

Chapter 3 Regulation of Chinese Medicines

In order to ensure the safe use of Chinese medicines, the Chinese Medicine Council of Hong Kong (the Council) implemented the regulatory measures for the licensing of Chinese medicines traders and registration of proprietary Chinese medicines (pCm) in April and December 2003 respectively. These measures serve to better protect the general public and to enhance the confidence of the public in using Chinese medicines.

To fully effect the licensing and control regime for Chinese medicines traders, the provisions governing the control over the possession, sale, import and export of Chinese herbal medicines (CHM), and over the manufacture, sale by way of wholesale, import and export of pCm under the Chinese Medicine Ordinance and Chinese Medicines Regulation, as well as import and export control over relevant CHM commenced on 11 January 2008. The commencement of the legislative provisions will enhance the regulation of Chinese medicines traders and facilitate a more effective monitoring of the origins and destinations of the CHM and pCm imported to, and exported from, Hong Kong. All these measures will further protect public health and enable the public to purchase Chinese medicines of good quality from licensed Chinese medicines traders.

With a view to stepping up the regulation of Chinese medicines, the legislation regarding mandatory registration of pCm under the Chinese Medicine Ordinance came into effect on 3 December 2010. Besides, the legislative provisions regarding the requirements of label and package inserts for all registered pCm came into force on 1 December 2011. Commencing the legislative provisions will make the regulation of pCm more comprehensive and enhanced. This can further protect public health and meet the general expectation over medicinal product safety. The enactment of these provisions will also provide a legal basis for combating more effectively the selling of unregistered pCm, and boost public confidence in Chinese medicines and in turn foster the development of Chinese medicines in Hong Kong.

Licensing of Chinese Medicines Traders

Under the system for the licensing of Chinese medicines traders, any persons engaged in any of the four types of Chinese medicines trade (namely, retail and wholesale trade in CHM; and manufacture and wholesale of pCm) are required to apply for a licence with the Chinese Medicines Board (the Medicines Board) under the Council. The applicants for Chinese medicines trader licences must fulfill the relevant licensing requirements, and upon a 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 adequate, and suitable, facilities for the storage of CHM. Moreover, if a retailer engages in the dispensation of CHM, his/her business premises must be equipped with suitable dispensing facilities, and the person who is responsible for supervising the dispensation should possess the appropriate level of knowledge and experience, as prescribed in the Chinese Medicines Regulation.

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

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

The licensing requirements for pCm manufacturers include: sanitary premises; adequate space and adequate, and suitable facilities, for the storage of ingredients, packing materials, intermediate products and pCm; suitable fittings and equipment for the manufacturing of pCm; and the premises must also be suitable for manufacturing pCm in all other respects. Furthermore, the person who supervises the manufacturing process should possess the appropriate level of knowledge and experience, as prescribed in the Chinese Medicines Regulation.

To enable those Chinese medicines traders who were already conducting their Chinese medicines businesses at 3 January 2000 to continue to carry on their businesses, a system of transitional licensing was provided under the Chinese Medicine Ordinance. Any Chinese medicines traders who were operating their businesses in Chinese medicines as at 3 January 2000 were eligible for application of a Chinese medicines trader transitional certificate. The application period for transitional certificates was from 5 May to 15 July 2003. A transitional certificate would be valid until the issue of a Chinese medicines trader licence, or until the refusal of his/her application for a licence or until such date as is promulgated by the Secretary for Food and Health (whichever date is the earliest).

Applicants for Chinese medicines traders licences will be issued with such licences only if they have fulfilled the requirements stipulated in the Chinese Medicines Regulation and the licensing requirements. To expedite the processing of applications for Chinese medicines traders licences, the Medicines Board has delegated the authority for approving such applications to the Chinese Medicines Traders Committee (CMTC). The Department of Health provides administrative support to the Medicines Board and the CMTC for the licensing of Chinese medicines traders, including the inspections of the trading premises and the preparation of the inspection reports. After consideration of the relevant information, the CMTC would decide whether or not to approve such applications.

