

CHAPTER 4

**Department of Health
Food and Health Bureau**

Control of Chinese medicines

**Audit Commission
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Report No. 53 of the Director of Audit contains 11 Chapters which are available on our website at <http://www.aud.gov.hk>.

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CONTROL OF CHINESE MEDICINES

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PART 1: INTRODUCTION

1.1 This PART describes the background to the audit and outlines the audit objectives and scope.

Importance of medicine regulation

1.2 The Department of Health (DH) is the health advisor and agency to execute health care policy, statutory functions, licensing, inspection and drug safety. Its regulatory role includes ensuring the safety, quality and efficacy of medicines (both western and Chinese medicines) used in Hong Kong. If medicines (both western and Chinese medicines) are not properly regulated, Hong Kong people could be exposed to potential health and safety risks.

1.3 The regulatory frameworks for western and Chinese medicines were established under different Ordinances and at different times. This audit review mainly covers the control of Chinese medicines and undesirable medical advertisements. In parallel with this review, the Audit Commission (Audit) has conducted a review of the control of western medicines. The audit findings are contained in a separate report (see Chapter 5 of the Director of Audit's Report No. 53).

Regulation of Chinese medicines

1.4 Chinese medicines are an integral part of the Chinese culture and have been used in Hong Kong for many years. In the past, there was no specific regulation on the practice, use and trading of Chinese medicines. Other legislation (such as the Pharmacy and Poisons Ordinance (PPO — Cap. 138)) was used for regulating medicines (including Chinese medicines). In 1997, the Chief Executive announced in his Policy Address the Administration's commitment to establish a sound regulatory framework for Chinese medicines to safeguard public health. A sound regulatory system will also lay a solid foundation for the development of Chinese medicines.

Chinese Medicine Ordinance

1.5 In 1999, the Chinese Medicine Ordinance (CMO — Cap. 549) was enacted to provide a statutory framework for the regulation of Chinese medicines (Note 1). There are two categories of Chinese medicines under the regulation of the CMO:

Note 1: *The CMO also provides for a regulatory system for Chinese medicine practitioners. This is not within the scope of this audit.*

- (a) **Chinese herbal medicines.** There are 31 types of toxic herbal medicines (such as Arsenic trioxide 砒霜) and 574 types of commonly used herbal medicines (such as Radix Ginseng 人參) specified in Schedules 1 and 2 respectively of the CMO; and
- (b) **Proprietary Chinese medicines (pCms).** They are proprietary products:
 - (i) composed solely of the following as active ingredients: any Chinese herbal medicines or any materials of herbal, animal or mineral origin customarily used by the Chinese;
 - (ii) formulated in finished dose form; and
 - (iii) used for the diagnosis, treatment, prevention or alleviation of any disease or any symptom of a disease in human beings, or for the regulation of the functional states of the human body.

1.6 Taking into account the impact on the public, the readiness of the trade and the availability of laboratory services to support compliance by the trade, the Administration has adopted a **phased approach** in implementing the regulatory regime of Chinese medicines (see Appendix A for a chronology of key events):

- (a) **Establishment of Chinese Medicine Council (CMC).** In September 1999, the CMC was set up as a statutory body to develop and implement regulatory measures for Chinese medicines. The CMC is underpinned by two boards and eight committees in carrying out its regulatory functions (the CMC structure is shown at Appendix B). The membership of the CMC and its boards and committees consists of professionals and traders of Chinese medicines, academics, lay persons and government officials (with the Director of Health as an ex-officio member of the CMC);
- (b) **Licensing of Chinese medicines traders.** In April 2003, a system for the licensing of Chinese medicines traders commenced. Four types of traders, namely, retailers and wholesalers (Note 2) of Chinese herbal medicines, and wholesalers and manufacturers of pCms, must apply for a licence from the Chinese Medicines Board (CMB — Note 3) of the CMC before they can engage

Note 2: *Under the CMO, wholesale dealing includes importing and selling.*

Note 3: *The CMB is chaired by the Director of Health. Its main function is to carry out regulatory measures of Chinese medicines, including the licensing of Chinese medicines traders and registration of pCms.*

in the respective trades. The CMO provides for the following two types of licensing arrangements:

- (i) non-transitional licensing for the above four types of traders; and
 - (ii) transitional licensing for those who were in business on 3 January 2000. The transitional licensing arrangement has been put in place to minimise disruption to traders; and
- (c) **Registration of pCms.** In December 2003, a system for the registration of pCms commenced. All pCms manufactured or offered for sale in Hong Kong need to be individually registered having regard to their safety, quality and efficacy. The CMO provides for the following two types of registration arrangements:
- (i) non-transitional registration for pCms manufactured or sold in Hong Kong; and
 - (ii) transitional registration for those manufactured or sold in Hong Kong on 1 March 1999.

The transitional registration arrangement has been put in place to minimise the disruption to the pCm trade. For registration applications submitted within the specified period (19 December 2003 to 30 June 2004), the CMB has indicated (in an application handbook for registration of pCms) that it would complete processing them before implementing section 119 of the CMO. Section 119 provides that no person shall sell, import or manufacture any pCm unless it is registered with the CMB.

Role of DH

1.7 The DH is responsible for providing executive and technical support to the CMC, its boards and committees. The main work is carried out through its Chinese Medicine Division (see organisation chart at Appendix C) which has responsibilities for:

- (a) enforcing the CMO and its subsidiary legislation. The main enforcement actions include conducting inspections and investigations;
- (b) providing technical and administrative support to the CMB and its Committees for implementing regulatory measures on licensing of Chinese medicines traders and registration of pCms;
- (c) issuing import and export licences for pCms and 36 specified Chinese herbal medicines in accordance with the provisions of the Import and Export Ordinance (Cap. 60); and

- (d) monitoring adverse drug reaction relating to Chinese medicines.

The Chinese Medicine Division is assisted by the DH's Pharmaceutical Service (responsible for the control of western medicines) in issuing import and export licences for pCms (Note 4) and sample checking pCms sold in the market.

Regulation of undesirable medical advertisements

1.8 Advertisements of medicines (whether western or Chinese) are governed by the provisions of the Undesirable Medical Advertisements Ordinance (UMAO — Cap. 231). The aim is to protect the public from being misled into improper self-medication instead of consulting medical practitioners.

1.9 With an increasing number of “health food” products claiming beneficial health effects in the local market, in June 2005, the Undesirable Medical Advertisements (Amendment) Ordinance 2005 (UMA (Amendment) Ordinance) was enacted. The Amendment Ordinance extends the prohibition of high-risk advertisement claims to all orally consumed products (including health food). The relevant trade and industry were given a grace period of 18 months to prepare for the new regulation which was expected to take effect in 2007.

Present position

1.10 Up to September 2009 (10 years after the enactment of CMO), section 119 of the CMO had not been put into operation to restrict the sale, manufacture and import of unregistered pCms (see para.1.6(c)). Besides, the UMA (Amendment) Ordinance had not taken effect (over 2 years after its expected commencement in 2007 — see para. 1.9).

Audit review

1.11 Against the above background, Audit has recently reviewed the implementation of the CMO and the UMA (Amendment) Ordinance. The review has focused on the following areas:

Note 4: *In 2008, the DH issued about 7,900 import and export licences for pCms, and 54 import and export licences for Chinese herbal medicines. Audit findings on import and export control of medicines (including Chinese medicines) are presented in PART 2 of Chapter 5 of the Director of Audit's Report No. 53.*

- (a) registration of proprietary Chinese medicines (PART 2);
- (b) licensing of Chinese medicines traders (PART 3);
- (c) surveillance of Chinese medicines (PART 4); and
- (d) regulation of undesirable medical advertisements (PART 5).

Audit has found room for improvement in the above areas and has made a number of recommendations to address the issues.

General response from the Administration

1.12 The **Secretary for Food and Health** and the **Director of Health** agree with the audit recommendations. The **Director of Health** has said that he appreciates the efforts devoted by Audit in reviewing the DH's work in the regulation of Chinese medicines and undesirable medical advertisements.

