For Information

On 19 March 2013

Legislative Council Panel on Commerce and Industry

Good Manufacturing Practice System for Proprietary Chinese Medicine in Hong Kong

Purpose

This paper briefs Members on the background information on and the progress of the implementation of Good Manufacturing Practice for proprietary Chinese medicines in Hong Kong.

Background

2. In accordance with the Chinese Medicine Ordinance (Cap 549), proprietary Chinese medicine (pCm) manufacturers must apply for licences issued by the Chinese Medicines Board (CMB) under the Chinese Medicine Council of Hong Kong. There are at present 295 pCm manufacturers in Hong Kong. Most of them are small and medium enterprises*.

3. At present, the Good Manufacturing Practice (GMP) requirement in respect of pCm in Hong Kong is not mandatory. However, manufacturers holding a pCm manufacturer licence may apply to CMB for a Certificate for Manufacturer, certifying that they follow the requirements of good practices in manufacture and quality control of pCm. CMB issued the "Hong Kong GMP Guidelines for Proprietary Chinese Medicines" in 2003 with reference to the relevant GMP guidelines published by the World Health Organization and the Pharmacy

---

* i.e. with less than 100 employees

and Poisons Board of Hong Kong. Up to the present, 11 local pCm manufacturers have been awarded with GMP Certificates.

4. To ensure the safety of pCm and enhance its quality, and to keep up with international trends of developing GMP for medicines, it was announced in the 2010-11 Policy Address that the Government would actively engage the industry to work out a timetable for mandatory compliance with the GMP for the manufacture of proprietary Chinese medicines.

Progress

5. Having taken reference of the development of GMP in other countries and regions, CMB recommended in May 2011 adoption of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP standard as a licensing requirement for local pCm manufacturers. Since May 2011, CMB has been in wide consultation with the Chinese medicines trade to gather the views of the trade through various channels on the timetable and specific arrangements, including the conduct of a series of briefings through the Department of Health (DH) and attending meetings with Chinese medicine associations and various pCm manufacturers. Local and Mainland experts have also been invited to brief the Chinese medicines traders on the GMP requirements, training and consultancy services and share their experiences in the implementation of GMP. DH has provided information on the proposed GMP implementation plan to all licensed Chinese medicines traders through the Chinese Medicines Traders Newsletter. All relevant information is available online for reference and comment by the trade. To assist pCm manufacturers in the implementation of GMP, DH will meet with manufacturers who are interested in the implementation of GMP and already have preliminary designs of their factory premises, and explain to them the requirements of the current GMP guidelines.

6. On the other hand, the Government is now proactively examining the development needs of the Chinese medicine sector, so that traditional Chinese medicine, as widely recognised by the general public, can play a more active role in promoting the health of the general public. The Chief Executive announced in the 2013 Policy Address the setting up of the Chinese Medicine Development Committee. The Committee will focus its study on policies and measures in four key areas, including personnel training and professional development, Chinese medicine services, research and development, and promotion of the Chinese medicine industry.

7. On the development of Chinese medicine industry, the Committee will examine the problems currently encountered by the trade in the implementation of GMP, and consider the complementary measures (such as provision of a one-stop technical support) that can be put in place by the Government to provide the necessary support. The Committee will also explore measures to enhance the training for people engaged in the manufacture of Chinese medicines in order to raise the quality standards for manufacture of Chinese medicines in Hong Kong. To promote the trading and management and the scientific research of Chinese medicines as well as putting in place the requirements for the manufacture of Chinese medicines, the Committee will study ways to encourage Chinese medicine graduates to participate in related work and examine their needs for on-the-job training. Besides, the Committee will also study means to enhance the training for Chinese medicine dispensers, and examine the feasibility of setting up a registration system for Chinese medicine pharmacists.

8. The Legislative Council Panel on Health Services will discuss the development of Chinese medicine in Hong Kong at its meeting on 18 March. The paper on this subject to be tabled by us is at Appendix for members' reference.

Advice Sought

9. Members are invited to note the content of this paper.

Food and Health Bureau

March 2013

Appendix

For Information

On 18 March 2013

Legislative Council Panel on Health Services

Development of Chinese Medicine in Hong Kong

Purpose

This paper seeks to brief Members on the work of the Government for development of Chinese medicine in Hong Kong.

