

Regulation of Chinese Medicines

In April and December 2003, the Chinese Medicine Council of Hong Kong (the council) implemented two important systems for regulation of Chinese medicines, viz. the system for licensing of Chinese medicines traders and the system for registration of proprietary Chinese medicines (pCms). Subsequent to the full implementation of the system for regulation of Chinese medicine, it will serve to better protect the health of the general public, as well as enhance the confidence of the public in using Chinese medicines.

Licensing of Chinese Medicines Traders

On 30th April 2003, the council implemented the system for licensing of Chinese medicines traders, which was passed by the Legislative Council. Any persons engaged in any of the four types of Chinese medicines trade [namely, retail and wholesale of Chinese herbal medicines (CHM), and manufacture and wholesale of pCms] are required to apply for a licence with the Chinese Medicines Board (the Medicines Board) under the council. The relevant provisions of the Chinese Medicine Ordinance, Chinese Medicines Regulation, Chinese Medicine (Fees) Regulation, and the Chinese Medicines Traders (Regulatory) Regulation, took effect from that same date.

Requirements for Licensing of Chinese Medicines Traders

The purposes of implementing the system for licensing of Chinese medicines traders are to protect public health and to ensure the safe use of Chinese medicines. Applicants for Chinese medicines trader licences must fulfill the relevant licensing requirements, and upon payment of the relevant fees, the Medicines Board will issue a licence to them.

The licensing requirements for CHM retailers include: sanitary premises, adequate space, and installation of adequate and suitable facilities for storage of CHMs. Moreover, if the retailer dispenses CHMs, the trading premises must be equipped with suitable dispensing facilities, a responsible person and not more than 2 deputies must be appointed, and the dispensation must be supervised by a responsible person and his/her deputies who possess the knowledge and experience prescribed in the Chinese Medicines Regulation.

The licensing requirements for CHM wholesalers include: sanitary premises, adequate space, and suitable facilities for storage of CHM. The premises should be suitable for carrying on a CHM wholesale trade in all other respects.

The licensing requirements for pCm wholesalers include: sanitary premises, adequate space, and suitable facilities for storage of pCm. The premises should be suitable for carrying on a pCm wholesale trade in all other respects.



The licensing requirements for a pCm manufacturer include: sanitary premises; adequate space and suitable facilities for storage of pCm; suitable fittings and equipment for manufacturing pCm; and suitable humidity, lighting, temperature and ventilation. Besides, the manufacturer should appoint a responsible person and not more than 2 deputies to supervise the production of pCm, and the relevant responsible person and deputies should possess the necessary knowledge and experience as prescribed in the Chinese Medicines Regulation.

Transitional Licensing of Chinese Medicines Traders

Taking into account the actual situation of the trade, an arrangement of transitional licensing is provided under the Chinese Medicine Ordinance. Any Chinese medicines traders who carried on their businesses in Chinese medicines as at 3 January 2000 were eligible for transitional licensing. The application period for transitional licensing was from 5 May to 15 July 2003. Those Chinese medicines traders who were not eligible for transitional licensing were also required to apply for a licence during that same period, for the Medicines Board to process their applications and issue licences as soon as possible. When the first round of licensing work has been completed, any person without a relevant licence will not be allowed to engage in the relevant Chinese medicines trade.

From May to July 2003, the Medicines Board and

Department of Health conducted nine briefings to introduce to the Chinese medicines traders the procedure for application for Chinese medicines trader licences, and the information and documentation that need to be submitted by applicants. For applications for a non-transitional licence, the Department of Health will send inspectors to the trading premises to check if the licensing requirements are being fulfilled, before deciding to issue a licence. For applications for a transitional licence, if it is satisfied that an applicant was operating the relevant business as at 3 January 2000, the Medicines Board will issue a transitional licence to him/her upon verification of the relevant documents. The Department of Health will, at a later date, inspect the premises, in connection with issuing the formal licence. From May to December 2003, the Medicines Board received about 6,900 applications for Chinese medicines trader licences.

