Chapter III

Regulation of Chinese Medicines

Chinese medicines are commonly used in Hong Kong and play an important role in the treatment of diseases and in the preservation of the health of citizens. There is a myriad of Chinese medicines on the market and the citizens often take proprietary Chinese medicines, or preparations of Chinese herbal medicines, to treat illness or to preserve good health. To ensure the quality, efficacy and safety of proprietary Chinese medicines and Chinese herbal medicines, and to safeguard the citizens in using them, the council is going to implement a regulatory system on the manufacture, sale and use of Chinese herbal medicines and a registration system for proprietary Chinese medicines, in accordance with the Chinese Medicine Ordinance. In doing so, the council has conducted extensive consultation with the Chinese medicines trade.

The Three Items of Subsidiary Legislation on Regulation of Chinese Medicines

The council has established the Chinese Medicines Board. The major functions of this board are to implement regulatory measures on Chinese medicines; to make transitional arrangements; to make proposals for drafting the Chinese Medicines Regulation, the Chinese Medicines Traders (Regulatory) Regulation, and other substantive regulatory programs. There are three committees under the Chinese Medicines Board, namely the Chinese Medicines Committee, the Chinese Medicines Traders Committee, and the Regulatory Committee of Chinese Medicines Traders. The Chinese Medicines Board and its committees started work on drafting the two pieces of subsidiary legislation soon after their establishment, in 1999.

The Chinese Medicines Board, in conjunction with the trade associations, conducted extensive consultation. These reviewed the practical circumstances of the Chinese medicines trade, and were aimed at securing the acceptance of the traders, in drafting the subsidiary legislation on the regulation of Chinese medicines. From February 2000 to September 2002, more than twenty consultation sessions were organized to seek the views of the trade on the contents of the subsidiary legislation, and other regulatory measures. In these meetings, the traders expressed many views, which were carefully considered by the Chinese Medicines Board in drafting the subsidiary legislation.

The Chinese Medicines Regulation

The contents of the Chinese Medicines Regulation mainly cover the licensing conditions and the duties of retailers and wholesalers of Chinese herbal medicines, and the wholesalers and manufacturers of proprietary Chinese medicines. They also cover the requirements on packaging, labelling, package insert, transportation, storage, record, sale and manufacture of Chinese medicines, registered particulars of proprietary Chinese medicines, and various types of exemption.

The Chinese Medicines Traders (Regulatory) Regulation

To conduct the regulatory procedures on Chinese medicines traders fairly and equitably, the Chinese Medicines Board consulted the trade extensively, before drafting the Chinese Medicines Traders (Regulatory) Regulation. This legislation chiefly covers the ways of lodging a complaint against Chinese medicines traders; the procedures for handling complaints by the Regulatory Committee of Chinese Medicines Traders; and the procedures of the Chinese Medicines Board in considering complaints.

The council thoroughly discussed the drafts of the Chinese Medicines Regulation and the Chinese Medicines Traders (Regulatory) Regulation in November and December 2001. The two items of subsidiary legislation were subsequently submitted, together with the Chinese Medicine (Fees) Regulation, to the Legislative Council by the Health, Welfare and Food Bureau in December 2002. They were enacted on 18 January 2003. In 2003, the Chinese Medicines Board planned to implement first, the traders licensing system, to be followed by the registration of proprietary Chinese medicines. Together, these developments represent an important step forward in the regulation of Chinese medicines.

Transitional Arrangements for the Regulation of Chinese Medicines

Chinese medicines have a long history of use in Hong Kong and the system to regulate them must be implemented gradually. In order not to adversely affect the operation of the Chinese medicines trade, a transitional licensing arrangement for the Chinese medicines traders, and a transitional registration arrangement for proprietary Chinese medicines, are provided in the Chinese Medicine Ordinance. Any Chinese herbal medicines retailer or wholesaler, or proprietary Chinese medicines wholesaler or manufacturer, who was operating on 3 January 2000, will qualify for a transitional licence.

On the other hand, any proprietary Chinese medicines already on sale or manufactured in Hong Kong on 1 March 1999 are eligible to apply for transitional registration of proprietary Chinese medicines.

