines specialising in the scientific research on the testing of Chinese medicines, with a view to establishing reference standards and testing methods for Chinese medicines and promoting them as authoritative international benchmarks. This would enhance the testing competence in Hong Kong, thereby improving the quality of Chinese medicines and paving the way for internationalisation of the Chinese medicines industry. The CMISC also considered that the role of the Government should be to formulate policies, set directions and provide appropriate legal framework. Hence the testing centre for Chinese medicines 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 of the industry. The recommendations of the CMISC were accepted by the CMDC and submitted to the Government for consideration.

16. In the 2015 Policy Address, the Government announced that it has accepted the recommendation of the CMDC to set up a testing centre for Chinese medicines to be managed by the DH. The testing centre for Chinese medicines will specialise in the scientific research on the testing of 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 for Chinese medicines 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 for Chinese medicines 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 medicines industry. The DH has started the preparatory work for setting up the testing centre for Chinese medicines.

17. Separately, manufacturers and traders of Chinese medicines can make use of the testing services provided by Hong Kong's testing and certification bodies to show whether a product is genuine and safe. Testing service can thus help enhancing the confidence in using Chinese medicines products among customers (including Chinese medicine practitioners), and reducing the chance of recalls and lawsuits due to failure of meeting the concerned regulatory requirements. On

certification, stringent product certification requirements may help the improvement of product quality. The Hong Kong Certification Scheme for Chinese Materia Medica ("the Certification Scheme") is a voluntary certification scheme that the Hong Kong Productivity Council developed by making reference to the relevant ISO standard[1]. Businesses in Hong Kong which are engaging in the Chinese medicines trade can apply for certification of their Chinese medicines products from a third party, i.e. accredited private certification body. For a Chinese herbal medicine to be certified and the certification mark be labelled on the package, the applicant must comply with the management requirements specified by the Certification Scheme, and pass the tests as set out in the HKCMMS. In case the herbal medicine is not covered by the HKCMMS, it should be tested against standards of the Chinese Pharmacopeia.

R&D

18. For the development of Chinese medicines, the CMISC discussed the progress of 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 CMDC submitted the following recommendations of the CMISC on the further development of the HKCMMS for Government's consideration:

(a) Support the continued implementation of the HKCMMS project to study and formulate standards for more Chinese herbal medicines; and
(b) Launch studies 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 medicines industry should also be sought.

19. The Government accepted the recommendations of the CMISC mentioned in paragraph 18 above. In future, the HKCMMS will be targeted at developing standards for about 30 Chinese herbal medicines each year and will include, as recommended by the CMDC, the study of Chinese medicines decoction pieces.

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[1] ISO/IEC 17607 Conformity assessment – Fundamentals of product certification and guidelines for product certification schemes.

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 Innovation and Technology 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.

Infrastructure

21. The Hong Kong Science Park ("Science Park") under HKSTPC provides enterprises with research infrastructure, including the two biotechnology buildings in Science Park Phase 2 as well as laboratory facilities for companies in the Park. Construction of Phase 3 is progressing on schedule. 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).

22. To cope with the longer-term development of the innovation and technology industries, the Government and the HKSTPC reviewed the effectiveness and long-term development direction of the Science Park and industrial estates last year. In accordance with the recommendations of the review, the Government has revised the industrial estate policy to enhance the value chain of the innovation and technology industries in Hong Kong and further revitalise the industrial estates.

23. To better support the trade in implementing GMP, the ITF and the Hong Kong Jockey Club Charities Trust have jointly supported HKIB in August 2015 to conduct a three-year project, under which the existing GMP consultancy services and contract manufacturing facilities of HKIB will be expanded. Upon completion of the project, HKIB's existing pCm GMP production area will be expanded from 2,880ft^2 to 8,500ft^2; and production lines for 2 new types of pCm solid dose forms (i.e. pills

and granules; the existing two are capsules and powder) will be established, which will enable HKIB to provide GMP contract manufacturing services for the 4 most common types of pCm solid dose forms in Hong Kong. The project will also provide internship opportunities for Chinese medicines workers and students (such as students studying relevant professional programmes at the Vocational Training Council) so as to equip them with the necessary skills and practical experience which will be conducive to supporting the upgrading and development of local Chinese medicines industry.

Advice Sought

24. Members are invited to note the content of the paper.

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