

Chapter 3

Regulation of Chinese Medicines

In order to ensure the safe use of Chinese medicines, the Council implemented the systems for licensing of CMTs and registration of pCm in April and December 2003 respectively. These measures not only serve to better protect the general public, but also enhance the confidence of the public in using Chinese medicines.

To fully effect the licensing and control regime for CMTs, the provisions governing the control over the possession, sale, import and export of CHM, and over the manufacture, sale by way of wholesale, import and export of pCm under the Chinese Medicine Ordinance and Chinese Medicines Regulation commenced on 11 January 2008. The commencement of the legislative provisions has enhanced the regulation of CMTs and facilitated a more effective monitoring of the origins and destinations of the CHM and pCm imported to, and exported from, Hong Kong. All these measures have enabled the public to purchase Chinese medicines of good quality from licensed CMTs and further protected public health.

With a view to stepping up the regulation of Chinese medicines, the legislative provisions regarding the mandatory registration of pCm (section 119) and clinical trials and medicinal test (section 129) 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 (section 143 and section 144) came into force on 1 December 2011. Implementation of the legislative provisions regarding the mandatory registration of pCm has made the regulation of pCm more comprehensive, meeting the public's expectation over drug safety. The commencement of these provisions has also provided a legal basis for combating the sales of unregistered pCm, and has boosted public confidence in Chinese medicines, thereby fostering the development of Chinese medicines in Hong Kong.

Licensing of Chinese Medicines Traders

Under the system for licensing of CMTs, 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 Medicines Board under the Council. 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; as well as 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; as well as 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 wholesale trade in pCm in all other respects.

The licensing requirements for pCm manufacturers include: sanitary premises; adequate space as well as 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 CMTs who were already conducting their Chinese medicines businesses on 3 January 2000 to continue to carry on their businesses, a system of transitional licensing was provided under the Chinese Medicine Ordinance. CMTs who were operating their businesses in Chinese medicines as on 3 January 2000 were eligible for application of a Chinese medicines trader transitional certificate¹. 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 CMTs licences will be issued with such licences only if they have fulfilled the requirements stipulated in the Chinese Medicines Regulation and the licensing requirements stipulated by the Council. To expedite the processing of applications for CMTs 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 CMTs, including the inspections of the trading premises and the preparation of the inspection reports. After considering relevant information, the CMTC would decide whether or not to

approve such applications.

Since April 2003, the Medicines Board has received a total of 18,315 applications for traders licences, among which 4,169 also applied for transitional certificates at the same time. The remaining 14,146 are non-transitional licence applications. The assessment of all applications for transitional certificates was completed. As at 31 December 2020, there were a total of 7,583 holders of CMTs licences issued by the Medicines Board and 194 applications are being processed. The number of licensed CMTs is illustrated in Table 5 on page 116.

► CMTs Shall Not Operate at 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, had decided that it was not suitable for CMTs to conduct Chinese medicines business at domestic premises. Hence, starting from June 2011, the Medicines Board would not accept any new application for licences operating at domestic premises (premises which are constructed or intended to be used for habitation). Having considered that a number of licensed CMTs were still carrying out their business at domestic premises, the Medicines Board had allowed sufficient time for the traders concerned to find and/or relocate to suitable premises to continue their business. The grace period started from 1 January 2012 and lasted until 31 December 2013; or the date of enforcement action against operation of business at domestic premises taken by the Buildings Ordinance,

¹ Processing of all Chinese medicines trader transitional certificates had been completed and converted into licenses.

whichever is the earlier. No CMTs can conduct business of Chinese medicines at domestic premises after 31 December 2013.

► Chinese Medicines Regulation and Practising Guidelines for CMTs

The Chinese Medicines Regulation stipulates the specific measures on the regulation of Chinese medicines, such as licensing requirements, duties of licensed CMTs, and particulars to be registered for pCm. Apart from the statutory provisions, the Medicines Board also compiled four sets of practising guidelines, namely “Practising Guideline for Retailers of Chinese Herbal Medicines”, “Practising Guideline for Wholesalers of Chinese Herbal Medicines”, “Practising Guideline for Manufacturers of Proprietary Chinese Medicines”, and “Practising Guideline for Wholesalers of Proprietary Chinese Medicines”, 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 changing circumstances. In November 2017, the Medicines Board endorsed the amendment to section 5.4.1 of the “Practising Guideline for Retailers of Chinese Herbal Medicines” on inspection and acceptance of processed herbal medicines. With the amendment, it is acceptable for CHM retailers to record CHM batch numbers on documents other than purchase invoices to achieve prompt traceability of batches when required. The relevant amendment took effect on 1 January 2018. The regulation on online sale of CHM became effective on 1 December 2018, and relevant provisions were included in the “Practising Guidelines for Retailers of Chinese Herbal Medicines” and the “Practising Guidelines for Wholesalers of Chinese Herbal Medicines” in the form of appendices. In addition, after considering the characteristics of Arsenic hyperaccumulator plant Herba Pteridis Multifidae, the market circulation and use