The Regulatory System for Chinese Medicines

The Chinese Medicines Board notes that many aspects are involved in the distribution of Chinese herbal medicines, and proprietary Chinese medicines, on the market. These encompass import and export, wholesale, retail, processing, dispensation and manufacture. Problems arising in any aspect may affect the quality and safety of Chinese herbal medicines or proprietary Chinese medicines. If the problems are serious, the health of citizens may be jeopardized. Therefore, the Chinese Medicines Board has formulated substantive regulatory measures covering every aspect related to the sale of Chinese herbal medicines, and to the manufacture of proprietary Chinese medicines.

The Chinese Medicines Traders Committee, under the Chinese Medicines Board, held 37 meetings from November 1999 to December 2002. Their deliberations covered the licensing conditions and various regulatory measures concerning warehouse, shop and factory hygiene; the qualifications of the responsible persons of Chinese herbal medicines retailer and proprietary Chinese medicine manufacturer; the sale and manufacturing records; and the handling of poisonous Chinese medicines. The committee also arranged many consultation meetings to obtain the views of the trade. In addition, to enhance the standards of the proprietary Chinese medicines manufacturing industry in Hong Kong, the committee assisted in drafting the "Guidelines on Good Manufacturing Practice in respect of Proprietary Chinese Medicines".

Chinese Medicines Traders Licensing System

According to the Chinese Medicine Ordinance, any persons engaged in the following four types of Chinese medicines trade must apply for a licence:

(1) retail of Chinese herbal medicines;
(2) wholesale of Chinese herbal medicines;
(3) manufacture of proprietary Chinese medicines; and
(4) wholesale of proprietary Chinese medicines.

Practising Guidelines for Chinese Medicines Traders

In addition to relying on the statutory measures contained in the Chinese Medicine Ordinance, the Chinese Medicines Regulation and other relevant legislation, the Chinese Medicines Board and the Chinese Medicines Traders Committee have also compiled four practising guidelines to regularize the Chinese medicines trade, after extensive consultation with the trade. These guidelines cover the retail and wholesale of Chinese herbal medicines and the manufacture and wholesale of proprietary Chinese medicines. The aims of these guidelines are to encourage the tradesman to meet high standards of professional knowledge and ethics,

with a view to enhancing the standard of the whole of the Chinese medicines trade. They will be issued to the traders upon implementation of the licensing system, and their major contents are described below.

1. Practising Guidelines for Chinese Herbal Medicines Retailers

To protect the health and the rights of the consumers, the Chinese Medicines Board will regulate the scope of the retail business in Chinese herbal medicines. The "Practising Guideline for Chinese Herbal Medicines Traders" requires the retailers to sell Chinese medicines of good quality, to list the prices clearly and correctly, to use proper weighing instruments, and to provide correct information to customers. The retail personnel should have basic knowledge in differentiating, preparing and dispensing Chinese medicines. The dispensers must exercise due care in examining prescriptions, preparing preparations, reviewing prescriptions and preparations, packing, dispensing and concocting medicines. If there are doubts about the names, species, quantity or contraindications, they should consult the concerned CMPs.

Appropriate facilities and work areas should be provided in the Chinese herbal medicines retail shop. The premises should be kept clean, with sufficient space for the counter, passageway and dispensing area. The medicine drawers should be arranged according to rational principle, and the size of the storeroom should correspond to the scale of the operation.

Other than standard herbal tea and soup mixes for routine health preservation, the Chinese herbal medicines retailers should not sell multiple Chinese herbal medicines packages for therapeutic purposes. Moreover, when proposing proven prescriptions to customers, the dispensers should carefully consider the nature and any contraindications of the medicines, and remind customers to consult a CMP as necessary.

To ensure the quality of Chinese herbal medicines, the Chinese Medicines Board recommends that Chinese herbal medicines retailers should purchase Chinese herbal medicines from licensed wholesalers of Chinese herbal medicines, and should properly store the medicines, having regard to their quality and nature. The names of the medicines should be clearly, and correctly, printed on the container or package. All transaction invoices and documents should be kept systematically, to facilitate inspection. All dispensation of Chinese herbal medicines listed in Schedule 1 of the Chinese Medicine Ordinance (Schedule 1 Chinese herbal medicines) should be recorded.