Background

2. The Government has been adopting an approach based on the concept of "evidence-based medicine" to facilitate the development of the Chinese medicine industry in Hong Kong. Since the enactment of the Chinese Medicine Ordinance in 1999, we have strived to establish and improve the regulatory regime for Chinese medicine to safeguard health of the general public and consumers' rights while strengthening consumers' confidence in Chinese medical services and Chinese medicines, in order to accord a professional status for Chinese Medicine Practitioners and ensure the safety, quality and efficacy of Chinese medicines.

3. With a well-established regulatory regime for Chinese medicines, the Government is now proactively examining the future development needs of the Chinese medicine sector, so that traditional Chinese medicine, which has been widely recognised by the public, can play a more active role in promoting the health of the general public. The Chinese medicine sector also has high expectation on its development.

4. In this regard, the Chief Executive proposed in his Manifesto to set up a Chinese Medicine Development Committee (the Committee). The Committee with representatives from the Chinese medicine sector will study the policies and measures to further the development of the Chinese medicines, and to make recommendations to the Government. In August 2012, the Government set up the Preparatory Task Force on the Chinese Medicine Development Committee. The Preparatory Task Force held meetings in August and December 2012 to discuss and put forth recommendations on the terms of reference, composition, structure and directions of the Committee. The Chief Executive accepted the recommendations of the Preparatory Task Force and announced in January 2013 in the Policy Address the establishment of the Committee.

Chinese Medicine Development Committee

5. The Committee is chaired by the Secretary for Food and Health and comprises members from the Chinese medicine practitioners, the Chinese medicine trade, academia,

research institutes, healthcare sectors and lay persons. The composition of the Committee is at **Annex 1** and its terms of reference are at **Annex 2**.

6. At its first meeting held on 4 March 2013, on the basis of the recommendations put forth by the Preparatory Task Force, the Committee discussed the directions and objectives for development of Chinese medicine in Hong Kong, and agreed to focus on the four key areas elaborated below for further deliberation and study.

Personnel Training and Professional Development

7. To ensure that academic curriculum and personnel training could support the professional development of the Chinese medicine industry, the Committee will review relevant programmes currently provided by Schools of Chinese Medicine, and explore ways to allow Chinese medicine students/graduates to have more opportunities for internship and clinical practice.

8. To promote the testing and certification, trading and management and the scientific research of Chinese medicines as well as putting in place the requirements for manufacture of Chinese medicines, the Committee will explore ways to encourage Chinese medicine graduates to participate in related work and examine their needs for on-the-job training. The Committee will also enhance the training for Chinese medicine dispensers and study the feasibility of setting up a registration system for Chinese medicine pharmacists.

9. On promoting the development of medical specialisation of Chinese medicine practitioners, the Committee considers that it is advisable to first identify suitable pilot specialties and formulate the implementation details, including whether it is necessary to make amendments to existing legislation, qualification framework, and academic curriculum.

Chinese Medicine Service

10. The Committee will study the establishment of Chinese medicine hospitals and measures to facilitate development of Chinese medicine in-patient services. In particular, the Committee considers that priority should be given to the drawing up of pre-requisites for the development of Chinese medicine hospitals in Hong Kong, including the positioning of Chinese medicine hospitals in the healthcare system in Hong Kong, the operation mode and service scope of Chinese medicine hospitals under the legal and administrative framework governing hospitals and medical facilities in Hong Kong etc.

11. To enhance the collaboration between Chinese medicine practitioners and medical doctors, the Committee will work with the Hospital Authority, related healthcare service and research organisations to consolidate their experience and to identify priority and focused service areas to be the pilot areas for provision of Chinese medicine service as well as integrated Chinese and Western medical service within the public healthcare system.

Research and Development (R&D)

12. The Committee will review the existing situation regarding basic and clinical research in Chinese medicine in order to explore ways to enhance the relevant research and promote the development of evidence-based Chinese medicine. In collaboration with the Committee on Research and Development of Chinese Medicines, the Committee will map out priority areas for research and development of Chinese medicines/clinical research and identify projects for focused clinical research targeted at prevalent diseases in Hong Kong that Chinese medicine practitioners may provide more effective and better treatment.