Since April 2003, the Medicines Board has received a total of 12,357 applications, among which 4,169 applied for transitional certificates at the same time. The remaining 8,188 are non-transitional licence applications. The assessment of all applications for transitional certificates was completed. By 31 December 2012, there were a total of 6,680 holders of Chinese medicines traders licences issued by the Medicines Board and 83 applications were being processed. The number of licensed Chinese medicines traders is illustrated in Table 5 on page 50.

Chinese Medicines Traders Operating in Domestic Premises

According to the Chinese Medicine Ordinance, the premises to which the trader licence relates shall in all other respects suitable for carrying on a business of Chinese medicines. The Medicines Board having regard to the practising requirements and the operation of Chinese medicines trade, and after consultation with the Buildings Department, has decided that Chinese medicines traders are not suitable to conduct Chinese medicines business at domestic premises. The Medicines Board, therefore will not accept any new application for licences operating in domestic premises (premises which are constructed or intended to be used for habitation). Having considered that a number of licensed Chinese medicines traders are still carrying out their business at domestic premises, the Medicines Board has allowed sufficient time for the traders concerned to find and/or relocate to suitable premises to continue their business. The grace period has started from 1 January 2012 and will last until 31 December 2013; or the date of enforcement action taken by the Buildings Ordinance, whichever is the earlier.

Chinese Medicines Regulation and Practising Guidelines for Chinese Medicines Traders

The Chinese Medicines Regulation stipulates the specific measures on the regulation of Chinese medicines, such as licensing conditions, duties of licensed Chinese medicines traders, and details of the registration of pCm. Apart from the statutory measures, the Medicines Board also compiled four sets of practising guidelines, for the four respective types of Chinese medicines trade, to provide guidance to the trade. The Medicines Board would revise the practising guidelines as appropriate, by taking into account the current circumstances.

The System for the Regulation of Chinese Medicines Traders

The licensed Chinese medicines traders should comply with the Chinese Medicine Ordinance and its subsidiary legislation, the practising guidelines and other laws, when carrying on their business. Otherwise, the Medicines Board may consider taking disciplinary actions against them. If the Medicines Board considers it necessary in the public interest, or is satisfied that a licensed trader has (i) failed to comply with the licensing conditions or restrictions; (ii) failed to comply with any prescribed conditions, or duty, in respect of the practice of his/her trade; or (iii) has been convicted of an offence of the Chinese Medicine Ordinance, the Medicines Board may temporarily suspend or revoke his/her licence; vary the licensing conditions or restrictions; or issue a warning to him/her.

According to the procedures as prescribed in the Chinese Medicines Traders (Regulatory) Regulation, any complaint or information against a licensed Chinese medicines trader should be made to the Medicines Board. In receiving any complaint or information, the Medicines Board would refer the case to the Regulatory Committee of Chinese Medicines Traders (CMRC) for investigation and consideration. The CMRC will then make a recommendation to the Medicines Board. If a trader is aggrieved by the decision of the Medicines Board, he/she may appeal to the Court of First Instance

within one month from the date of service of the relevant notice.

By the end of 2012, the CMRC received 141 complaints against licensed Chinese medicines traders. These complaints are mainly related to basic knowledge and responsibilities of the personnel of wholesalers in pCm and retailers in CHM; the scope of business of retailers in CHM, such as dispensing of processed herbal medicines; and conviction of offence(s) punishable with imprisonment by Chinese medicines traders violating the practising guidelines. Apart from cases which could not be further processed, comprising 3 cases in which the complainants withdrew their complaints, 12 cases in which the complainants had not made a statutory declaration and 7 cases of which the licence of the traders concerned expired or the traders concerned closed down the business, the Medicines Board had considered 91 cases. Of the remaining 28 cases, 20 cases had been considered by CMRC and pending consideration by the Medicines Board, and 8 cases were pending consideration by CMRC. The statistics on the complaints against licensed Chinese medicines traders are illustrated in Table 6 on page 51.