Acknowledgement

1.13 Audit would like to acknowledge with gratitude the full cooperation of the staff of the DH, and the Food and Health Bureau (FHB) during the course of the audit review.

PART 2: REGISTRATION OF PROPRIETARY CHINESE MEDICINES

2.1 This PART examines the implementation of the CMO for the registration of pCms.

Registration arrangements

2.2 In December 2003, the CMO provisions for pCm registration (i.e. sections 121 and 128) came into effect. All pCms manufactured or offered for sale in Hong Kong need to be individually registered with the CMB having regard to their safety, quality and efficacy. Upon implementation of section 119 of the CMO at a later date, no person shall sell, import or manufacture any pCm unless it is registered.

Types of registration

2.3 Depending on the manufacture and sales history of the pCms concerned, there are two types of registration:

- (a) ***Non-transitional registration.*** Section 121 of the CMO provides for the non-transitional registration of a pCm manufactured or sold in Hong Kong. Application for a locally manufactured pCm shall be made by the relevant manufacturer while that imported shall be made by the wholesaler. **If the application is made within the specified period from 19 December 2003 to 30 June 2004, the CMB has indicated that it would complete processing of the application before implementing section 119 of the CMO (see para. 1.6(c)).** For any application made after 30 June 2004, the applicant concerned may continue to manufacture or sell the pCm until the implementation of section 119 of the CMO. If the pCm has not yet been registered by then, the applicant has to recall the pCm product from the market. For an approved application, the CMB will issue a registration certificate which is valid for 5 years. The holder of a registration certificate may apply to the CMB for renewal of the pCm registration; and
- (b) ***Transitional registration.*** Section 128 of the CMO provides for the transitional registration of pCms manufactured or sold in Hong Kong on 1 March 1999. Such pCm shall be deemed to have been registered once an application for registration is made within the specified period from 19 December 2003 to 30 June 2004, and subject to any conditions as may be imposed by the CMB. The transitional registration shall continue to be valid until the issue of a registration certificate for the pCm concerned (see (a) above), or the refusal of the application for a registration certificate, or such date to be specified by the Secretary for Food and Health.

Registration requirements

2.4 According to section 122 of the CMO, the CMB shall take into consideration the safety, quality and efficacy of a pCm in determining its application for registration. In developing the registration requirements, the CMB has made reference to international control measures of Chinese medicines and consulted Chinese medicine experts, traders and laboratory representatives. The CMB has laid down the following registration requirements:

- (a) **Basic requirements.** All pCms must:
 - (i) not exceed the specified limits of heavy metals and toxic element, pesticide residues and microbes (three safety test reports in this regard have to be submitted);
 - (ii) not be adulterated with western medicine; and
 - (iii) comply with the Protection of Endangered Species of Animals and Plants Ordinance (Cap. 586) requirements; and
- (b) **Detailed registration requirements.** The detailed requirements for registration of a pCm are dependent on its classification category and the registration group selected by the applicant:
 - (i) **Classification category of pCms.** Based on the composition, usage and sales history, a pCm is classified into one of three different categories, namely the “Established medicines”, “Non-established medicines”, or “New medicines” (see Appendix D); and
 - (ii) **Registration group of pCms.** There are three registration groups of pCm (Groups I, II and III — see Appendix E). For a pCm to be registered under Group I, the applicant is only required to submit basic supporting documents to prove the safety, quality and efficacy of the pCm. For registration under Group II or III, the applicant is required to submit more comprehensive supporting documents. For pCms under the “Established medicines” category and “Non-established medicines” category, applicants may choose to apply for registration in any of the three groups. However, for pCms in the “New medicines” category, they must be registered under Group III as their compositions, routes of administration, indications or dose forms are different from traditional use and hence more scientific evidence is essential to ensure their safety and efficacy. Documents required for the three registration groups are listed at Appendix E.

Time for submission of supporting documents

2.5 ***Non-transitional registration.*** For non-transitional registration of a pCm, an applicant is required to submit at the time of application **all** prescribed supporting documents (see Appendix E). The CMB will issue a registration certificate after satisfying that all the supporting documents are acceptable.

2.6 ***Transitional registration.*** For an application under the transitional registration arrangement, the CMB has allowed the applicant to submit supporting documents **by phases** (see Table 1).

Table 1

Submission of documents under transitional registration

Phase	Submission of supporting documents
(a) First	All applicants should submit at the time of application (19 December 2003 to 30 June 2004) documentary proof that the pCms were manufactured or sold on 1 March 1999. Other general information to be submitted included applicant's personal information and master formula of the pCms.
(b) Second	Applicants of all three registration groups should submit by 30 June 2005 the same supporting documents, including three safety test reports (on heavy metals and toxic element, pesticide residues and microbes — see para. 2.4(a)(i)).
(c) Third	Applicants should submit by 30 June 2009 the remaining supporting documents of their respective registration groups (see Appendix F for details). The CMB will issue a registration certificate to an applicant who has submitted all supporting documents that meet the registration requirements.
(d) Extension (2013 to 2015)	<p>In response to the traders' concern over the technical difficulties and cost involved in preparing some documents specified for the Third Phase (namely general stability test reports — see item 13 of Appendix F), the CMB has decided to allow applicants more time to submit these documents, as follows:</p> <p>(a) For pCms with defined product specification (such as those documented in the Pharmacopoeia of the People's Republic of China), the applicants should submit by 30 June 2009, the first batch of general stability test reports (and other Third Phase documents) for the CMB's consideration of issuing a registration certificate. The remaining general stability test reports should be submitted when their pCm registrations are due for renewal, i.e. around 2015; and</p> <p>(b) For other types of pCms, the applicants should submit general stability test reports by 2 stages, i.e. by 30 June 2013 and around 2015 (see Appendix G for details).</p>

Source: DH records

2.7 In March 2008, the CMB started to issue:

- (a) “Notices of confirmation of (non-transitional) registration application of pCm” (**Non-transitional Registration Notices**) to applicants who have submitted the three safety test reports (see para. 2.4(a)(i)) under non-transitional registration (including those found not qualified for transitional registration and could only apply for non-transitional registration); and
- (b) “Notices of confirmation of transitional registration of pCm” (**Transitional Registration Notices**) to applicants who have submitted the First and Second Phases supporting documents under transitional registration.

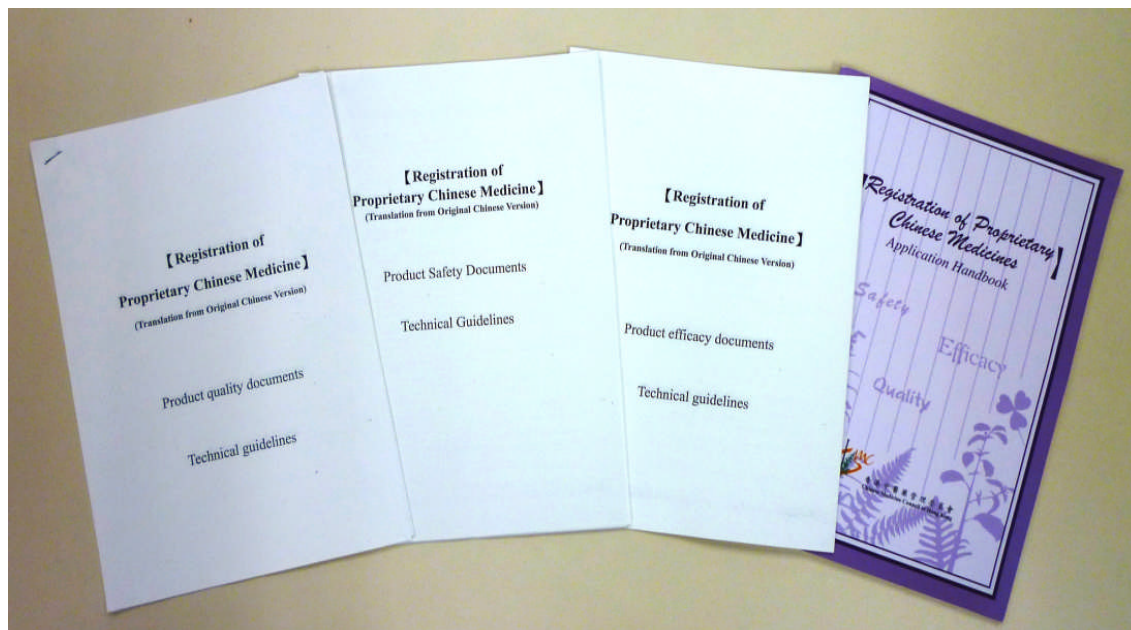
Publicity and education

2.8 To enhance traders’ understanding of the pCm registration requirements and procedures, the CMB has launched a series of publicity and educational activities. These included the displaying of posters at DH offices and clinics, issuing of letters to traders and relevant organisations, and conducting seminars (Note 5). In addition, the CMB has issued an application handbook and technical guidelines (see Photograph 1). The same information is also made available on the CMC website. Since 2009, the CMB has issued newsletters to enhance communication with the traders.