Practising Guidelines for Chinese Medicines Traders

The Medicines Board compiled four sets of practising guidelines on the retail and wholesale of CHM, and manufacture and wholesale of pCms. These provide detailed guidance to traders on various aspects, such as business premises, storage space, equipment and facilities, and qualification of personnel.

The "Practising Guidelines for Retailers of Chinese Herbal Medicines" describe the good practices for

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the retail of CHMs. These are that CHM retailers should purchase good-quality CHMs from licensed CHM wholesalers, and arrange for proper storage; retail personnel should possess basic knowledge in differentiating, preparing and processing CHM; dispensers should dispense CHMs with caution; CHM retail shop should be equipped with appropriate and sanitary facilities, and medicine drawers should be properly arranged, with clear indication of medicine names on the containers or package; transaction invoices and documents must be kept systematically; and every dispensation of a Schedule I CHM must be recorded.

The "Practising Guidelines for wholesalers of Chinese Herbal Medicines" require CHM wholesalers to have warehouse facilities which can control the temperature, humidity, and ventilation, and prevent sunlight, rodents and insects, formation of mould, or fire. The warehouse should be kept in sanitary conditions, to avoid confusion or cross-contamination. The personnel of a CHM wholesaler should possess basic knowledge in differentiating and processing CHMs, and they must dispatch and transport CHMs with caution. CHM wholesalers should only sell schedule I CHMs to persons, or institutions, listed in section 12 of the Chinese Medicines Regulation; implement an appropriate labelling system; and establish a complaint and recall system. All transaction records and documents should be maintained carefully, to allow for the later

tracking of the source and distribution of any problematic medicines.

The "Practising Guidelines for Wholesalers of Proprietary Chinese Medicines" requires pCm wholesalers to deal in good-quality pCms; and to employ suitable personnel who possess good knowledge in dealing with and storing pCms. The pCm warehouse should be equipped with suitable facilities, and kept in a sanitary condition, to avoid confusion or cross contamination. pCm wholesalers should purchase pCms from reputable suppliers, and store and transport them with caution. In addition, they should establish a complaint and recall system to allow for the tracing and recall of any problematic medicines. For pCms sold in Hong Kong, they must enclose suitable labels and package inserts, printed with the prescribed information.

The "Practising Guidelines for Manufacturer of Proprietary Chinese Medicines" require pCm manufacturers to employ suitable personnel, who possess the necessary knowledge and skills in the manufacture of pCm, to be complemented by the provision of suitable equipment, storage facilities, manufacturing procedures and quality control procedures, to ensure the quality of pCm products. In addition, pCm manufacturers should suitably record the purchase of raw materials, production procedure, and distribution of the products, and



establish a complaint and recall procedure to enable the swift recovery of any problematic medicines.

The System for Regulation of Chinese Medicines Traders

The Department of Health will send inspectors to the premises of the licensed Chinese medicines traders. Other than complying with the requirements of the law, licensed Chinese medicines traders should also follow the practising guidelines, to maintain the standards of the Chinese medicines trade. If a licensed Chinese medicines trader violates the law or the licensing requirements, the Medicines Board may consider suspending or revoking his/her licence, in accordance with Chinese Medicines Traders (Regulatory) Regulation. If a trader is dissatisfied with the decision of the Medicines Board, he may appeal to the Court of First Instance within one month from the date of service of the relevant notice.

Exemption of Chinese Medicine Practitioners from Licensing

To cater for the operation of the Chinese medicine profession, for listed Chinese medicine practitioners or registered Chinese medicine practitioners to dispense CHM to patients under their direct care, their business premises may be exempted from the need for a CHM retailer licence. However, if a Chinese medicine practitioner sells

CHMs to any patients not under his direct care, he needs to apply for a CHM retailer licence.

Guidelines on Recall of Chinese Medicinal Products

According to Chinese Medicines Regulation, wholesalers of CHMs or pCm, and manufacturers of pCm, are required to set up and maintain a system of complaint and recall of Chinese medicinal products. This is to enable the rapid and, as far as practicable, complete recall of any medicinal products sold, or distributed, and found to be dangerous, injurious to health, or unsuitable for human consumption. To assist Chinese medicines traders in setting up an effective system of recall, the Medicines Board developed the "Guidelines on Recall of Chinese Medicinal Products", by making reference to the recall procedures for Western medicines, and similar guidelines adopted by other nations, for the information of the trade.