2. Practising Guidelines for Chinese Herbal Medicines Wholesalers

The scope of the Chinese herbal medicines wholesale business generally covers many aspects such as the purchase, inspection, acceptance, storage, sale, distribution and transportation of Chinese herbal medicines. The Chinese Medicines Board has formulated the "Practising Guideline for the Chinese Herbal Medicines Wholesaler" to regularize the Chinese medicines trade, and to encourage the personnel engaged in the wholesale business of Chinese herbal medicines to meet high professional standards of knowledge and ethics.

These guidelines also require the Chinese herbal medicines wholesaler to set up an appropriate warehouse, according to the scale of operation and the nature of the Chinese herbal medicines. The warehouse should be kept in a sanitary condition, to avoid confusion or cross contamination. Generally speaking, Chinese herbal medicines wholesale warehouses should be equipped with appropriate facilities for the purposes of: regulating temperature, humidity and ventilation; blocking of direct sunlight; prevention of rodents and insects; avoidance of humidity and mould formation; and prevention of fire. According to operational needs, facilities for independently storing Schedule 1 Chinese herbal medicines should be provided.

The Chinese Medicines Board recommends that the Chinese herbal medicines wholesale personnel should have a basic knowledge of differentiating and processing Chinese herbal medicines. Before dispatching Chinese herbal medicines, the wholesaler should check the names, specifications, quantity, and the batch number of the medicines, and examine their quality. In dispatching, the wholesaler should arrange suitable transportation, to avoid leakage or contamination.

Other than standard herbal tea and soup mixes for routine health preservation, the Chinese herbal medicines wholesalers should not sell multiple Chinese herbal medicines packages for therapeutic purposes.

On the other hand, the Chinese Medicines Board limits Chinese herbal medicines wholesalers to selling or distributing Schedule 1 Chinese herbal medicines only to persons, or institutions, listed in section 12 of the Chinese Medicines Regulation. They should also consistently implement an appropriate labelling system and establish a complaint and recall system to recover any problematic medicines swiftly and effectively. All transaction records and documents in respect of Chinese herbal medicines should be kept carefully, in accordance with the requirements of the Chinese Medicine Ordinance and the Chinese Medicines Regulation, to facilitate the tracking of the source and distribution of any problematic medicines.

3. Practising Guideline for Manufacturer of Proprietary Chinese Medicines

Manufacture of proprietary Chinese medicines is a specialized task. In the "Practising Guideline for Manufacturer of Proprietary Chinese Medicines", the Chinese Medicines Board requires the manufacturers to employ suitable personnel who have the required knowledge and skills in manufacturing proprietary Chinese medicines. This is to be complemented by suitable factory management, to ensure the production of quality proprietary Chinese medicines in protecting the health of the citizens.

The guidelines require the proprietary Chinese medicines manufacturer to provide suitable premises for manufacture, examination and storage of proprietary Chinese medicines, or intermediate products. The manufacturer should also provide appropriate fittings and equipment whose design, model and installation should be suitable for the manufacturing procedures, and be easy to operate, clean and maintain.

The Chinese Medicines Board recommends the manufacturer to follow established manufacturing procedure in production, and to conduct quality control work. The package of proprietary Chinese medicines should carry suitable labels and package inserts, printed with the prescribed information.

The guidelines also require the proprietary Chinese medicines manufacturer to inspect each batch of proprietary Chinese medicine, or intermediate product, to ensure that the quality is up to standard, before dispatch for sale. The medicines should be stored in an environment of the prescribed nature. The container of proprietary Chinese medicines, or intermediate product, should be sufficiently strong to prevent leakage or contamination.

Lastly, the Chinese Medicines Board requires the proprietary Chinese medicines manufacturer to record suitably the purchase of ingredients; the conduct of the manufacturing process; and the distribution of products. The manufacturers should set up a complaint and recall system to swiftly recall any medicines, or intermediate products, that are found to have problems.

