

**Bills Committee
Chinese Medicine Bill**

**The regulatory systems for traditional medicine in some
places outside Hong Kong**

Purpose

This paper informs Members about the regulatory systems for traditional medicine adopted in various places, including the Mainland, Taiwan, Korea, Malaysia, Singapore and State of Victoria of Australia.

Background

2. At the Bills Committee meeting held on 4 March 1999 for examination of the Chinese Medicine Bill, Members requested the Administration to provide more information regarding the regulatory frameworks for traditional medicine.

Regulatory systems

3. The regulatory systems for regulating the practice, use and trading of Chinese medicine in the Mainland and Taiwan are the most developed among the places listed in para. 1.

4. In the Mainland, the State Administration of Traditional Chinese Medicine (SATCM) and the State Drug Agency (SDA) are the regulatory bodies for Chinese medicine. Chinese medicines manufacturers and traders are required to obtain licences in order to conduct business. Proprietary Chinese medicines have to be registered. It is planned that a licensing system for Chinese medicine practitioners will commence in mid 1999.

5. In Taiwan, the Committee on Chinese Medicine and Pharmacy, an administrative body under the Department of Health of the Executive Yuan, is the regulatory body for Chinese medicine.

6. The Korean Treatment Act provides a framework for the registration of “medical persons” which include doctors and herb doctors.

7. The regulatory system for Chinese medicine in Singapore is being developed. The Ministry of Health set up a traditional Chinese medicine unit in November 1995 to oversee and co-ordinate implementation of recommendations made by a committee for review of the practice of traditional Chinese medicine. It is adopting a phased approach to regulation. Statutory regulation of acupuncturists will be in place by the year 2000. The statutory regulation of Chinese medicine practitioners is expected to be underway several years after.

8. In Malaysia, there are various types of traditional medicine practices based on the ethnic origin, namely the traditional Malay medicine, the traditional Chinese medicine and the traditional Indian medicine. The Ministry of Health of Malaysia has formed a Steering Committee on Traditional Medicine comprising members from research institutions, government agencies, universities, and professional bodies. The main objectives are to advise the Ministry on policies and strategies, on the role, position and utilization of traditional medicine in the country. Sub-committees have been formed to advise on products, practitioners and training.

9. In Australia, the State of Victoria is considering different options for regulating Chinese medicine. A review on regulating Chinese medicine is being carried out by the Victorian Ministerial Advisory Committee on Traditional Chinese Medicine. The Committee recommended a statutory framework for regulating the profession of Chinese medicine. Under the system, self-financing registration boards are recommended to be established under a statute of Parliament. The Committee suggested that the practice of acupuncture and Chinese herbal medicines should be regulated while it is believed that further work would be needed to determine whether Chinese orthopedics and manipulation should also be regulated.

Regulatory Bodies

10. In the Mainland, the State Administration of Traditional Chinese Medicine (SATCM) and State Drug Agency (SDA) are the regulatory bodies. The Taiwan's Committee on Chinese Medicine and Pharmacy performs a similar functions as Mainland's SATCM and SDA.

11. In Korea, an oriental medicine bureau was established in November 1996 under the Ministry of Health and Welfare. The bureau consists of two divisions: oriental medicine policy division and oriental medicine division.

12. In Singapore, Malaysia and Victoria of Australia, the statutory bodies for regulation of Chinese medicine are yet to be set up. The State of Victoria of Australia made some recommendations regarding establishing a regulatory body in a report published in July 1998, The report suggested that a registration board comprising about seven members be established under a statue of Parliament and that majority of board members should be Chinese medicine practitioners.

Regulation of Chinese Medicine Practitioners

13. A licensing system for practising Chinese medicine practitioners will be implemented in the Mainland. Formal education and training are offered through university level programmes. Graduates of the Chinese medicine programmes have to undergo internship, pass a licensing examination before they can obtain their licences. Taiwan adopts an examination and licensing system for Chinese medicine practitioners similar to the one used in the Mainland.

14. Korean herb doctors are required to hold specific qualifications that are related to a national examination conducted each year by the Minister of Health and Social Affairs before they could be registered under the Korean Medical Treatment Act as “medical persons”. Only such licensed medical persons are permitted to engage in herbal medical treatment and provide herbal guidance to promote public health.

15. In Singapore, Chinese medicine practitioners are currently self-regulated. Statutory regulation of acupuncturists will be in place by the year 2000. It is expected that statutory regulation of traditional Chinese medicine practitioners will be underway several years after.

16. In Malaysia, their regulatory framework for regulating Traditional Medicine is not in place yet. The Government will encourage traditional medicine practitioners to form their own self-regulatory bodies so that a system of recognition/registration can be developed.

17. In Victoria of Australia, it is recommended that the proposed Traditional Chinese Medicine Board should be responsible for determining the standard of training required for registration as traditional Chinese medicine practitioners and accrediting courses that meet this standard, with input from the profession if necessary.

Regulation of Chinese medicines

18. In the Mainland, there is a system of licensing for manufacturers and traders, and registration for proprietary Chinese medicine. Special requirements for sale and use of potent/toxic herbal medicines are in place. A similar regulatory system is also in place in Taiwan.

19. In Singapore, there is legislation in place which prohibits herbal medicines from containing prohibited substances or excessive amounts of heavy metals. For Chinese proprietary medicines, new legislation will be in place in future which require those sold are safe and are of good quality. This will be achieved through the licensing of local importers, wholesalers, manufacturers and assemblers of Chinese proprietary medicine products.

20. In Malaysia, registration for traditional medicines has been implemented since 1992. Traditional medicines are evaluated in terms of their quality, safety and GMP compliance.

21. In Australia, certain herbs traditionally used by Traditional Chinese Medicine practitioners are restricted by the Standard for Uniform Scheduling of Drugs and Poisons (SUSDP) and State and Territory legislation. The Committee is reviewing the current restrictions on use of

these herbs by trained Chinese herbal medicine practitioners, with the involvement of the profession.

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Health and Welfare Bureau