Guidelines on Good Manufacturing Practice

To enhance the quality of pCm production in Hong Kong, the Medicines Board and the Chinese Medicines Traders Committee developed the "Guidelines on Good Manufacturing Practice in respect of Proprietary Chinese Medicines". If a pCm manufacturer follows the guidelines in manufacture and quality control of pCms, he may apply for a Certificate for Manufacturer (Good Manufacturing Practice). The contents of the guidelines make reference to international standards (including the

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guidelines issued by the World Health Organization and the State Food and Drug Administration of Mainland China), covering such areas as personnel, factory premises, facilities, documentation record, validation, manufacturing management, quality control, and product recall.

Delegation of Authority on Licensing of Chinese Medicines Traders and Issuance of Certificate for Manufacturer

To expedite the procedure for licensing of Chinese medicines traders and related matters, the Medicines Board delegated the authority on licensing of Chinese medicines traders, validity of licence, renewal of licence, and issuance of the certificate for manufacturer to the Chinese Medicines Traders Committee, under section 157 of the Chinese Medicine Ordinance. If any person is dissatisfied with a decision of the committee, he may request the Medicines Board to review the decision, within 14 days from the date of service of the relevant notice.

Implementation of the System for Registration of Proprietary Chinese Medicines

On 19 December 2003, the council implemented the system for registration of proprietary Chinese medicines, which was passed by the Legislative Council. Any pCm manufactured, imported or possessed in Hong Kong must be registered with

the Medicines Board. The relevant provisions of the Chinese Medicine Ordinance, Chinese Medicines Regulation, and Chinese Medicine (Fees) Regulation came into effect on that same date. The pCm registration system is a very important measure in regulating the Chinese medicines trade. It ensures the quality and efficacy of pCm, promotes the safe use of pCm on the part of the consumers, and protects the health of the public.

In December 2003, the Medicines Board and the Department of Health conducted four briefings to introduce to the Chinese medicines traders the requirements for registration of pCm, the application procedure, and the documents and information required to be submitted by applicants.

Definition of Proprietary Chinese Medicines

According to the Chinese Medicine Ordinance, 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.

Applicants for Registration of Proprietary Chinese Medicines

For pCm manufactured in Hong Kong, the application for registration should be made by the relevant local manufacturer. For pCm made in places outside Hong Kong, the application should be made by the importer or the local agent or representative of the manufacturer outside Hong Kong. In applying for pCm registration, the applicants should determine the classification category for the relevant pCms, choose the registration group, and provide the required documents and information. After assessment and approval by the Medicines Board and payment of the necessary fees, the applicants will be issued with a "Certificate of Registration of pCm", which is valid for five years, and is renewable after expiry. All registered pCms must indicate their registration numbers on the external package.

Transitional Registration of Proprietary Chinese Medicines

The Chinese Medicine Ordinance provides for an arrangement of transitional pCm registration to protect the interests of the Chinese medicines

traders. pCms manufactured or sold in Hong Kong on 1 March 1999 will be granted transitional registration, provided the relevant manufacturer or wholesaler made an application for registration during the designated application period. The application period for transitional pCm registration was from 19 December 2003 to 30 June 2004. After approval by the Medicines Board, the relevant Chinese medicines trader would be issued with a "Certificate for Transitional Registration of Proprietary Chinese Medicines", which is valid until the pCm is registered formally, or until the refusal of its application for registration, or until a date to be promulgated by the Secretary for Health, Welfare and Food - whichever date is the earliest.

pCm manufactured or sold in Hong Kong after 1 March 1999 are not eligible for transitional registration. However, the relevant traders should still apply for registration during the application period for transitional pCm registration, to facilitate the Medicines Board in processing the applications and issue the certificate of registration as soon as possible. When the application period for transitional pCm registration is over, the pCms for which an application for registration has not been made, shall not be allowed to be imported into Hong Kong. When the offence provisions on pCm registration take effect, no person shall sell, import or possess any unregistered pCm, otherwise, he violates the law and would need to recall the medicines.