Exemption of Chinese Medicine Practitioners from Licensing

Registered CMPs and listed CMPs may dispense CHM to or manufacture pCm for those patients under their direct care. Their business premises may be exempted from the requirement of a CHM retailer licence or a pCm manufacturer licence. However, if a CMP sells CHM or manufacture pCm to any patients not under his/her direct care, he/she needs to apply for a CHM retailer licence and a pCm manufacturer licence.

Guidelines on Recall of Chinese Medicinal Products

According to the Chinese Medicines Regulation, wholesalers of CHM 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, which may later be found to be dangerous or injurious to health, or unsuitable for human consumption. To assist the Chinese medicines traders in setting up an effective system of recall, the Medicines Board developed the “Guidelines on Recall of Chinese Medicinal Products” to provide guidance to the trade.

Good Manufacturing Practice in respect of proprietary Chinese medicines (pCm)

To enhance the quality of pCm production in Hong Kong, the Chinese Medicine Ordinance stipulates that a pCm manufacturer who follows good practices in the manufacture and quality control of pCm may apply to the Medicines Board for a Certificate for Manufacturer (Good Manufacturing Practice in respect of pCm) (i.e. GMP Certificate). To facilitate the implementation of quality management, the Medicines Board developed the “Hong Kong Good Manufacturing Practice Guidelines for Proprietary Chinese Medicines” to provide guidance to pCm manufacturers. The guidelines cover such areas as personnel, factory premises, facilities, documentary records, validation, manufacturing management,

quality control, and product recall. Up to 31 December 2012, the Medicines Board issued ten Certificates for Manufacturer (Good Manufacturing Practice in respect of pCm). The relevant information has been uploaded to the Council's website (www.cmchk.org.hk).

In response to the 2010-11 Policy Address related to working out a timetable for mandatory compliance with the Good Manufacturing Practice (GMP) for the manufacture of pCm, the Medicines Board has recommended the adoption of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP standard as a licensing requirement for local manufacturers of pCm, and implementation of PIC/S GMP standard in 4 years. To cater for the operational needs of the trade and allow sufficient preparation time for the implementation of GMP, the Department of Health is collecting opinions from the trade with a view to understanding their needs and difficulties encountered in the implementation of GMP.

The Licensing Arrangement of Chinese Herbal Medicines Trade Show Licence

Many CHM trade shows have been held in Hong Kong over recent years. The Medicines Board believes that the arrangements of selling CHM in a mobile manner is in general unfavourable to effective monitoring and is not desirable in the public interest. Therefore, retailing of CHM in mobile premises by Chinese medicines traders is not encouraged. Pursuant to the spirit of the Chinese Medicine Ordinance, and to facilitate traders to take part in Chinese medicines trade shows, the Medicines Board has formulated "The Licensing Arrangement of Chinese Herbal Medicines Trade Show Licence". If a Chinese medicines trader retails CHM, he/she must apply to the Medicines Board for a "retailer licence in Chinese herbal medicines (trade show)". The applicant should hold a retailer or wholesaler licence in CHM, or a wholesaler or manufacturer licence in pCm. The CMTC would process the applications and applications for renewal of the licences under the delegated authority from the Medicines Board. The "Licensing Arrangement of Chinese Herbal Medicines Trade Show Licence" has been uploaded to the Council's website for reference of the trade.

The Import and Export Control of Chinese Medicines

Starting from 11 January 2008, an application of an import/export licence should be submitted to the Chinese Medicines Section, Chinese Medicine Division of the Department of Health for any import or export of the 31 types of Schedule 1 CHM and 5 types of Schedule 2 CHM (including Flos Campsis, processed Radix Aconiti, processed Radix Aconiti Kusnezoffii, Radix Clematidis and Radix Gentianae) stipulated in the Chinese Medicine Ordinance. The applicants should either be a licensed wholesaler in CHM or a licensed manufacturer in pCm. Besides, starting from the aforesaid date, applicants of import/export licences of pCm should also either be a licensed wholesaler or a licensed manufacturer in pCm. The relevant regulations and guidelines have been uploaded to the Council's website for reference of the trade.