Note 5: *For example, briefings on applications for registration of pCms were held in 2003 and 2004, and letters were issued to traders in June 2006 concerning the time for submitting product specification documents and general stability test reports.*

Photograph 1

Application handbook and technical guidelines for pCm registration



Source: Photograph taken by Audit

Progress of registration

2.9 ***Applications received.*** During the specified application period (ended 30 June 2004), the DH received 16,051 applications. Up to 31 July 2009, the DH received 16,481 applications (comprising 2,389 for non-transitional registration and 14,092 for transitional registration).

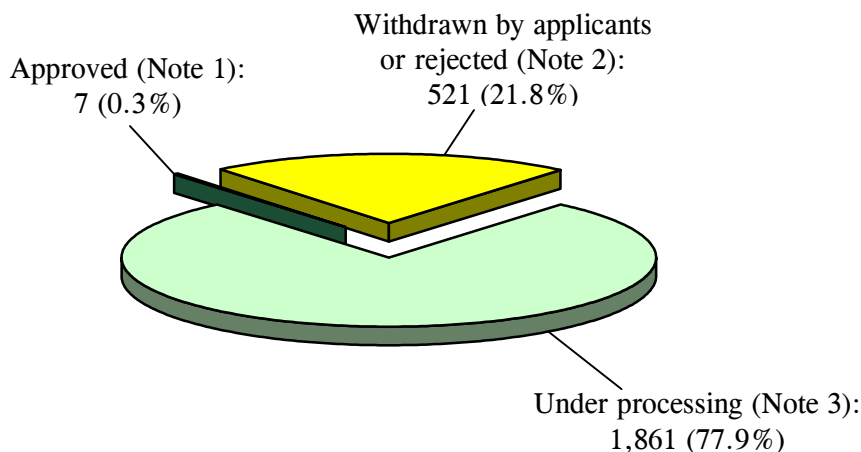
2.10 ***Applications processed.*** As at 31 July 2009, the CMB (Note 6) had assessed 550 applications for non-transitional registration and all the applications for transitional registration. The outcomes are summarised in Figure 1.

Note 6: Since 2003, the CMB has delegated to its Chinese Medicines Committee the authority to approve application for non-transitional pCm registration.

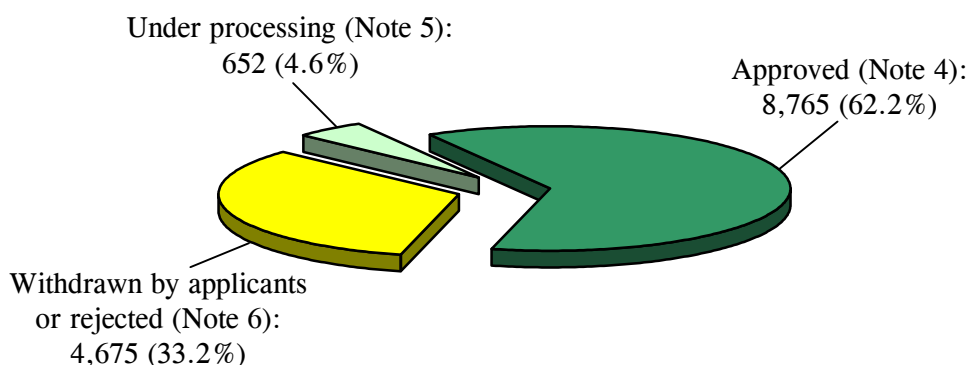
Figure 1

**Progress of pCm registration
(31 July 2009)**

(a) Non-transitional registration applications (2,389)



(b) Transitional registration applications (14,092)



Source: DH records

Note 1: These 7 cases were approved by the Chinese Medicines Committee pending the issue of registration certificates.

Note 2: This included 14 cases for which the applicants had applied for a review of the Chinese Medicines Committee's decision.

Note 3: This included 22 cases assessed by the Chinese Medicines Committee which required further supporting information from the applicants concerned and 1,809 cases issued with Non-transitional Registration Notices.

Note 4: The approved cases comprised 8,600 with Transitional Registration Notices issued and 165 approved by the CMB pending issue of Transitional Registration Notices.

Note 5: Of the 652 cases, 281 were initially rejected for not providing three acceptable safety test reports (see para. 2.4(a)(i)). Processing of these cases resumed as the applicants applied for review under section 140 of the CMO and subsequently submitted the required reports. For the remaining 371 cases, the applicants' replies to substantiate the transitional registration status were awaited.

Note 6: This included 2,690 cases which were rejected for not providing three acceptable safety test reports or for not fulfilling the definition of a pCm.

Audit observations and recommendations

Slow progress in processing the applications for pCm registration

2.11 In October 2002, the DH briefed the Legislative Council (LegCo) Panel on Health Services (Health Panel) on the regulatory control of Chinese medicines to be implemented in 2003. In response to the Panel Chairman's enquiry, the DH said that it would take two to three years for all pCms to be registered under the CMO (i.e. expected completion by 2006). **However, as at 31 July 2009 (2.5 years after the expected completion time), 652 (4.6%) transitional registration applications and 1,861 (77.9%) non-transitional registration applications were still under processing (see Figure 1).** Audit noted that on the following two occasions the Health Panel was informed of the progress in registration of pCms:

- (a) in October 2005, the Panel was informed that registration of pCms was actively underway, with over 16,000 applications being processed; and
- (b) in October 2008, the Panel was informed that the CMB had issued the first batch of Transitional Registration Notices and it was planned to complete the transitional registration of all pCms in 2008-09.

There was however no reporting to the Health Panel that the implementation time would be later than expected.

Estimation of registration applications

2.12 In September 2006, the DH informed the FHB that the following major difficulties were encountered in the pCm registration process:

- (a) the staff establishment to handle pCm registration was calculated on the basis of 10,000 pCm registration applications. **Since 2003, more than 16,000 applications (see para. 2.9) had been received which had exceeded the original estimate by 60%;**
- (b) the majority of applicants had submitted incomplete or inaccurate information. Clarification with the applicants concerned greatly increased the workload and slowed down the vetting process;
- (c) the names and labels of many pCms were found to have infringed the provisions of the UMAO and the applicants had to be advised to make amendments before registration; and

- (d) in line with international development, the CMB had tightened the control on the use of endangered species and some herbs as ingredients resulting in the need for change of formulation of some pCms and additional test reports for evaluation.

2.13 In June 2009, in response to Audit's enquiries on the basis of pCm application estimation and the related DH staff deployment, the DH said that:

- (a) the estimation of 10,000 pCm applications was made after consulting the pCm trade associations;
- (b) the number of Non-transitional and Transitional Registration Notices issued by the CMB totalled around 10,460 (as at May 2009), which was pretty close to the original estimation of 10,000; and
- (c) through internal redeployment of resources, the DH had created a number of non-civil service contract posts for employing Chinese medicines experts and other supporting staff to deal with the additional workload.

