

## **Legislative Council Panel on Health Services**

### **Progress on the Registration of Chinese Medicine Practitioners, Regulation of Proprietary Chinese Medicines and Provision of Chinese Medicine Service in the Public Sector in Hong Kong**

#### **Introduction**

This paper briefs Members on the latest developments in the registration of Chinese medicine practitioners (CMPs), regulation of proprietary Chinese medicines (PCM), and provision of Chinese medicine service in the public sector in Hong Kong.

#### **Registration of CMPs**

2. The Chinese Medicine Practitioners Board (PB) promulgated the names of listed CMPs in December 2001, and completed vetting of the experience and academic qualifications of these listed CMPs by August 2002. Among them, 2 543 applicants were eligible to apply for direct registration, while the rest were required to sit for the Registration Assessment Examination or the Licensing Examination. The Chinese Medicine Council (CMC) promulgated the list of the first batch of 2 384 registered CMPs in the Gazette in November 2002. At present, there are about 3 300 listed CMPs, about 4 700 registered CMPs (including some 1 700 and 450 who were registered after passing the Registration Assessment and the Licensing Examination respectively), and 50 CMPs with limited registration.

#### *CMP Registration Assessment and Licensing Examination*

3. Under the transitional arrangement, two groups of listed CMPs are required to pass the Registration Assessment before they are qualified to apply for registration:-

- (i) those who have been practising Chinese medicine in Hong Kong for less than 15 years but not less than 10 years and have not obtained academic qualifications acceptable to the PB, or

- (ii) those who have less than 10 years' practising experience and have obtained academic qualifications acceptable to the PB.

The CMP Registration Assessment was held in January and February 2003, and was attended by more than 2 200 listed CMPs with an overall passing rate of about 83%. The PB has arranged another registration assessment in October for those who had not attended the registration assessment in January and February. A total of 37 candidates attended the assessment, of whom 15 passed the assessment.

4. Listed CMPs who failed the Registration Assessment or those who have less than 10 years' practising experience and do not possess academic qualification acceptable to the PB are required to undertake the Licensing Examination. The CMP Licensing Examination comprises two parts, including a written examination in Part I and a clinical examination in Part II.

5. The first CMP Licensing Examination Part I Written Examination was held in August 2003. Eligible candidates for the examination include:-

- (i) listed CMPs who are required to take the Licensing Examination under the transitional arrangements for CMPs; and
- (ii) holders of an undergraduate degree in Chinese medicine or equivalent recognised by the PB.

More than 1 400 candidates attended the written examination held on 15 and 18 August 2003, including 1 319 listed and 89 non-listed CMPs, with an overall passing rate of about 47%. Those who have passed the Part I Written Examination are eligible to sit for the Part II Clinical Examination. The Part II Clinical Examination was held in September to October 2003. 650 candidates attended the clinical examination and the passing rate is 82%.

#### *Disciplinary Mechanism for CMPs*

6. In order to raise the professional standard of CMPs, the CMC and PB introduced a code of practice for registered CMPs and listed CMPs.

Upon receipt of complaints against CMPs, the Disciplinary Committee of Chinese Medicine Practitioners will take follow-up action as stipulated in the Chinese Medicine Ordinance and the Code of Practice for CMPs. Last year, the Disciplinary Committee handled over 120 cases of complaints against CMPs. The majority of these cases were about advertising and canvassing. In the same year, 97 advisory letters were issued and eight cases were dismissed. During January to June 2003, the PB has received about 150 complaints against CMPs. 34 advisory letters were issued and 25 cases were dismissed during the period.

#### *Professional Guide on Issuing Sick Leave Certificate*

7. In early 2003, the PB, in consultation with local Chinese medicine practitioners associations, drafted a professional guide on issuing sick leave certificates for reference of registered CMPs. This is intended to assist CMPs in the issue of sick leave certificates in anticipation of the recognition of Chinese medicine under the labour legislation in future. In mid 2003, the draft guide was issued to over 40 local Chinese medicine associations for comment. The guide is being finalized and will be issued to all registered CMPs when ready.

#### **Registration of PCM**

8. The subsidiary legislation for regulation of Chinese medicines (including the Chinese Medicines Regulation, the Chinese Medicines Traders (Regulatory) Regulation, and the Chinese Medicine (Fees) Regulation) were passed and commenced in January and April 2003 respectively. The regulatory measures for licensing of Chinese medicines traders and registration of PCM will be implemented in phases.

#### *Licensing of Chinese medicines traders*

9. The licensing system for Chinese medicines traders has been implemented since May 2003. Four kinds of Chinese medicines traders including retailers and wholesalers of Chinese herbal medicines, and wholesalers and manufacturers of PCM, need to apply for a licence from the Chinese Medicines Board (CMB) under the CMC before they can engage in the respective trade. As at mid October, the Board received more than 6 800 applications, which are now being processed.