The implementation of the above requirements will enhance the regulation of Chinese medicines traders, strengthen the control over the dispensing, possession and sale of CHM, and facilitate a more

effective monitoring of the origins and destinations of the CHM and pCm imported to, and exported from, Hong Kong. All these measures will further protect public health and enable the public to purchase Chinese medicines of good quality from licensed Chinese medicines traders. This will also foster the development of Chinese medicine in Hong Kong, and enhance Hong Kong's status in Chinese medicine internationally.

System for Registration of Proprietary Chinese Medicines

The system for registration of pCm was implemented in December 2003. Any pCm manufactured, imported or possessed in Hong Kong must be registered with the Medicines Board. The pCm registration system is a very important measure in regulating the manufacture of pCm. It ensures the quality and efficacy of pCm, promotes consumers' safe use of pCm, and protects the health of the public. The definition of a pCm is set out in section 2 of the Chinese Medicine Ordinance.

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 manufactured outside Hong Kong, the application should be made by the importer, or by the local agent or representative of the manufacturer. After approval is given, the applicants will be issued with a "Certificate of Registration of pCm", valid for five years, and renewable upon expiry.

Transitional Registration of Proprietary Chinese Medicines

To enable the continued sale and manufacture of existing pCm, an arrangement of transitional registration was provided under the Chinese Medicine Ordinance. Provided that an application was made within the period for transitional registration (i.e. 19 December 2003 to 30 June 2004), a pCm manufactured or sold in Hong Kong as at 1 March 1999 would be issued with a "Notice of confirmation of transitional registration of pCm" valid until the pCm is formally registered, or until the refusal of its application for registration, or until a date to be promulgated by the Secretary for Food and Health (whichever date is the earliest).

By 31 December 2012, the Medicines Board received some 17,560 applications for registration, among which about 14,170 applied for transitional registration at the same time. The remaining some 3,390 are applications for non-transitional registration. The Medicines Board finished processing all applications for transitional registration. With a view to speeding up the processing procedures, the Medicines Board has delegated the authority to approve non-transitional applications to the Chinese Medicines Committee (CMSC).

Since March 2008, the Medicines Board has been issuing a "Notice of confirmation of transitional registration of pCm" to applicants of products confirmed to be eligible for transitional registration of pCm. By 31 December 2012, the Medicines Board issued some 8,990 "Notice of confirmation of

transitional registration of pCm”.

With the complete processing of all applications for transitional registration of pCm by the Medicines Board, the legislative provisions on mandatory registration of pCm in the Chinese Medicine Ordinance commenced on 3 December 2010. Upon commencement of the legislative provisions, any person who sell, import or possess any unregistered pCm in Hong Kong will be an offence and shall be liable to a fine at level 6 (i.e. \$100,000) and imprisonment for two years.

Starting from November 2010, the Medicines Board has issued a “Certificate of registration of pCm” for product meeting the safety, quality and efficacy requirements of the Medicines Board. By the end of December 2012, 306 of such certificates have been issued.

Labels and Package Inserts of Registered Proprietary Chinese Medicines

The provisions of the Chinese Medicine Ordinance related to mandatory registration of pCm were commenced on 3 December 2010. In general, the commencement was smooth and well-supported by the general public, traders and stakeholders. The provisions relating to the requirements of labeling and package inserts of pCm were commenced on 1 December 2011, and this made the regulatory regime more comprehensive and enhanced. As stipulated in the Chinese Medicine Ordinance and the Chinese Medicines Regulation, apart from some prescribed packages, pCm shall have a proper label which contains at least the following nine particulars:

- (a) the name of the medicine;
- (b) the name of each kind of active ingredient (all the names of each kind of active ingredient should be listed if the medicine is composed of less than three kinds of active ingredients; more than half of the total number of kinds of active ingredients should be listed if the medicine is composed of three or more kinds of active ingredients);
- (c) the name of the country or territory in which the medicine is produced;
- (d) the registration number of the medicine as specified in its certificate of registration;
- (e) (for outermost package) the name of the holder of the certificate of registration, or (for package other than outermost package) the name of the holder of the certificate of registration / the name of the manufacturer who produces the medicine;
- (f) packing specification;
- (g) dosage and method of usage;
- (h) expiry date; and
- (i) batch number.