2.14 However, the DH had not maintained supporting documents for the pCm estimation. Audit considers that the DH should keep supporting documents for key estimates used for planning the manpower requirement of a new service. A post-implementation review can be carried out whenever warranted (such as the 60% under-estimation in registration application noted in this case) to draw lessons for the future.

Limitations before implementing section 119 of CMO

2.15 The CMB has indicated that it would complete processing registration applications submitted by 30 June 2004 before implementing section 119 of the CMO (see para. 2.3(a)). **However, because of the slow progress in processing the pCm registration applications (see para. 2.11), as at September 2009, there was no scheduled date for implementing section 119 of the CMO.** The following are two examples of the limitations before implementing section 119 of the CMO:

- (a) ***Manufacture of pCms.*** While all pCm manufacturers have been subject to licensing control since January 2008 (see para. 3.9), there is no restriction that they cannot manufacture unregistered pCms as section 119 of the CMO has not yet been implemented. Based on the DH's inspection records of licensed manufacturers (Note 7), Audit selected 5 product lists for cross-checking against the pCm registration records. The checking revealed that, of the 76 products

Note 7: *As part of the laid down inspection procedures, product lists would be obtained.*

shown in the 5 product lists, 12 (16%) products had not applied for registration (Note 8). Before implementing section 119 of the CMO, the DH staff could only **advise** manufacturers to cease manufacturing unregistered pCms; and

- (b) ***pCms sold in the market.*** Each year, the DH conducts market surveillance to ascertain whether medicines and related products (including pCms) sold in the market are safe and of good quality, and whether products for sale have been adulterated with western medicines or excessive heavy metals (see details in PART 4). In 2008, the DH tested 2,555 samples (Note 9) relating to 1,420 types of products (Note 10). Audit cross-checked the names of these 1,420 products against the pCm registration records and found that 227 (16%) of them matched with those of registered pCms. The registration records also showed that 9 (0.6%) products were pCms but their applications for registration had been rejected or withdrawn (see Note 17 to para. 4.8(a)), indicating that there were unregistered pCms for sale in the market. At present, the DH cannot take any enforcement action against such sale. The continued sale of unregistered pCms might pose a public health risk as their safety, quality and efficacy have not been proven to meet the registration requirements (such as the microbe and pesticide residue levels — see para. 2.4(a)(i)).

2.16 **To safeguard public health and to effectively control unregistered pCms in the market, the DH should expedite action to complete the pCm registration and commence section 119 of the CMO as early as possible. In this connection, Audit noted that the DH had worked out a plan for commencing section 119 and would consult relevant parties (including the trade) on the plan in due course.**

Issues relating to non-transitional registration

2.17 As at 31 July 2009, there were 1,861 applications still under processing (see Figure 1(a) in para. 2.10). Of these 1,861 applications, 1,551 (83%) were submitted by 30 June 2004 and had to be processed before commencing section 119 of the CMO. The DH only processed three safety test reports of these applications for the issue of

Note 8: *The names of these products (e.g. 六味地黃丸) are similar to those of some registered pCms although verification on whether these products fall within the definition of pCm under the CMO has not been carried out.*

Note 9: *Of the 2,555 samples, 2,361 were purchased by the DH and 194 were provided by the Hospital Authority and the public for the DH's investigation. In addition, the DH tested 30 samples of western medicines in its 2008 market surveillance.*

Note 10: *The DH had not differentiated the 1,420 types of products into pCms and other products.*

Non-transitional Registration Notices (see para. 2.7(a)), and had yet to process other test reports required for registration.

2.18 ***Incomplete registration documents.*** In early 2009, the DH proceeded to process the toxicity test reports and product specifications of the non-transitional registration applications (which were compulsory documents for all three registration groups — see items (B)4 and (D)3 of Appendix E). **In May 2009, the DH informed the Chinese Medicines Committee (see Note 6 to para. 2.10) that, of the 1,808 applications under processing as at 30 April 2009, 884 (49%) applications had not submitted relevant toxicity test reports and/or product specifications.** The Chinese Medicines Committee then asked the DH to require the applicants concerned to submit the reports by 30 June 2009.

2.19 According to the registration procedures, all the registration documents for non-transitional registration must be submitted at the time when an application is made (see para. 2.5). As at 31 July 2009, there were still 817 applications without the relevant toxicity test reports and/or product specifications, although 789 (97%) of them had been received by 30 June 2004. The DH should have taken early action on the outstanding reports. **Audit considers that the DH should:**

- (a) **expedite the checking of the completeness of registration documents at the time of receipt of an application; and**
- (b) **in processing the non-transitional applications in hand, accord priority to those submitted by 30 June 2004 so that section 119 of the CMO can be implemented early.**

2.20 ***Performance pledge.*** Audit notes that for registration of pharmaceutical products, the Pharmaceutical Service of the DH has a performance pledge to approve applications for registration within five months if the required documents are available and the criteria of registration are met. This is a good management practice to help engender a customer service culture. **Audit considers that the DH should draw on the experience in processing the pCm registration applications over the past years and set a performance pledge for registration of pCms.**

Issues relating to transitional registration

2.21 As at 31 July 2009, there were 652 transitional registration applications under processing (see Figure 1(b) in para. 2.10). There is a need to expedite action to complete processing of these outstanding applications so as to pave the way for the early implementation of section 119 of the CMO.

2.22 ***Submission of supporting documents.*** As for the 8,765 pCms approved under transitional registration (see Figure 1(b) in para. 2.10), there is a need to process their other registration documents required to fully prove their quality and efficacy for the issue of registration certificates. According to the timetable under the transitional registration, the Third Phase documents were due on 30 June 2009 (see Table 1 in para. 2.6). In mid-June 2009, in response to traders' requests, the DH consulted the CMB on the arrangements for handling cases with difficulties in submitting by 30 June 2009 some of the Third Phase documents (e.g. product specifications — see item 12 of Appendix F), including revising the deadline for such documents.

2.23 As at 27 August 2009, the DH received the Third Phase documents for 6,991 (80%) of the 8,765 pCms. However, of these 6,991 submissions, the DH found that only 1,663 (24%) submissions were complete. The remaining 5,328 (76%) cases were incomplete, with 729 of them (14%) asking for more time to submit the outstanding documents. **Audit considers that the DH should closely monitor the submission of supporting documents under the transitional registration.**

Audit recommendations

2.24 **Audit has recommended that the Director of Health should:**

Slow progress in processing the applications for pCm registration

- (a) **inform the Health Panel if the actual implementation time of a public health related service turns out to be later than expected;**

Estimation of registration applications

- (b) **keep supporting documents used for planning the manpower requirement of a new service so that a post-implementation review can be carried out whenever warranted to draw lessons for the future;**

Limitations before implementing section 119 of CMO

- (c) **expedite action to complete the pCm registration so that section 119 of the CMO can be implemented early for the effective control of unregistered pCms;**

- (d) accord priority to processing the non-transitional applications submitted by 30 June 2004 and the 652 outstanding transitional applications so that section 119 of the CMO can be implemented early;

Issues relating to non-transitional registration

- (e) expedite the checking of the completeness of registration documents at the time of receipt of an application;
- (f) draw on the experience in processing registration applications of pCms over the past years and set a performance pledge for their registration; and

Issues relating to transitional registration

- (g) closely monitor the submission of supporting documents under the transitional registration.

Response from the Administration

2.25 The **Director of Health** agrees with the audit recommendations. He has said that:

- (a) the Administration will consider providing more frequent updates to LegCo on the progress of the registration of pCms;
- (b) the estimation on the number of pCms was based on information gathered from the trade. It was found that the estimated figure was close to the number of pCms to be registered. The excess number of applications was mainly due to applications of products that are not pCms and/or do not fulfil the requirements for pCm registration. The recommendation in paragraph 2.24(b) is agreed in principle;
- (c) the DH has put in place a system to check the completeness of all registration documents upon application since July 2005; and
- (d) the CMB, in its meetings held in March, April and July 2009, discussed the method for handling applications which failed to submit the required supporting documents. The progress of submission of these documents was reported to the CMB in its meeting held on 31 August 2009.