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Classification Category for Proprietary Chinese Medicines

Having extensively consulted the views of the Chinese medicines traders, the Medicines Board announced that pCms shall be registered under three categories, namely- established medicines, non-established medicines, and new medicines. Established medicines refer to pCms, the formulations of which belong to ancient prescriptions, modified ancient prescriptions, prescription listed in the Pharmacopoeia of the People's Republic of China, or prescriptions originated from the national drug registration standards, and which are accepted by the Medicines Board. The original dose form of such prescriptions should not be changed as a principle, lest the medicines shall be regarded as new drugs; however, where the change in the dose forms will not lead to any change in the principal manufacturing methods, the relevant pCms may still be registered under the category of an established medicine. pCm under application for registration as established medicines must comply with the testing requirements set by the Medicines Board. Otherwise, their applications may be refused by the Medicines Board. Injections are not eligible for registration as established medicines, and they can only apply for registration as new medicines.

The category of non-established medicines includes health products and other products. For Chinese

medicinal products that fulfill the definition of pCm, but which are intended for preserving health instead of treating illness, they may choose to apply for registration as health products. Other products include single Chinese medicine granules.

The category of new medicines refer to medicines, the prescriptions of which include a newly - discovered Chinese herb, a new medicinal part of a Chinese herb, an active group extracted from a Chinese herb, or a set of active groups extracted from a compound prescription; injections; preparation of a new Chinese medicine prescription; and pCm with newly added indications or altered route of application.

Registration Groups for Proprietary Chinese Medicines

According to section 122 of the Chinese Medicine Ordinance, in determining an application for pCm registration, the Medicines Board shall in particular take into consideration the safety, quality and efficacy of the product. Therefore, the applicants for pCm registration should provide information on these three aspects, for the Medicines Board to be able to make an assessment. To protect the health of consumers, and to enhance the confidence of the public in Chinese medicines, the Medicines Board has adopted a 3-group registration system of groups I, II and III, following a thorough discussion, and extensive consultation with the Chinese medicines trade. Except for new medicines



for which group III registration needs to be applied, established medicines and non-established medicines may seek registration under any of the three groups. Information would need to be provided on their safety, quality and efficacy, according to the registration requirements of the specific group.

Information on Safety

The applicants for registration of pCm should provide basic safety information, including heavy metals and toxic element test reports, pesticides residues test reports, and microbial limits test reports. In addition, depending on the registration group, they may be required to provide further toxicity test reports, and/or other test reports.

Information on Efficacy

The applicants for pCm registration are required to provide information on efficacy, including interpretation and principle of formulating the prescription, to describe the properties, the flavours, the channel tropism, the functions, the compatibility of the medicines, and to analyze the prescriptions and their clinical application. Depending on the classification category and registration group, the applicants may be required to provide reference materials on product efficacy, study reports, or clinical trial protocols.

Information on Quality

The basic information on product quality for registration of pCm includes the manufacturing method, the physiochemical properties of the crude drugs, the product specifications, the method of analysis, the certificate of analysis, and the stability test report of the relevant pCm.

Because of the long lead-time in completing a stability test (in certain cases as long as four years), the Chinese medicines traders requested a longer period to prepare the required reports. The Medicines Board agreed that the stability reports may be submitted before the expiry of the 5-year registration period.

Non-adulteration with Western Medicine and Compliance with Animal and Plants (Protection of Endangered Species) Ordinance

Other than fulfilling the registration requirements on product safety, efficacy and quality, the applicants for pCm registration should declare that the relevant pCms are not adulterated with Western medicine, and that they fulfill the requirements of Animal and Plants (Protection of Endangered Species) Ordinance (Cap. 187).

Test of Proprietary Chinese Medicines

The Medicines Board also regulates the standards of the laboratories conducting the safety tests, quality tests, and efficacy tests, to ensure the quality

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of the testing process. The laboratories must fulfill the norms developed by the International Standards Organization (i.e. ISO/IEC 17025), Good Laboratory Practice, Good Clinical Practice. Any other laboratories that are recognized by the Medicines Board will also be accepted.