of CHM Herba Pteridis Multifidae and pCm containing Herba Pteridis Multifidae, and the potential health risk of taking high concentration of Arsenic, the Medicines Board endorsed the strengthening regulation of CHM Herba Pteridis Multifidae on 19 September 2019. The regulation restricts CHM wholesalers and pCm manufacturers that they shall ensure each batch of Herba Pteridis Multifidae obtained is tested and confirmed to be in compliance with the limit set by the CMCHK in respect of Arsenic content before it may be sold or used for manufacture pCm. The regulation took effect on 1 December 2019, and relevant provisions were included in the “Practising Guidelines for Wholesalers of Chinese Herbal Medicines” and the “Practising Guidelines for Manufacturer of Proprietary Chinese Medicines” in the form of appendices.

► The System for the Regulation of CMTs

The licensed CMTs 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 2020, the CMRC received 267 complaints against licensed CMTs. These complaints were mainly concerned with conviction of offence(s) punishable with imprisonment by CMTs violating the practising guidelines; and matters related to the personnel and the scope of business of retailers in CHM, wholesalers in CHM, wholesalers in pCm and manufacturers in pCm. Apart from cases which could not be further processed, comprising 4 cases in which the complainants withdrew their complaints, 13 cases in which the complainants had not made a statutory declaration and 23 cases of which the licences of the traders concerned expired or the traders concerned closed down the business, the Medicines Board had considered 216 cases. Of the remaining 11 cases, 7 cases had been considered by CMRC and pending consideration by the Medicines Board, and 4 cases were pending consideration by CMRC. The statistics of the complaints against licensed CMTs are illustrated in Table 6 on page 116 to 119.

► Exemption of CMPs 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 manufactures 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.

► Recall Guidelines for Chinese Medicine Products

Chinese Medicine (Amendment) Bill 2017 (the Bill) was passed by the Legislative Council on 29 March 2018. The Bill was gazetted on 6 April 2018 and came into operation on the same day. The Director of Health was empowered to make the Chinese medicine safety order on the grounds stipulated in the Chinese Medicine Ordinance to prohibit the sale and/or direct to recall the problematic CHM, pCm and/or intermediate product in order to safeguard public health. According to the Chinese Medicines Regulation, wholesalers of CHM or pCm, and manufacturers of pCm, are required to set up and maintain a recall system. This is to enable the rapid and, as far as practicable, complete recall of any CHM, pCm and/or intermediate product sold, or distributed. To assist the CMTs in setting up an effective system of recall, the Medicines Board has formulated the “Recall Guidelines for Chinese Medicine Products” to provide guidance to the trade.

► Good Manufacturing Practice in respect of pCm

To enhance the quality management of pCm manufacturing industry in Hong Kong, the Chinese Medicine Ordinance stipulates that a pCm manufacturer who follows the requirements of 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) (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, premises, equipment, documentation, validation, manufacturing management, quality control, and product recall. Up to 31 December 2020, the Medicines Board issued 21 GMP Certificates. The relevant

information has been uploaded to the Council's website (www.cmchk.org.hk).

To implement the policy of working out a timetable for mandatory compliance with the GMP for the manufacture of pCm, the Medicines Board has conducted a thorough discussion and recommended the adoption of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP as a licensing criterion for local manufacturers of pCm. To cater for the actual operational needs of the trade and allow the trade to have sufficient time to prepare for the implementation of GMP, the Department of Health will continue to collect opinions from the trade, with a view to thoroughly understanding their difficulties and needs encountered before the Medicines Board draws up the timetable for implementation of GMP.

► The Licensing Arrangement of CHM Trade Show Licence

Many CHM trade shows have been held in Hong Kong over recent years. The Medicines Board believes that the way 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 CMTs is not encouraged. However, in order 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 puts CHM on retail sale at a trade show, 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 relevant applications for renewal of 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 Management Division, Chinese Medicine Regulatory Office of the Department of Health for any import or export of the 31 types of Schedule 1 CHM or five 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 applicant should either be a licensed wholesaler in CHM or a licensed manufacturer in pCm. Besides, starting from the aforesaid date, an applicant of import/export licences of pCm should also 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 would enhance the regulation of CMTs, 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 would enable the public to purchase Chinese medicines of good quality from licensed CMTs and further protect public health. This would also facilitate the future development of Chinese medicine in Hong Kong, and enhance Hong Kong's status in Chinese medicine internationally.