PART 3: LICENSING OF CHINESE MEDICINES TRADERS

3.1 This PART examines the implementation of the CMO for the licensing of Chinese medicines traders.

Licensing arrangements

3.2 In April 2003, the CMO provisions for licensing of Chinese medicines traders (i.e. sections 114, 115, 118, 132, 135 and 138) came into effect. Four types of traders are subject to licensing control to ensure the proper storage, handling and dispensing of Chinese herbal medicines and manufacturing of pCms. They are:

- (a) retailers of Chinese herbal medicines;
- (b) wholesalers of Chinese herbal medicines;
- (c) wholesalers of pCms; and
- (d) manufacturers (Note 11) of pCms.

Types of licensing arrangement

3.3 Depending on the business history of the traders concerned, there are two types of licensing arrangements:

- (a) ***Non-transitional licensing.*** According to the CMO, four types of Chinese medicines traders (see para. 3.2) must apply for a formal licence under the non-transitional licensing arrangement. The CMB had urged traders, who were in business between 4 January 2000 and 15 July 2003, to submit their applications within the specified application period (5 May to 15 July 2003).

Note 11: *According to the CMO, a licensed pCm manufacturer who follows the requirements of good practices in the manufacture and quality control of pCms may apply to the CMB for a Certificate for Manufacturer (Good Manufacturing Practice — GMP). A step-by-step approach in implementing the GMP has been adopted as many local pCm manufacturers are not yet ready to meet the GMP standards.*

The restriction sections of the CMO (Note 12) that no person shall engage in the Chinese medicine trade without a licence would take effect after such applications have been processed. If an application is approved by the CMB, a 2-year formal licence will be issued; and

- (b) ***Transitional licensing.*** Sections 118 and 138 of the CMO provide for the transitional licensing of traders who were already in business on 3 January 2000 (eligible traders). Once an application is made to the CMB within the specified application period (see (a) above), an eligible trader is deemed to have been granted a formal licence subject to any conditions as may be imposed by the CMB. The CMB will issue a **transitional certificate** which is valid until the issue of a formal licence, or the refusal of the trader's application for a formal licence, or such date as specified by the Secretary for Food and Health.

Licensing requirements

3.4 The issue of licences to Chinese medicines traders is subject to their compliance with the requirements of the CMO and the Chinese Medicines Regulation (CMR — Cap. 549F). The scope of control under the CMR includes traders' premises, storage, facilities, personnel qualifications and record keeping. The main provisions of the CMR are summarised in Table 2.

Note 12: *They are sections 109, 110, 111, 131 and 134 of the CMO.*

Table 2

Main provisions of CMR

Scope of control	Licensing requirements
(a) Premises	<ul style="list-style-type: none"> ✧ All 4 types of traders should ensure that their business premises are maintained in a sanitary condition, and suitable storage area and facilities are available. Wholesalers and retailers of Chinese herbal medicines and pCm manufacturers should also ensure that Schedule 1 Chinese herbal medicines are stored separately from Schedule 2 medicines (see para. 1.5(a)). ✧ For pCm manufacturers, the humidity, lighting, temperature and ventilation of their premises for manufacturing pCms and storing their intermediate products should be suitable for the purpose.
(b) Personnel	<ul style="list-style-type: none"> ✧ For Chinese herbal medicine retailers and pCm manufacturers, their personnel for supervising dispensing service and manufacturing process should possess the required qualification and experience (see details at Appendix H).
	Licensee's duties
(c) Record keeping	<ul style="list-style-type: none"> ✧ All traders should keep record of transactions for at least 2 years.
(d) Sale and purchase of medicine	<ul style="list-style-type: none"> ✧ A wholesaler should sell Schedule 1 Chinese herbal medicines only to authorised persons, including registered Chinese medicine practitioners and licensed retailers/wholesalers. ✧ A retailer should acquire processed Chinese herbal medicines from licensed wholesalers only.
(e) Recall system	<ul style="list-style-type: none"> ✧ All traders (except Chinese herbal medicine retailers) should have a system of control to enable a complete, practicable and rapid recall of their problematic Chinese medicines.

Source: CMR

Processing of applications

3.5 For an application under the non-transitional licensing arrangement, the DH will conduct a pre-licensing inspection of the applicant's business premises to confirm his compliance with the CMR requirements.

3.6 To minimise disruptions to the Chinese medicines trade, transitional licensing arrangement had been introduced so that the traders could continue with their business, pending the completion of the concerned licensing procedures. For an application under the transitional licensing arrangement, the applicant is required to provide supporting documents for trade transactions carried out on 3 January 2000. The DH will conduct a documentary check but **not** a pre-licensing inspection for the purpose of processing the application.

Publicity and education

3.7 To enhance traders' understanding of the licensing requirements and procedures, the CMB has launched a series of publicity and educational activities. These included the mounting of posters at shopping centres and markets, issuing of letters to traders and relevant organisations, and conducting seminars (Note 13). In addition, the CMB has issued an application handbook and practising guidelines (see Photograph 2). The same information is also made available on the CMC website. From February to July 2008, the DH organised an enhanced educational programme for traders. Under the programme, students (studying Chinese medicine in tertiary education institutions) were recruited as part-time workers to visit the business premises of 6,500 licensed traders to help them familiarise with the statutory and practising requirements. Since 2009, the CMB has issued newsletters to keep traders updated of the licensing requirements.

Note 13: *For example, briefings on application for trader licences and implementation of legal provisions on the practices of traders were held in 2003 and 2007 respectively. Posters on application for trader licences were distributed for display in January 2007.*

Photograph 2

Application handbook and practising guidelines for Chinese medicines traders



Source: Photograph taken by Audit

Progress of licensing

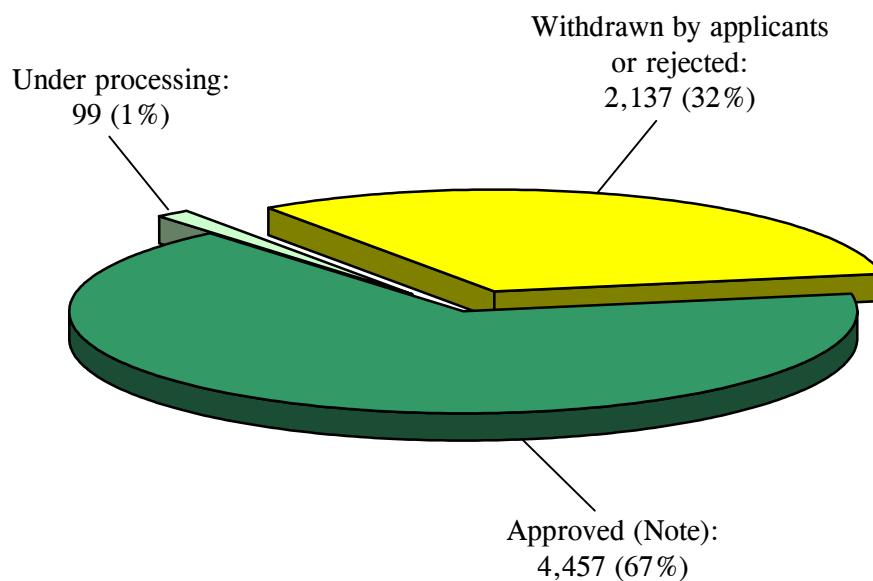
3.8 ***Applications received.*** During the specified application period (see para. 3.3(a)), the DH received 6,648 applications. Up to 31 July 2009, the DH received 10,302 applications (3,609 for transitional certificates and 6,693 for formal licences).

3.9 ***Applications processed.*** As at 31 December 2007, the processing of applications for transitional certificates and formal licences (received up to that date) was substantially completed. **On 11 January 2008, the restriction provisions of the CMO came into effect (see para. 3.3(a)), requiring all new traders to obtain a licence before starting their business.** As at 31 July 2009, 10,302 applications were received and 7,174 trader licences were issued (2,717 transitional certificates and 4,457 formal licences). The position is summarised in Figure 2.