10. The Chinese Medicine Ordinance (the Ordinance) provides for a transitional arrangement for Chinese medicines traders who were in the business on 3 January 2000. Where an application is made during the period specified by the CMB (from 5 May to 15 July 2003), the trader or manufacturer will be deemed to be licensed until the application is accepted/refused, or such date as is appointed by the Secretary for Health, Welfare and Food, whichever is earlier.

*Registration System for PCM*

11. To safeguard public health, the Ordinance stipulates that all PCM manufactured, or sold, in Hong Kong must be registered. We propose that the system for registration of PCM be commenced on 19 December 2003, so that the CMB can invite applications for PCM registration. The commencement notices of the relevant provisions of the Chinese Medicine Ordinance, the Chinese Medicines Regulation and the Chinese Medicine (Fees) Regulation were published in the Gazette on 24 October 2003 and are being examined by a subcommittee set up for this purpose. When the relevant offence provisions are brought into effect at a later date to be decided, any unregistered PCM shall not be allowed to be manufactured, sold or possessed in Hong Kong.

12. Like the licensing system for Chinese medicines traders, the Ordinance also provides for a transitional arrangement for the registration of PCM which were manufactured, or sold, in Hong Kong on 1 March 1999. The PCM will be eligible for transitional registration if the concerned Chinese medicines trader submits an application during the application period for transitional registration.

*Registration Requirements for PCM*

13. It is stipulated in the Ordinance that, in assessing an application for PCM registration, the CMB shall take into consideration the safety, quality and efficacy of the PCM. Having extensively consulted the Chinese medicines traders, the CMB has formulated the registration requirements for PCM. The basic registration requirements include limits on heavy metal and toxic elements, limits of pesticide residues and microbes, non-adulteration with western medicine, and compliance with the requirements of Animals and Plants (Protection of Endangered Species) Ordinance, etc.

*Chinese Medicines Traders Practising Guidelines and Hong Kong Good Manufacturing Practice Guidelines for PCM*

14. To raise the standards of practice of Chinese medicines traders, the CMB has, after extensive consultations with the trade and making reference to international and regional experiences, developed practising guidelines for four kinds of Chinese medicines traders – “Practising Guidelines for Retailers of Chinese Herbal Medicines”, “Practising Guidelines for Wholesalers of Chinese Herbal Medicines”, “Practising Guidelines for Manufacturers of Proprietary Chinese Medicines” and “Practising Guidelines for Wholesalers of Proprietary Chinese Medicines”. The CMB has also developed the “Hong Kong Good Manufacturing Practice Guidelines for Proprietary Chinese Medicines” to ensure the quality of PCM production in Hong Kong. If a PCM manufacturer satisfies CMB that he has complied with the requirements of the Guidelines, he may apply for a “Certificate for Manufacturer (Good Manufacturing Practice in respect of Proprietary Chinese Medicines)”.

*Implementation of the System for Regulation of Chinese Medicines Traders*

15. The Regulatory Committee of Chinese Medicines Traders has been established under the CMB. It is responsible for investigation of complaints against licensed Chinese medicines traders, and making recommendation to CMB on the appropriate courses of disciplinary action.

**Provision of Chinese Medicine Service in the Public Sector**

16. On 10 February 2003, this Panel discussed the implementation plan on the introduction of Chinese Medicine (CM) outpatient clinics attached to selected public hospitals or health centres. The setting up of the CM clinics will be based on a tripartite model of service delivery in which the Hospital Authority (HA) will collaborate with non-governmental organisations (NGOs) and universities to provide a research-oriented and evidence-based CM service.

17. The first phase of the CM service provision will involve the establishment of three CM clinics in 2003. Each of these clinics will be attached to a HA hospital, namely Tung Wah Hospital (TWH), Yan Chai Hospital (YCH) and Alice Ho Miu Ling Nethersole Hospital (AHNH). The CM clinic at TWH which was established by initiative of the Tung Wah Group of Hospitals was already in operation and had joined the HA

on 1 December 2003 as the first CM clinic in the public sector. Commissioning work, including renovation work, of the CM clinics at YCH and AHNH is progressing as planned and the two clinics will commence operation in late December 2003.

18. As set out in the Panel paper for the February 2003 meeting, patients will be charged a fee of \$120 per attendance which includes consultation and two prescriptions.

19. To promote development of research-based CM service, research protocols are being drawn up with the input from clinicians of relevant hospitals where the CM clinics are located, as well as respective universities which are collaborating with the CM clinics. These research projects are proposed with reference to the prevailing diseases specific to the demographic profile of the population and for which treatment by CM is considered to be beneficial.

20. A Toxicology Reference Laboratory has been set up in Princess Margaret Hospital to analyse clinical specimen for toxicity of CM and to build up a database to support the overall development of an evidence-based CM service.

## **Discussion**

21. Members are invited to note the progress reported in this paper.

Health, Welfare and Food Bureau  
December 2003