Development of Chinese Medicine Industry

13. In order to enhance the quality standards for manufacture of Chinese medicines and clinical trials, the Committee will review the needs of both the Chinese medicines market and the Chinese medicines traders and examine how to provide support to the trade. For instance, consideration can be given to putting in place complementary measures by the Government to address problems encountered by the trade in the implementation of "Good Manufacturing Practices (GMP)". The Committee will also explore measures to enhance training for people engaged in the manufacture of Chinese medicines and facilitate the adoption and implementation of Good Clinical Practice (GCP) by Chinese medicine scientific research institutions.

14. Under the promotion and leadership of the Department of Health, the Government launched a research programme on the Hong Kong Chinese Materia Medica Standards (HKCMMS) in 2002 to establish standards recognised by internationally renowned experts and to align the standards with international requirements. As at January 2013, this programme has established safety and quality standards for around 200 Chinese herbal medicines. To expedite the internationalisation of Chinese medicines, the HKCMMS programme will be expanded to cover more Chinese herbal medicines commonly used in Hong Kong and proprietary Chinese medicines, and to enhance the recognition of these standards in the Mainland and internationally. The Committee will also explore measures to promote Hong Kong as a centre for testing and certification of Chinese medicines.

15. To focus the study on the above specific areas of concern, the Committee endorsed at its meeting the formation of the Chinese Medicine Practice Sub-committee and the Chinese Medicines Industry Sub-committee. The terms of reference of these sub-committees are set out in **Annex 3**.

Advice Sought

16. Members are invited to note the content of this paper.

Food and Health Bureau

March 2013

Annex 1

Membership of
Chinese Medicine Development Committee

Chairman:	Secretary for Food and Health
Ex-officio Members:	Permanent Secretary for Food and Health (Health) Commissioner for Innovation and Technology (or representative) Director of Health (or representative) Chief Executive of the Hospital Authority (or representative)
Non-official Members:	Professor Andrew Chan Chi-fai Mr Abraham Chan Yu-ling Mr Paul Fan Chor-ho Ms Feng Jiu Mr Hui Sang Professor Kwan Hoi-shan Professor Albert Leung Wing-nang Mr Tommy Li Ying-sang Professor Lu Ai-ping Mr Luk Shun-hoi Ms Teresa Ngan Man-shan Dr Stewart Tung Yuk Mr Wong Kit Dr Andrew Yip Wai-chun Dr Edwin Yu Chau-leung Professor Zhao Zhong-zhen

Annex 2

Chinese Medicine Development Committee
Terms of Reference

- Examine the current landscape and the needs of the Chinese medicine sector in the areas of personnel training and professional development, services, scientific research and the industry development, etc;

- Explore the future development directions and goals of the above areas;

- Set priorities for the development goals of the above areas;

- Recommend feasible strategies and measures for projects for priority development; and

- Monitor the implementation of relevant measures.

Annex 3

Terms of Reference of Sub-committees under the Chinese Medicine Development Committee

The Chinese Medicine Practice Sub-committee

- study the needs for professional development of Chinese medicine practitioners and explore means for the development of Chinese medicine practice specialties, in collaboration with the Chinese Medicine Practitioners Board of the Hong Kong Chinese Medicine Council and the Steering Committee on Strategic Review on Healthcare Manpower Planning and Professional Development;

- explore means to facilitate the collaboration of Chinese medicine practitioners and medical doctors in the provision of clinical services to patients;

- explore means to expand the role of Chinese medicine in the public healthcare system; and

- study the feasibility of establishing a Chinese medicine hospital.

Chinese Medicines Industry Sub-committee

- explore means to safeguard and enhance the quality of Chinese medicines in Hong Kong in collaboration with the Chinese Medicines Board of the Hong Kong Chinese Medicine Council, including ways to facilitate the implementation of requirements such as the Good Manufacturing Practice and Good Clinical Practice requirements;

- set the priority areas of and facilitate researches on Chinese medicines in collaboration with the Committee on Research and Development of Chinese Medicines;

- explore means to promote Hong Kong as a centre for testing and certification of Chinese medicines; and

- promote the status of and explore business opportunities for Chinese medicines industry in Hong Kong.