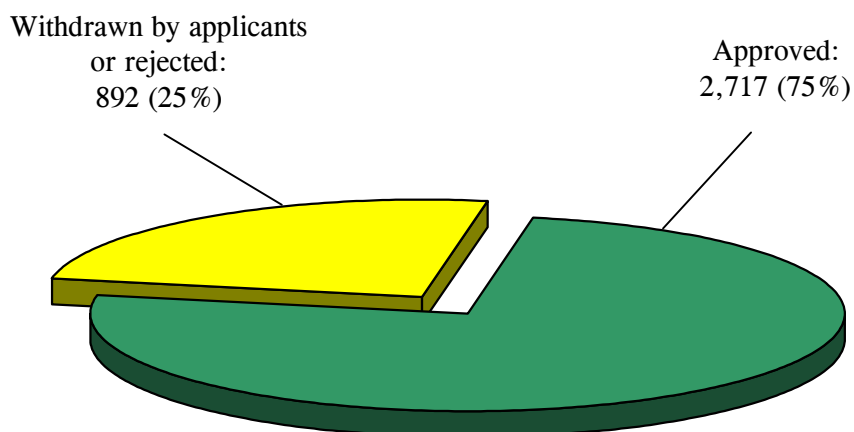
Figure 2

Progress of issuing Chinese medicines trader licences
(31 July 2009)

(a) Non-transitional licensing applications (6,693 — Note)



(b) Transitional licensing applications (3,609)



Source: DH records

Note: These included 560 cases of formal licensing of transitional certificate holders.

Audit observations and recommendations

Estimation of licence applications

3.10 On 25 October 2002, the DH briefed the Health Panel on the regulatory control on Chinese medicines. In response to the Panel Chairman's enquiry, the DH said that it would take about two to three years to complete the licensing of traders (i.e. by July 2006, counting from the end of the specified application period in July 2003 — see para. 3.3(a)). In September 2006, the DH informed the FHB that:

- (a) over 7,300 applications had been received, exceeding the original estimate of 4,000 by 80%;
- (b) the DH manpower provision was based on the estimate of 4,000; and
- (c) about 700 applications remained to be processed at that time.

3.11 In June 2009, in response to Audit's enquiry, the DH said that the application estimate was based on the number of different licences kept by the Pharmaceutical Service before the commencement of trader licensing in 2003. However, the DH has not maintained supporting documents for the estimation. Audit considers that the DH should keep supporting documents for key estimates used for planning the manpower requirement of a new service so that a post-implementation review can be carried out whenever warranted (such as the 80% under-estimation noted in this case) to draw lessons for the future. The audit recommendation mentioned in paragraph 2.24(b) also applies in this case.

Need to expedite formal licensing of transitional certificate holders

3.12 As at 30 April 2009, there were 2,844 traders holding transitional certificates (i.e. 1,778 Chinese herbal medicine retailers, 451 Chinese herbal medicine wholesalers, 256 pCm wholesalers and 359 pCm manufacturers). These traders have been in business for over 9 years (i.e. on or before 3 January 2000) and are allowed to continue their business until they are granted a formal licence or when their applications for a formal licence are rejected. **In accordance with the transitional licensing arrangement (see para. 3.6), the DH had not inspected the business premises of these 2,844 traders before issuing transitional certificates to them. While the enhanced educational programme of 2008 (see para. 3.7) has helped these traders improve their operating conditions, DH inspections are still necessary to ensure that their business premises, facilities and personnel are up to the requirements laid down in the CMR (see Table 2 in para. 3.4).** For example, the DH records showed that, among the 2,844 traders holding transitional certificates, there were:

- (a) 20 pCm manufacturers and 170 Chinese herbal medicine retailers whose business premises were located in residential (or suspected residential) units which might not fully meet the licensing requirements; and
- (b) 1,337 Chinese herbal medicine retailers providing dispensing services and 359 pCm manufacturers. According to the DH's operational procedures, the original documents recording the qualification and experience of personnel responsible for supervising the dispensing and manufacturing process would only be checked during pre-licensing inspections.

3.13 The DH usually inspects the premises of the transitional certificate holders when processing their applications for formal licences or upon receipt of complaints concerning these traders. In early March 2009, the CMB noted the DH's plan to complete the formal licensing of all transitional certificate holders within 3 years, with priority given to those with business premises located in residential units (see para. 3.12(a)). The CMB expressed concern about the 3-year timetable and urged the DH to expedite action to safeguard public health. In April 2009, the DH informed the CMB that after reassessing its resources deployment, the DH aimed to complete the pre-licensing inspections of all transitional certificate holders within 2 years (i.e. by March 2011).

3.14 For the four months from April to July 2009, the DH completed 491 pre-licensing inspections (i.e. 17% of the 2,884 transitional certificate holders as at 25 March 2009). The DH needs to sustain its efforts in order to complete the pre-licensing inspection work by the target completion date of March 2011.

Audit recommendations

3.15 **Audit has recommended that the Director of Health should:**

- (a) **expedite the pre-licensing inspections of transitional certificate holders; and**
- (b) **closely monitor the progress of the pre-licensing inspections to meet the target completion date of March 2011.**

Response from the Administration

3.16 The **Director of Health** accepts the audit recommendations. He has said that the DH already has a work plan in place to expedite the processing of licence applications and the progress has been reported to the CMB.

Licensing inspections

3.17 The DH has laid down procedures and standard inspection report forms for its Pharmacist Inspectors (PIs) to conduct licensing inspection. The same set of procedures is used for both applications for new licence and licence renewal. The report forms specifically require a PI to state whether the applicant has complied with the basic licensing requirements concerning the business premises and personnel (i.e. items (a) and (b) of Table 2 in para. 3.4). As for licensee's duties such as keeping of transaction records (i.e. item (c) of Table 2), the DH procedures also require the PI to note the licensee's record keeping system and record any observations.

Audit observations and recommendation

3.18 In July 2008, the Chinese Medicines Traders Committee (Note 14) discussed the arrangements for handling traders' non-compliance with the CMR requirements as noted by the DH staff when conducting licensing inspections. The Committee decided that:

- (a) for non-compliance not affecting public interest, the Committee would consider approving the application while the DH could make appropriate recommendations to the applicant concerned; and
- (b) for major non-compliance, the DH should report the case to the Committee.

3.19 In May and June 2009, Audit staff attended as observers in four of the DH's licensing inspections of traders. For one of the inspections (see details in Case 1), Audit noted that there was inadequate checking on the trader's compliance with the CMR requirements on record keeping.

Note 14: *Since 2003, the CMB has delegated to its Chinese Medicines Traders Committee the authority to approve non-transitional licensing applications.*

Case 1

Need to improve the checking of trader's transaction records

Case particulars

1. In connection with an application for the renewal of a Chinese herbal medicine **wholesaler licence** and a **retailer licence** by the same applicant (Trader A) operating the two businesses at the same premises, a PI conducted a pre-licensing inspection on 3 June 2009. During the inspection, the PI's checking mainly focused on basic licensing requirements of premises, facilities and personnel qualification. As for Trader A's transaction records, the PI selected the transactions of one type of Schedule 1 Chinese herbal medicine for checking. At the request of Audit staff, the PI retained a copy of the transaction records checked by him.

2. On 4 June 2009, the PI completed:

- (a) an inspection report for Trader A's retailer licence application, in which he recommended the CMB's approval of the application; and
- (b) an inspection report for Trader A's wholesaler licence application, in which he stated that there were no irregularities noted in his sample checking of the transaction records of the Schedule 1 Chinese herbal medicine and recommended CMB's approval of the application.