According to the Chinese Medicine Ordinance and the Chinese Medicines Regulation, apart from pCm intended for export only, pCm should have a proper package insert which contains at least the following 12 particulars:

- (a) the name of the medicine;

- (b) the name of each kind of active ingredient and its quantity (all the names of each kind of active ingredient and its quantity should be listed if the medicine is composed of less than three kinds of active ingredients; more than half of the total number of kinds of active ingredients and their respective quantities should be listed if the medicine is composed of three or more kinds of active ingredients);
- (c) the name of the holder of the certificate of registration or the name of the manufacturer who produces the medicine;
- (d) dosage and method of usage;
- (e) functions or pharmacological action;
- (f) indications (if any);
- (g) contra-indications (if any);
- (h) side-effects (if any);
- (i) toxic effects (if any);
- (j) the precautions to be taken regarding its use (if any);
- (k) storage instructions; and
- (l) packing specification.

Exemptions for Proprietary Chinese Medicines Compounded by a Chinese Medicine Practitioner or According to Prescription Given by a Chinese Medicine Practitioner

In accordance with section 36 of the Chinese Medicines Regulation, the requirements for label and package inserts shall not apply in pCm which is compounded by or under the supervision of a registered or listed CMP at the premises where he/she practises, and only if, such pCm is being used for the purpose of administering or supplying to a patient under his/her direct care. In addition, exemption for label and package insert shall be given to pCm individually prepared or compounded by a responsible person of a licensed retailer of CHM in accordance with a prescription given by a registered or listed CMP.

Labeling Requirement for Proprietary Chinese Medicines Entrusted by a Chinese Medicine Practitioner to be Manufactured by Licensed Manufacturers

According to section 26(4) of the Chinese Medicines Regulation, if a CMP entrusts a licensed manufacturer of pCm to manufacture pCm for internal application; both internal and external application; or external application only, and gives to patient under his/her direct care, the pCm can be exempted from providing a package insert, but a label on the package of the pCm should include the following particulars:

- (a) the name and address of the CMP;
- (b) the name and address of the manufacturer who produces the medicine;
- (c) its batch number;
- (d) the date on which it is produced;

- (e) its dose form;
- (f) its packing specification;
- (g) its expiry date;
- (h) the name and quantity of each ingredient listed in the prescription;
- (i) a statement containing the following Chinese text – “須按照中醫指示使用” ; and
- (j) if the pCm is indicated for internal; or both internal and external application, a statement containing the following Chinese text – “只供中醫施用於或供應予獲開給本成藥的處方,並且是由他直接治理的病人” ; or if the pCm is indicated for external application only, statements containing the following Chinese text – “只供中醫施用於或供應予由他直接治理的病人” and “只供外用” .

CMPs should pay attention that if the pCm, be it self-manufactured or manufactured by manufacturers, is for sale in the market, the pCm should be registered by fulfilling the safety, quality and efficacy requirements and by complying with the requirements for label and package inserts of pCm. The provisions of the Chinese Medicine Ordinance and the Chinese Medicines Regulation are available on www.legislation.gov.hk.

Enforcement Arrangement upon the Commencement of the Provisions Related to the Requirements for Labeling and Package Inserts of Proprietary Chinese Medicines

Having considered the current operation of the Chinese medicines trade, the Medicines Board decided upon the commencement of the provisions related to the requirements for labeling and package inserts of pCm on 1 December 2011 that, if a pCm is found in violation of the legislative requirements, the Department of Health will require the trader concerned to cease selling that pCm, and issue warning letter to the trader, provided that no hazard to public health will be caused. However, the Department of Health may take prosecution action against serious offense. The pCm, after rectification, complies with the requirements for labeling and package insert would be approved for resumption of sale. The legislative provisions have commenced for over one year. The above enforcement policy is being reviewed with due consideration to the compliance of provisions of the trade.

Advice of Panel for Registration of Proprietary Chinese Medicine

The processing of the applications for pCm registration involves professional and technical evaluation in many aspects. Therefore, the Medicines Board has invited Chinese medicine advisors to provide professional and technical advice on various technical questions, including the formulation of prescriptions, pharmaceuticals, pharmacology, toxicology and clinical applications.