► Online Sale of CHM

Starting from 1 June 2018, retailers or wholesalers in CHM who wish to conduct online sale of CHM must apply to the Medicines Board with specified website. If the application is approved, the website will be listed on the retailer or

wholesaler licence in CHM. The traders concerned are only allowed to conduct online sale of CHM through the website specified on the licences. The CHM sold through the website must also be supplied from the premises specified in the licences.

Relevant provisions of the regulatory measures had been included in the “Practising Guidelines for Retailers of Chinese Herbal Medicines” and the “Practising Guidelines for Wholesalers of Chinese Herbal Medicines” in the form of appendices on 1 December 2018. If a Chinese medicines trader operates online sale of CHM without the approval of the Medicines Board, it will be considered as failing to comply with the practising guidelines and the case will be referred to the Council for consideration of disciplinary action. Information of approved websites for online sale of CHM has been published on the Council’s website.

► External Packing of pCm

Since 1 March 2017, any person who wishes to engage in the business of external packing of pCm must apply for the manufacturer licence in pCm (external packing). External packing is a manufacturing process involving the labelling, re-labelling, cartoning, re-cartoning or adding supplementary information (including inserts) to pCm which are already enclosed in the container in which they are to be sold or supplied. The Medicines Board has set a grace period of two and a half years (i.e. from 1 March 2017 to 31 August 2019). After 31 August 2019, no person (including licensed wholesaler in pCm) shall conduct external packing unless holding a relevant licence. Otherwise, it will be regarded as illegal manufacturing of pCm and the Department of Health will conduct enforcement action accordingly.

System for Registration of pCm

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 safeguards the quality and efficacy of pCm and ensures consumers’ safe use of pCm, thereby protecting 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 pCm

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”, with a validity period of five years, and can apply for renewal of registration according to prescribed requirements.

► Transitional Registration of pCm

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, if eligible, 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).

As at 31 December 2020, the Medicines Board received some 18,200 applications for registration, among which about 14,100 applied for transitional registration at the same time. The remaining some 4,100 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) under it.

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. As at 31 December 2020, there were 5,585 pCm issued with “Notice of confirmation of transition registration of pCm” by the Medicines Board.

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 sells, imports or possesses 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 2020, 2,668 of such certificates were issued.

► Labels and Package Inserts of Registered pCm

The provisions of the Chinese Medicine Ordinance relating to the mandatory registration of pCm 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 label and package insert of pCm commenced on 1 December 2011, and this made the regulatory regime more comprehensive and consolidated. 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/ 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 pCm Compounded by a CMP or According to Prescription Given by a CMP

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.

► Labelling Requirements for pCm Entrusted by a CMP 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.elegislation.gov.hk.

► Enforcement Arrangement upon the Commencement of the Provisions Related to the Requirements for Label and Package Insert of pCm

Having considered the actual operation of the Chinese medicines trade, the Medicines Board decided upon the commencement of the provisions related to the requirements for label and package insert of pCm on 1 December 2011 that, if a pCm is found in violation of the label and package insert 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 cases involving serious offence. Resumption of sale will only be allowed when the pCm, after rectification, is found to be in compliance with the requirements for label and package insert. The above enforcement arrangements have been reviewed after the first, the second, and the third year of implementation of the legislative provisions respectively. In general, the implementation of the legislative provisions was well received by the community and the trade. The majority of the pCm complied with the legal requirements. The Medicines Board agreed to continue with the existing enforcement arrangements and subsume the active surveillance of CMTs under the prevailing market surveillance mechanism, and to continue with the related publicity and educational work.

► Advice of Panel for Registration of pCm

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 pCm

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.

There are three classification categories for pCm registration, 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 those of their crude drugs.

New Medicines

Any pCm 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. 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 applicants for pCm registration includes interpretation and principle of formulating the prescription, in which descriptions of the properties, flavours, channel tropism, functions, indications, and compatibility of the medicines, and analysis of the prescriptions and their clinical applications should be illustrated. Depending on the classification category and the registration group, reference materials on product efficacy, study reports, 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 Other Legal Requirements

In addition to fulfilling the product safety, efficacy and quality requirements, 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.

► Testing of pCm

The Medicines Board also sets the standards required for laboratories conducting safety, quality and efficacy tests in order to ensure that such testings will meet the required level of standards. Laboratories conducting these tests must meet requirements set by the International Organization for Standardization (i.e. ISO/IEC 17025), Good Laboratory Practice or have been recognised by the Medicines Board.

Currently, a total of 10 local laboratories have been accredited to meet the standards for conducting tests on pCm. In addition, the Medicines Board also accepts test reports issued by the 27 Institutes for Drug Control recommended by the National Medical Products Administration. Relevant information has been uploaded onto the Council's website.