3. Audit noted that Trader A's wholesaler licence was for the trading of both Schedules 1 and 2 Chinese herbal medicines, and his retailer licence was for the trading of Schedule 2 Chinese herbal medicines. As such, the PI's checking of Trader A's transaction records of the Schedule 1 Chinese herbal medicine only covered Trader A's wholesaling transactions. **A separate checking of Trader A's retailing transaction records for Schedule 2 Chinese herbal medicines should have been conducted.**

4. According to the CMR, a wholesaler should sell Schedule 1 Chinese herbal medicines only to authorised persons, including registered Chinese medicine practitioners and licensed retailers/wholesalers (see item (d) of Table 2 in para. 3.4). Based on the copy of Trader A's transaction record of the Schedule 1 Chinese herbal medicine checked by the PI, Audit has checked the purchasers' names therein against the DH registered practitioner and licensed trader lists. Audit noted that one purchaser was a licensed retailer of Schedule 2 (**not** Schedule 1) Chinese herbal medicines.

5. In response to Audit's enquiry, the DH obtained clarification from Trader A in August 2009 that the purchaser of the Schedule 1 Chinese herbal medicine was in fact a registered Chinese medicine practitioner who worked for the retailer named in the transaction record. The DH had advised Trader A to correctly record his transactions in future.

Source: Audit field observations and DH records

Audit recommendation

3.20 **Audit has recommended that the Director of Health should step up the checking of traders' compliance with the CMR requirements on record keeping.**

Response from the Administration

3.21 The **Director of Health** agrees with the audit recommendation. He has said that the main focus for a renewal inspection, as illustrated in Case 1, is to check compliance with the licensing requirements, i.e. premises, facilities and personnel qualifications. For more efficient use of resources, checking of record keeping during the licence renewal inspection is risk-based. Routine inspections and unannounced visits will be conducted to check compliance with practising duties, including record keeping and labelling of herbal medicines.

Control over unlicensed traders

3.22 With the implementation of the restriction provisions of the CMO in January 2008, anyone engaging in the Chinese medicine trade without a licence commits an offence. The penalty is a fine up to \$100,000 and imprisonment of two years. To remind traders to apply for a licence and comply with the legislation requirements, the DH held a press conference and organised a series of other publicity and educational activities (see para. 3.7) before the commencement of the restriction provisions.

Audit observations and recommendations*Unlicensed pCm manufacturers and wholesalers*

3.23 In 2006, the DH noted that some applicants for pCm registration had not obtained trader licences. In September 2006, the DH sought legal advice on how to deal with such pCm registration upon the implementation of the restriction provisions of the CMO. Having regard to the advice, it was considered not appropriate to reject such pCm registration unless there was insurmountable difficulty to ensure the safety, quality and efficacy of pCms supplied by unlicensed traders, or there were public interest grounds to do so. This was because there was no requirement for a trader to be licensed before he could apply for pCm registration.

3.24 In June 2009, Audit reviewed the above situation by cross-checking the DH's pCm registration records against its list of licensed traders. **While the restriction provisions of the CMO prohibiting the manufacture and import of pCms by unlicensed traders have been implemented since January 2008, the review revealed that there**

were 82 pCms registered under the transitional arrangement relating to 30 unlicensed traders (i.e. 21 manufacturers and 9 wholesalers). These 82 pCms have been issued with Transitional Registration Notices (i.e. passed three safety tests) but the DH has not examined whether the conditions of manufacturing and handling these pCms were up to the licensing requirements. **Audit noted that since June 2008, the DH has published information on pCms issued with Transitional Registration Notices (including the 82 pCms in question) on the CMC website for public information.** To safeguard public health, the DH needs to:

- (a) urge the 30 unlicensed traders to obtain relevant trader licences as early as possible;
- (b) closely monitor the 30 unlicensed traders to ensure that they do not supply any pCms for sale in Hong Kong before they obtain relevant trader licences; and
- (c) consider not posting the 82 pCms in question on the CMC website or alternatively, alert the public (on the relevant webpage) to the risk of consuming these pCms.

Illegal sale of Chinese herbal medicines

3.25 The DH has laid down procedures for conducting inspection of retailers and test purchase of Chinese medicines around the territory with a view to detecting and investigating illegal Chinese medicine business. The DH mainly acts upon receipt of public complaints and referrals from organisations (such as the CMC). In 2008, the DH investigated 19 complaints/referrals about unlicensed Chinese herbal medicine traders and found 43 retailers operating without a retailer licence. Upon the DH's advice, these retailers have either applied for retailer licences or ceased their operation.

3.26 In June and July 2009, Audit field inspections also found that 19 retailers of Chinese herbal medicines were operating without a licence. According to the DH records, 13 of the 19 retailers had not applied for a licence (see details in Table 3). While the remaining 6 retailers were applying for a retailer licence, they commenced operation before the issue of the licence (see details in Table 4). In mid-July 2009, Audit referred the 19 cases to the DH for follow-up action.

Table 3
13 unlicensed retailers of Chinese herbal medicines
(June and July 2009)

District	Date of Audit inspection (Note)	Unlicensed retailer found
Kwun Tong	5 and 6 July 2009	5
Shamshuipo	30 June and 6 and 15 July 2009	4
Lok Fu	16 July 2009	1
North Point	15 July 2009	1
Shaukeiwan	1 July 2009	1
Tsuen Wan	7 July 2009	1
Total		13

Source: Audit inspections and DH records

Note: Audit conducted test purchase of Schedule 2 Chinese herbal medicines during the inspections.

Table 4
6 retailers commenced operation before issue of licence
(July 2009)

Retailer	District	Date of receipt of licence application	Pre-licensing inspection by DH (Note 1)	Date of unlicensed operation found by Audit (Note 2)
1	Shatin	3 June 2009 (Note 3)	30 June 2009	1 July 2009
2	Shatin	18 May 2009	26 May and 25 June 2009	1 July 2009
3	Shamshuipo	14 May 2009	20 May 2009	2 July 2009
4	Lok Fu	5 June 2009	12 June 2009	3 July 2009
5	Ngau Tau Kwok	29 May 2009	5 June 2009	3 July 2009
6	Kwun Tong	8 May 2009	9 June 2009 (Note 4)	5 July 2009

Source: Audit inspections and DH records

Note 1: Up to 9 July 2009, the DH had not issued retailer licences to the 6 retailers. For Retailer 6, the application was endorsed by the Chinese Medicines Traders Committee (see Note 14 to para. 3.18) on 26 June 2009.

Note 2: Audit conducted test purchase of Schedule 2 Chinese herbal medicines during the inspections.

Note 3: The DH received complete documents for the application on 25 June 2009.

Note 4: The inspection was rescheduled from 25 May 2009 as the applicant was not available on that day.

3.27 In September 2009, the DH informed Audit that:

- (a) as at 31 August 2009, of the 13 unlicensed retailers mentioned in Table 3, 3 had obtained trader licences, 8 were applying for licences and the remaining 2 had ceased their retailing of Chinese herbal medicines; and
- (b) trader licences had been issued to the 6 retailers mentioned in Table 4.

3.28 The DH needs to step up control over illegal sale of Chinese herbal medicines by:

- (a) reminding trader licence applicants not to commence operation before obtaining a licence; and
- (b) taking proactive action to detect illegal sale of Chinese herbal medicines, such as conducting inspections and test purchases.

Need to expedite the processing of trader licence applications

3.29 The DH has a performance pledge to conduct pre-licensing inspection of an applicant's trading premises within two weeks after receipt of completed application form and supporting documents. The achievement of this target for 2008-09 was 77.5%. According to the DH, there was a sudden increase in applications in September 2008 which affected the achievement of the performance pledge in September and October 2008.

3.30 At a CMB meeting of March 2009, a member considered that there was a need to expedite the processing of a trader licence application to minimise the applicant's rental loss while waiting for the outcome of his application. In Audit's view, the DH needs to make a greater effort to expedite the processing of trader licence applications, such as conducting pre-licensing inspections within two weeks.