Classification Categories and Registration Groups of Proprietary Chinese Medicines

The requirements for registration of a pCm are subject to the classification category of the pCm under application, and the registration group selected by the applicant.

Proprietary Chinese medicines are registered under three classification categories, namely – (1) established medicines, (2) non-established medicines and (3) new medicines.

Established Medicines

Except for Chinese medicine injections, a pCm that fulfills any of the following shall be regarded as an established medicine:

- (a) Its prescription is:
 - (i) an ancient prescription (which has been documented in Chinese medicines bibliography in, or before, the Qing dynasty); or
 - (ii) a modified ancient prescription (the prescription of which is based on an ancient prescription, with reasonable and rational modifications); or
 - (iii) a pharmacopoeia prescription (which has been documented in the Pharmacopoeia of the People's Republic of China); or
 - (iv) any other prescriptions originating from the National Drug Standards of the People's Republic of China, and accepted by the Medicines Board.

The original dose form of the prescription should not be changed, otherwise the pCm will be regarded as new medicine (except for those ancient prescriptions, provided that their principal manufacturing method remains unchanged).

- (b) it is made from single Chinese herb, its claimed indications and functions are the same as its crude drug (except Single Chinese medicine granules).

The Medicines Board will adopt the following principles in deciding whether to accept a prescription originating from the National Drug Standards of the People's Republic of China as established medicines:

- (a) Accept only the latest promulgated standard of the prescription. For example, if a prescription is documented in both the Drug Standard of the Ministry of Health and the Pharmacopoeia of the People's Republic of China, the Medicines Board will only accept the prescription in the current edition of the Pharmacopoeia.
- (b) Consider the current use of the prescription. For example, the Medicines Board will not accept any Drug Registration Standards that have been withdrawn because of safety concerns.
- (c) The product specification of the pCm must fulfill the requirements imposed by the Medicines

Board.

If the prescription of a registered pCm (including transitional registration) is required to be amended in accordance with the country/district for sale, such pCm is required to be registered again. Moreover, if the manufacturer can provide the following evidence, the pCm can be regarded as “Established medicines”:

- (a) the amendment is according to the requirement or regulation of the country/district for sale;
- (b) the amendment is made to the prescription of a pCm that is qualified for transitional registration, transitionally registered or registered; and
- (c) the amendment does not affect the pharmacodynamic and pharmacological effects of the product. For example, the principal and assistant drug(s) shall not be changed.

Non-established Medicines

Non-established medicines include health-preserving medicines and other medicines. Except for Chinese medicine injections, any pCm which are used for the purpose of regulating the functional states of the human body shall be regarded as health-preserving medicines in the non-established medicines category. However, the prescription of the health-preserving medicines should not contain any newly-discovered CHM; new medicinal part(s) of Chinese herb; active group extracted from CHM; or set of active groups extracted from a compound prescription. Otherwise, the pCm will be required to be registered under the new medicines category. Single Chinese medicine granules are those granules that fall within the definition of a pCm, and are made from single CHM, and their claimed indications and functions are the same as for those of their crude drugs.

New Medicines

Proprietary Chinese medicines that meet any of the following descriptions shall be regarded as new medicines:

- (a) its prescription comprises any one (or several) of the following:
 - (i) a newly-discovered CHM;
 - (ii) a new medicinal part of a Chinese herb;
 - (iii) an active group extracted from a Chinese herb;
 - (iv) a set of active groups extracted from a compound prescription;
- (b) Chinese medicine injection;
- (c) preparation of a new Chinese medicine prescription;
- (d) pCm with altered route of administration;
- (e) pCm with new indication; and
- (f) pCm with altered dose form.