At the moment, 4 laboratories in Hong Kong are accredited for conducting product tests. Besides, 15 municipal institutes for drug control under the State Food and Drug Administration (SFDA) are also recognized for provision of pCm testing services for pCm manufacturers in Hong Kong. These 15 institutes have substantial experience in testing pCm, and they are mainly responsible for registration testing, technical assessment of the quality standards of new medicines, testing of imported drugs, monitoring quality tests of medicines under circulation, and drafting and amending national drug standards.

To facilitate the traders in conducting product testing and clinical tests, the Medicines Board developed three sets of technical guidelines on product safety, efficacy and quality tests for the Chinese medicines traders and the testing institutions, following consultation with local laboratories. The Medicines Board also developed the "Good Clinical Practice for Proprietary Chinese Medicines", to provide guidance to clinical test institutions. Suitable amendments were made to

the guidelines after consulting the University of Hong Kong, the Chinese University of Hong Kong, the Baptist University and the Hospital Authority.

System for Random Tests on Proprietary Chinese Medicines

Upon implementation of the pCm registration system, the Department of Health shall regularly conduct tests on pCms on the market on a random basis, and closely monitor the incidents of any adverse drug reactions caused by a pCm. When a registered pCm is found to be injurious to the health of the public, the Medicines Board shall revoke its registration, and the relevant trader will be required to recall the product from the market.

Requirements for Transitional Registration of Proprietary Chinese Medicines

For those pCm that are eligible for transitional registration, the required medicinal information may be submitted in phases. The test reports on heavy metals and toxic elements, pesticide residues and microbial limits may be submitted within one year of the closing date of the application period for transitional pCm registration (i.e. before 30 June 2005). The product quality standards, the testing methods and test reports, the stability test report, and the toxicity test reports may be submitted within five years of the closing date of the application period for transitional registration (i.e. before 30 June 2009). In addition, except for



injections, for all pCms that are qualified for transitional registration, a group I registration may be applied for.

For those pCm that are not qualified for transitional registration, all the registration documents should be submitted when making application. However, if the relevant products were manufactured, or sold, in Hong Kong before the commencement of the legislation on pCm registration (i.e. 19 December 2003), the applicants may submit the product quality standards, testing methods and test reports, stability test reports and toxicity test reports, when applying for renewal of registration.

Provision of Advice by Experts in Chinese Medicine

The processing of applications for pCm registration will involve a professional and technical judgement in many aspects. The Medicines Board invited dozens of Chinese medicine experts to provide professional and technical views on various technical questions, including the formulation of prescriptions, pharmaceuticals, pharmacology, toxicology, clinical and medicinal statistics. When there is a need, these experts may be invited to the meetings of the Medicines Board, or to the Chinese Medicines Committee, to give their opinions.

System of Maintaining Confidentiality of Information related to Registration of Proprietary Chinese Medicines

Chinese medicines traders are very concerned about the confidentiality of the prescriptions of their products. The Medicines Board will exercise meticulous care in guarding against any leakage of such information.

According to section 154 of the Chinese Medicine Ordinance, no public officer or member of the council, boards or committees shall, except under specific circumstances, disclose any information that concerns a trade, business or manufactory secret which has come to his/her knowledge or possession in the course of the discharge of his/her functions under the Ordinance. Otherwise, he/she shall break the law. Besides, in applying for pCm registration, while a Chinese medicines trader is required to provide the information on all of the ingredients and excipients, it is not necessary for him to indicate all the ingredients on the label or the package insert. On the other hand, the Medicines Board shall strengthen the mechanism for reporting any conflicts of interest.

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Delegation of Authority on Registration of Proprietary Chinese Medicines and Related Matters

To speed up the approval procedure for registration of pCm and related matters, the Medicines Board delegated the function relating to pCm registration, validity period of registration, renewal of registration, change of registered particulars, revocation of registration, clinical and medicinal tests, and issuance of certificate of sale, to the Chinese Medicines Committee, in accordance with section 157 of the Chinese Medicine Ordinance. Any person who is aggrieved by a decision of the committee may, within 14 days of the receipt of the relevant notification, apply to the Medicines Board for a review of the decision.