4. Practising Guideline for Wholesalers of Proprietary Chinese Medicines

The wholesale of proprietary Chinese medicines means the business of wholesale buying, or selling, proprietary Chinese medicines. Such business may include import, export, or sale in Hong Kong, or all. The guidelines require the proprietary Chinese medicines wholesalers to transact in proprietary Chinese medicines of good quality, and not to sell medicines of dubious quality, counterfeit products, or outdated products. The proprietary Chinese medicines wholesaler should employ suitable

personnel to carry out the wholesale work. These staff should be knowledgeable in arranging, selling and storing proprietary Chinese medicines.

The guidelines also require the provision of a suitable warehouse for proprietary Chinese medicines, having regard to the scale of operation and the nature of the relevant medicines. The warehouse should be kept in a sanitary condition, to avoid confusion or cross contamination, and be equipped with suitable facilities.

The Chinese Medicines Board recommends that the wholesalers of proprietary Chinese medicines should purchase proprietary Chinese medicines from reputable suppliers. When inspecting medicines for acceptance, the wholesalers should check the names, the specifications, the batch number, the quantity, and the expiry date. The medicines should then be put into the warehouse according to the prescribed environment. Proprietary Chinese medicines for sale in Hong Kong should carry suitable labels and package inserts, printed with the prescribed information.

These guidelines also require wholesalers of Proprietary Chinese medicines to ensure that suitable arrangements have been made for the transportation of proprietary Chinese medicines. The purpose of such arrangements is to avoid any leakage or contamination.

Lastly, the Chinese Medicines Board recommends that the wholesalers of proprietary Chinese medicines should set up a complaint and recall system so that if problems arise, the relevant medicines can be recalled swiftly and effectively. The records and documents related to transaction of proprietary Chinese medicines should be maintained appropriately, to facilitate the tracking of the source, or distribution, of any problematic proprietary Chinese medicines, as necessary.

The System of Registration of Proprietary Chinese Medicines

According to section 119 of the Chinese Medicine Ordinance, no person shall sell, import, or possess any proprietary Chinese medicines, unless the proprietary Chinese medicine is registered with the Chinese Medicines Board under section 121 of the Chinese Medicine Ordinance. After detailed discussion, the Chinese Medicines Board determined the registration requirements, the registered particulars, and other substantive arrangements for implementing the proprietary Chinese medicines registration system. For all proprietary products meeting the definition of proprietary Chinese medicine under the Chinese Medicine Ordinance, registration must be applied for. Proprietary Chinese medicine means any proprietary product -

(a) composed solely of the following as active ingredients:

(i) any Chinese herbal medicine; or

(ii) any materials of herbal, animal or mineral origin customarily used by the Chinese; or

(iii) any medicines and materials referred to in subparagraphs (i) and (ii) respectively;

(b) formulated in a finished dose form; and

(c) known or claimed to be used for the diagnosis, treatment, prevention or alleviation of any disease or symptom of a disease in human beings, or for the regulation of the functional states of the human body.

The Chinese Medicines Board is required under the Chinese Medicine Ordinance to consider the quality, efficacy and safety of a proprietary Chinese medicine, in deciding on an application for registration. The Chinese Medicines Board therefore requires the applicants to provide sufficient information to prove that the quality, efficacy and safety of the concerned proprietary Chinese medicines meet the prescribed standards. The Chinese Medicines Board and the Chinese Medicines Committee have, over the past three years, formulated the basic registration requirements. These include: not exceeding the limits of heavy metal and toxic elements; not exceeding the limits of pesticide residues and microbes; non-adulteration with western medicine; and compliance with the requirements of the Animals and Plants (Protection of Endangered Species) Ordinance. Besides, the applicants have to provide the Chinese Medicines Board with the complete prescription of the medicines, the manufacturing methods, and various test reports.

In devising the registration requirements, the Chinese Medicines Board has reviewed the international and Mainland drug control standards (such as World Health Organization, the State Food and Drug Administration of Mainland China, European Drug Assessment Bureau and the Food and Drug Administration of the USA). Experts from local universities have also been consulted. Furthermore, to cater for the practical operation of the Chinese medicines trade, the Chinese Medicines Board has conducted numerous consultations to obtain the views of the traders.