According to section 122 of the Chinese Medicine Ordinance, the Medicines Board shall, in

determining an application for pCm registration, take into consideration the safety, quality and efficacy of the product. The applicants for pCm registration should provide information on these three aspects, to enable the Medicines Board to make an appropriate assessment. Following extensive consultations with the trade, the Medicines Board adopted a three-group registration system, i.e. Groups I, II and III. Applicants should provide information on the safety, quality and efficacy of the pCm, according to the different registration groups. For pCm in the “Established medicines category” and “Non-established medicines category”, applicants may choose to apply for registration in any of the three groups. However, for pCm in the “New medicine category” (as their compositions, routes of administration, indications or dose forms are different from traditional medicines), scientific evidence is required to prove their safety and efficacy. They may only apply for Group III registration, and need to fulfill the necessary requirements. The details are set out in the “Application Handbook for Registration of Proprietary Chinese Medicines”.

Information on Safety

Basic safety information to be provided by applicants for registration of pCm includes: heavy metals and toxic element test reports, pesticides residue test reports, and microbial limits test reports. Depending on the registration group, additional toxicity test reports, and other test reports, may also need to be provided.

Information on Efficacy

The information on efficacy to be provided by the applicants for pCm registration includes interpretation and principle of formulating the prescription, descriptions of the properties, flavours, channel tropism, functions, indications, and compatibility of the medicines, and analysis of the prescriptions and their clinical applications. Depending on the classification category and the registration group, reference materials on product efficacy, study reports, and/or clinical trial protocols and summary reports may also need to be provided.

Information on Quality

The basic information on product quality to be provided by applicants for registration of a pCm includes the manufacturing method, the physiochemical properties of the crude drugs the product specifications; the method and certificate of analysis and the stability test report.

Non-adulteration with Western Medicines and Compliance with the Protection of Endangered Species of Animals and Plants Ordinance and Undesirable Medical Advertisements Ordinance

In addition to fulfilling the product safety, efficacy and quality requirements, the applicants for pCm registration are required to declare in the application form that the pCm concerned comply with the requirements of the Protection of Endangered Species of Animals and Plants Ordinance (Cap. 586)

and that they are not adulterated with Western medicines. The pCm should also comply with the Undesirable Medical Advertisements Ordinance (Cap. 231), and other laws.

Test of Proprietary Chinese Medicines

The Medicines Board also regulates the required standards of the laboratories conducting the safety tests, quality tests, and efficacy tests, to ensure that such testing processes meet international standards. The laboratories must meet the requirements set by the International Standards Organization (i.e. ISO/IEC 17025), Good Laboratory Practice, and Good Clinical Practice. Any other laboratories that are recognized by the Medicines Board will also be accepted.

Several laboratories in Hong Kong have been accredited for conducting pCm tests. In addition, the Medicines Board also accepts test reports submitted by the 17 municipal institutes for drug control, which are recommended by the Food and Drug Administration of the People's Republic of China. The relevant information has been uploaded to the Council's website (www.cmchk.org.hk).

To facilitate the conduct of pCm testing and clinical tests, the Medicines Board developed three sets of technical guidelines on product safety, efficacy and quality tests, for the reference of the trade. The Medicines Board also developed the "Good Clinical Practice for Proprietary Chinese Medicines" guidelines, to provide guidance to the relevant institutions in conducting clinical tests. Considering the practical circumstances of the trade, and in particular the quality of products manufactured by GMP manufacturers, the Medicines Board also accepts test reports produced by the GMP manufactory where the pCm are produced, subject to the condition that the test of the first batch of products must be conducted by a recognized laboratory. The relevant technical guidelines are available on the Council's website (www.cmchk.org.hk).

Requirements on Submission of Information for Registration of Proprietary Chinese Medicines

Non-transitional Registration

For pCm for which non-transitional registration is applied, all the registration documents must be submitted at the time of application. However, if the relevant products were manufactured, or sold, in Hong Kong before 19 December 2003, the applicants may submit the product quality standards, testing methods and test reports, stability test reports and toxicity test reports, with their application for renewal of registration.

Transitional Registration

For pCm eligible for transitional registration, the necessary registration information can be submitted to the Medicines Board in phases. The safety reports including the test reports on (i) heavy metals and toxic elements; (ii) pesticide residues; and (iii) microbial limits, were required to be submitted by 30

June 2005. In December 2005 the Department of Health notified those applicants who were unable to submit those three safety reports in time that their applications would not be processed further. Even if they submitted the reports later, there was no guarantee that their applications would be approved before the implementation of section 119 of the Chinese Medicine Ordinance, and the pCm concerned might have to be recalled. The Department of Health has not issued import licences to such pCm after 1 April 2006.