In order to facilitate the conduct of pCm testing and

clinical trials, the Medicines Board has developed three sets of technical guidelines on product safety, efficacy and quality as reference for the trade. The Medicines Board also developed the “Good Clinical Practice for Proprietary Chinese Medicines” document as guidance to relevant organisations in the conducting of clinical trials. Having considered the practical operations of the trade and that the quality of products manufactured by GMP manufacturers should have guaranteed standards, the Medicines Board also accepts test reports issued by GMP manufacturers where the pCm concerned are produced provided that the first of the 3 batches of the required stability test reports is conducted by a recognised laboratory. The relevant technical guidelines are available on the Council’s website.

► Requirements on Submission of Information for Registration of pCm

Non-transitional Registration

For pCm applying for non-transitional registration, all the registration documents must be submitted at the time of application, including the general information, safety information, efficacy information and quality information. However, if the relevant products were manufactured, or sold, in Hong Kong before 19 December 2003, the applicants may submit the assay of the product specifications, testing methods and test reports, and stability test reports at the time of 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. Amongst others, applicants were required to submit the basic testing information, including test reports on (i) heavy metals and toxic elements; (ii) pesticide residues; and (iii) microbial limits by 30 June 2005.

Besides, applicants should also submit the remaining information of their products by 30 June 2009 and 30 June 2013 respectively, for example the certificate of analysis of product specification documents and general stability test reports under the product quality document requirements. Having considered the practical circumstances and views of the trade, the Medicines Board postponed the submission deadline from 30 June 2013 to 30 June 2015. On 12 November 2015, the Chinese Medicines Committee under the Medicines Board issued letters for refusal of application for registration to applicants who could not submit the above-mentioned quality reports or provide sufficient justification (for example, objective information indicating tests being conducted by concerned laboratories), refusing the applications for registration of the products. The transitional registration of the concerned products had also expired on 17 November 2015.

In view of the practical circumstances of submission of registration documents by the applicants and the feedback from the trade, the Medicines Board adjusted the requirements for conversion of transitional registration to formal registration in May 2014 and July 2016 with a view to expediting the processing of the related applications. The adjusted arrangements mainly focus on the following five aspects:

- (a) the name of the pCm;
- (b) general documents: product sample and prototype sales pack, master formula;
- (c) product efficacy documents: interpretation and principle of formulating a prescription;
- (d) product quality documents: manufacturing method, physicochemical properties of crude drugs, product specification, method and certificate of analysis, general stability test report; and
- (e) change of particulars of the manufacturer: adjust the requirements for re-submission of documents.

► **Monitoring System of Chinese Medicines Sold on the Market**

The Department of Health conducts tests on pCm and CHM sold on the market on a regular and random basis, and closely monitors any adverse drug reactions due to the use of pCm. If a registered pCm or CHM is found to be injurious to the health of the public, the relevant Chinese medicines trader will have to recall it from the market. Apart from contemplating disciplinary inquiries against the registration holder or Chinese medicines trader concerned, the Medicines Board will also consider de-registering the pCm.

► **Use of Terms Implying Chinese Medicine Practice in the Chinese Medicines Trade Name**

To prevent those CMTs, who at the same time practise Chinese medicine, from contravening the Codes 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 Codes of Conduct in using trade names to promote their Chinese medicines business.

► **Maintaining Confidentiality of Information Related to Registration of pCm**

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 circumstances, 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. In addition, the traders must submit information on all the active ingredients and excipients of the product when they submit a registration application. However, they are only required to display information of the active ingredients of the pCm on the label and the package insert in accordance with the requirements of the Chinese Medicines Regulation.

► **Processing of Certificates 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, application may be made to the Medicines Board for a Certificate for Clinical Trial and Medicinal Test (the Certificate). After submission of the documents, information, samples and other materials as required by the Medicines Board and paying the prescribed fee, the Medicines Board may issue the Certificate to the applicant and impose conditions thereon as it thinks fit.

Section 129 of the Chinese Medicine Ordinance came into effect on 3 December 2010 and the Medicines Board has delegated the function of issuing the Certificate to the CMSC. If the applicant is aggrieved by CMSC's decision, he/she may, in accordance with section 140 of the Chinese Medicine Ordinance, request the Medicines

Board to review the decision stating the reasons relied upon within 14 days of receipt of the notification of the decision.

For more effective management of clinical trials of pCm and promoting the development of scientific research on pCm, the Medicines Board has formulated the “Guidance Notes on the Application for Certificate for Clinical Trial and Medicinal Test (2015)”, application form, checklist for application documents and the “Guidance notes for Holders of the Certificate for Clinical Trial and Medicinal Test”. The relevant application guidelines and application form have been uploaded onto the Council’s website in order to help applicants and Certificate holders understand and comply with the requirements.

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