The Chinese Medicines Committee, under the Chinese Medicines Board, conducted 43 meetings from November 1999 to December 2002, to discuss in detail the various regulatory measures required on proprietary Chinese medicines. These included: the drafting of the Chinese Medicines Regulation, the categorization and grouping of proprietary Chinese medicines; and the respective registration requirements.

Categorization of Registered Proprietary Chinese Medicines

There are many types of proprietary Chinese medicines in the Hong Kong market. Some of them are used for the treatment of diseases, whilst some are taken on a long-term basis to preserve good health. In terms of the history of use, they can be divided into medicines having a longer history of use, and new medicines. As the formulations, usage, indications and dosage of newly-developed products are different from the traditional medicines, the support of modern scientific data is necessary to ensure their safety and efficacy. As a result, the Chinese Medicines Board has decided to group proprietary Chinese medicines into three categories: established medicines, non-established medicines, and new medicines, to facilitate the registration work. Before implementing the proprietary Chinese medicines registration system, the Chinese Medicines Board will announce the registration categories and the respective registration requirements in detail to the trade.

1. The Category of Established Medicines

Established medicines mean - (other than hypodermic), medicines used, or sold, in Hong Kong for more than seven years; or medicines of ancient formulations; medicines of formulations published in the pharmacopoeia of the People's Republic of China (pharmacopoeia formulations); or medicines of ancient formulations with additional or subtracted ingredients. Ancient formulation means prescriptions recorded in medicinal literature in the Qing Dynasty or earlier. Ancient formulation with additional or subtracted ingredients means formulations prescribed on the basis of ancient formulations, with reasonable and suitable addition, or subtraction, of ingredients (but the dosage should not be changed). For formulations that are not published in the latest pharmacopoeia, the Chinese Medicines Board will consider the relevant medicines on a case-by-case basis.

2. The Category of Non-established Medicines

Non-established medicines can be divided into health-preserving medicines and other medicines. Health-preserving medicines mean (other than hypodermic), any proprietary Chinese medicines capable of regulating the functional states of the human body. Other medicines include single proprietary Chinese medicine granules. That means granules prepared from single Chinese herbal medicine, with indications and usage similar to the original Chinese herbal medicines, and fulfilling the definition of proprietary Chinese medicine.

3. The Category of New Medicine

New medicines mean - medicines comprising newly discovered Chinese herbal medicines; new medicinal portions of Chinese herbal medicines; extracts from single Chinese herbal medicine or multiple Chinese herbal medicines; Chinese medicinal hypodermic or new dosage; medicines prescribing new indications; or medicines for which the routes of application have changed. Any proprietary Chinese medicines that fulfill these definitions are classified as new medicines.

Guidelines on Good Manufacturing Practice

To ensure the quality of proprietary Chinese medicines production in Hong Kong and to enhance it, the Chinese Medicines Board and the Chinese Medicines Traders Committee have formulated the "Guidelines on Good Manufacturing Practice in respect of Proprietary Chinese Medicines". If a manufacturer follows the guidelines in manufacture and quality control of proprietary Chinese medicines, he/she can apply for a Certificate for Manufacturer (Good Manufacturing Practice).

To achieve international standards, in formulating the guidelines on good manufacturing practice, the Chinese Medicines Board has reviewed other international standards, including the guidelines issued by the World Health Organization and the State Food and Drug Administration of Mainland China. In addition, the Chinese Medicines Traders Committee invited local experts to its meeting in September 2001 for the committee to be briefed on the practical circumstances of the trade, and for the committee to receive their professional comments on the suggested contents of the guidelines.

The contents of the guidelines on good manufacturing practice cover such areas as personnel, factory premises, facilities, documentation record, validation, manufacturing management, quality control and product recall. Furthermore, to cater for the practical operation of the proprietary Chinese medicines manufacturing industry in Hong Kong, the Chinese Medicines Board conducted consultation sessions to obtain the views of the traders.