Applicants should also submit the remaining information of their products by 30 June 2009, for example the certificate of analysis of product specification documents and general stability test reports under the product quality document requirements. If the information required for registration is complete and fulfills the requirements, the Medicines Board would start processing applications for non-transitional (formal) registration as soon as practicable. If an applicant could not submit the required information and test reports by the said deadline but could provide evidence that the relevant tests have been commenced or reasonable justifications for not submitting the required information and test reports, the Medicines Board would consider on a case-by-case basis.

To protect the public health and uphold the principle of fairness, and to avoid delay to the registration process, the Medicines Board may consider not to process further the relevant applications, or to refuse the applications for registration in accordance with section 121 of the Chinese Medicine Ordinance, if the applicants are unable to submit the product quality information, or documents, in accordance with the arrangements set out above.

Random Tests of Proprietary Chinese Medicines

The Department of Health conducts tests on pCm sold on the market on a regular and random basis, and closely monitors any adverse drug reactions caused by pCm. If a registered pCm is found to be injurious to the health of the public, the Medicines Board will cancel its registration and the relevant Chinese medicines trader would have to recall the pCm from the market.

Use of Terms Implying Chinese Medicine Practice in the Chinese Medicines Trade

Name

To prevent those Chinese medicines traders, who at the same time practice Chinese medicine, from contravening the Code of Conduct for CMPs regarding the promotion of their practice, the Medicines Board formulated guidelines on the use of business names implying the practice of Chinese medicine, having regard to the practical circumstances. The guidelines are available at the Council's website and they have also been distributed to the traders, as a reminder of the need to comply with the Code of Conduct in using trade names to promote their Chinese medicines business.

Maintaining Confidentiality of Information related to Registration of Proprietary Chinese Medicines

The traders are very concerned about the confidentiality of the prescriptions of their products. The Medicines Board has exercised meticulous care to guard against leakage of the relevant information. According to section 154 of the Chinese Medicine Ordinance, no public officer, or member of the council, boards or committees shall, except in prescribed special circumstance, disclose or give to another person any information that concerns a trade, business or manufacturing secret which has come to his/her knowledge or into his/her possession in the course of the discharge of his/her functions under the Chinese Medicine Ordinance. Otherwise, he/she commits an offence. Moreover, under the system for declaration of interests, any member of the Medicines Board or its committees who has an interest in the subject matter would normally be excluded from taking part in considering an application. The traders are only required to publish some of the active ingredients of the pCm on the label on its package, and the package insert, under the requirements of the Chinese Medicines Regulation but they must submit the information on all the ingredients and excipients of the pCm product, when they submit a registration application.

Processing of Certificate for Clinical Trial and Medicinal Test

In accordance with section 129 of the Chinese Medicine Ordinance, for the purpose of conducting a clinical trial or medicinal test of any pCm, the Medicines Board may, upon application, issue a Certificate for clinical trial and medicinal test (the Certificate). By providing the documents, information, samples and other materials to the Medicines Board and paying a prescribed fee, the Medicines Board may issue the Certificate and impose conditions as the Medicines Board thinks fit. The relevant application guidelines and application form have been uploaded to the Council's website. All education and scientific research institutions have also been informed in writing separately.

Section 129 of the Chinese Medicine Ordinance came into effect on 3 December 2010. The Medicines Board has delegated the function of processing the applications for the Certificate to the CMSC. Any person aggrieved by the CMSC's decision may request the Medicines Board to review the decision within 14 days after the receipt of the notification of decision by stating the reasons relied upon according to section 140 of the Chinese Medicine Ordinance.

Separately, in accordance with section 158(5)(b) of the Chinese Medicine Ordinance, the pCm imported by a holder of the Certificate issued under section 129 and to be used for the purposes of the clinical trial or medicinal test to which the Certificate relates can be exempted from registration.