Audit recommendations

3.31 **Audit has recommended that the Director of Health should:**

Unlicensed pCm manufacturers and wholesalers

- (a) **urge the 30 unlicensed manufacturers/wholesalers (who have been issued Transitional Registration Notices for their pCms — see para. 3.24) to obtain relevant trader licences as early as possible;**
- (b) **conduct surprise inspections and test purchases to ensure that the 30 unlicensed manufacturers/wholesalers do not supply the pCms for sale in Hong Kong before they obtain relevant trader licences;**
- (c) **consider not posting the 82 pCms relating to unlicensed traders (see para. 3.24) on the CMC website, or alternatively alert the public (on the relevant webpage) to the risk of consuming these pCms;**

Illegal sale of Chinese herbal medicines

- (d) remind trader licence applicants not to commence operation before obtaining a licence;
- (e) take proactive action to detect illegal sale of Chinese herbal medicines, such as conducting inspections and test purchases; and

Need to expedite the processing of trader licence applications

- (f) make a greater effort to expedite the processing of trader licence applications.

Response from the Administration

3.32 The **Director of Health** agrees with the audit recommendations. He has said that:

- (a) in July/August, the DH notified the 30 unlicensed manufacturers/wholesalers not to conduct any business of pCms unless a valid licence is obtained;
- (b) the DH has started to conduct surprise inspection of the 30 unlicensed manufacturers/wholesalers since early September 2009;
- (c) the recommendation in paragraph 3.31(c) is agreed in principle and will be discussed with the CMB;
- (d) all along, all applicants for Chinese medicines trader licences are urged not to commence operation before obtaining a licence. Since August 2009, a written reminder has been issued to every applicant to reinforce the message; and
- (e) the DH considers that public education is the most important and effective way to ensure that the public will purchase Chinese herbal medicines from licensed retailers. The DH is planning to enhance publicity and education work. The DH will also continue to investigate and act against unlicensed traders upon receipt of complaint/intelligence, and conduct test purchases to detect illegal sale of Schedule 1 Chinese herbal medicines among licensed traders.

PART 4: SURVEILLANCE OF CHINESE MEDICINES

4.1 This PART examines the DH's measures for the surveillance of Chinese medicines sold in the market.

Market surveillance

4.2 To complement the registration of pCms and licensing of traders, the DH has put in place a surveillance system to monitor the safety and quality of Chinese medicines for sale in the market. Each year, the DH purchases about 2,400 medicines and related products (including pCms) and 400 Chinese herbal medicines for sample testing. Besides testing pCms sampled through the market surveillance programme, the DH also investigates pCms reported by the Hospital Authority to have caused adverse drug reaction. The tests for pCms (conducted with the assistance of the Government Laboratory) are mainly to ascertain whether the pCms have been adulterated with western medicines or excessive heavy metals. For pCms that fail the laboratory tests, the DH will take appropriate action such as demanding the traders to stop selling and recall the products with problem.

4.3 The responsibility for market surveillance of Chinese medicines is shared between the Inspection and Licensing Section of the Pharmaceutical Service (Note 15) and the Chinese Medicine Division. The former Section sample tests pCms while the latter Division tests Chinese herbal medicines.

Audit observations and recommendations

4.4 *Issue of public alert.* In 2008, the DH tested 2,555 samples (see Note 9 to para. 2.15(b)) relating to 1,420 types of products for sale in Hong Kong. The DH found that 31 sampled products had been adulterated with either western medicines or excessive heavy metals. In view of the health risk posed by these products, the DH required the traders concerned to recall their products from the market (Note 16). As for the DH's measures for informing the public of the risk in consuming these products, Audit found that:

Note 15: *Audit findings on the market surveillance strategy of the Pharmaceutical Service are presented in PART 3 of Chapter 5 of the Director of Audit's Report No. 53.*

Note 16: *In 2008, there was no recall case concerning Chinese herbal medicines.*

- (a) the DH only issued public alerts for 29 of the 31 sampled products that required recall action; and
- (b) the two products (both were registered pCms) for which public alert had not been issued were found to contain heavy metals. According to the relevant manufacturers' reports submitted to the DH, not all their products sold were successfully recalled from retailers. In one case, 107 (21%) of 500 boxes (300 capsules per box) of the pCm sold were recalled. In another case, 9 (5%) of the 191 boxes (26 capsules per box) of the pCm sold were recalled and the manufacturer said that most of the unrecalled pCm would have been sold to the Mainland. **In other words, some 575 (500 + 191 – 107 – 9) boxes of pCm would have been sold to uninformed consumers (locally and in the Mainland) who would use these two pCms without knowing their health risk.**

In response to Audit's enquiry, the DH said in September 2009 that based on risk assessment, no public alert had been issued for the two products mentioned in (b). However, there was no documentation of the rationale for not issuing public alert. Audit noted that since April 2009, the DH had required its staff to document their assessments in this regard.

4.5 ***CMB not informed of problems with registered pCms.*** Of the 31 sampled products found adulterated with either western medicines or excessive heavy metals (see para. 4.4), Audit examination revealed that:

- (a) 6 had registration records (i.e. 4 issued with Transitional Registration Notices, 1 with Non-transitional Registration Notice and 1 applying for non-transitional registration). According to registration requirements laid down by the CMB, registered pCms should not be adulterated with either western medicines or excessive heavy metals (see para. 2.4(a)); and
- (b) the CMB was not kept informed of these 6 cases although in 2005, the CMB decided that an applicant for pCm registration should be required to submit explanation if his pCm was found to have failed the safety tests (including those for heavy metals). In this connection, Audit noted that the Pharmaceutical Service had not always informed the Chinese Medicine Division (which provides secretarial support to the CMB — see para. 1.7) of its findings on pCms violating the registration requirement. Only in 2 of the 6 cases that the Pharmaceutical Service had informed the Chinese Medicine Division of its findings.

4.6 Since April 2009, the CMB has adopted a new regulatory procedure for pCms found (by DH's market surveillance and investigation) to have safety or quality problems during and after registration. The new procedure includes a requirement for a trader to submit within 14 days an explanation and improvement proposal if his pCm is found to contain heavy metals and toxic element, pesticide residues and microbes above the permitted levels. For pCms found to be adulterated with western medicines, the CMB may consider de-registration or rejection of their registration applications. There is a need to remind the Pharmaceutical Service of its role in keeping the Chinese Medicine Division informed of its market surveillance findings for effective implementation of the new procedure.

4.7 *Control over pCms with registration rejected.* As shown in Figure 1 in paragraph 2.10, as at 31 July 2009, there were 5,196 (4,675 + 521) applications for pCm registration rejected or withdrawn (rejected pCms). There may be a public health risk if the rejected pCms are offered for sale in Hong Kong. To facilitate screening out import licence applications for rejected pCms, the Chinese Medicine Division has copied all notices of rejection of pCm registration to the Clinic Service and Pharmaceuticals Import/Export Control Section of the Pharmaceutical Service for reference.

4.8 Audit cross-checked the DH's list of samples purchased in 2008 for market surveillance against its list of rejected pCms, Audit found that:

- (a) there were 9 rejected pCms purchased in 2008 (Note 17);
- (b) while the DH market surveillance did not find western medicines or excessive heavy metals in these pCms, their safety has not been proven (i.e. without three satisfactory test reports on heavy metals, pesticide residues and microbes); and
- (c) as the Inspection and Licensing Section of the Pharmaceutical Service was not informed of the list of rejected pCms, the 9 rejected pCms purchased in 2008 had gone unnoticed.

Note 17: *Of the 9 pCms, 5 were rejected registration because the applicants failed to provide their safety test results. For the remaining 4 pCms, the applicants withdrew their registration applications.*

4.9 Audit considers that the DH needs to make use of its market surveillance programme for monitoring any sale of unregistered pCms (including the rejected pCms imported or locally manufactured) in the market. The Chinese Medicine Division should keep the Inspection and Licensing Section informed of the rejected pCms so that any of them found in sample purchases could be promptly investigated and enforcement action taken where necessary.

Audit recommendations

4.10 **Audit has recommended that the Director of Health should:**

- (a) **ensure that the regulatory procedure laid down by the CMB for dealing with pCms found to have safety and quality problems during and after registration is strictly followed;**
- (b) **in connection with (a), remind the Pharmaceutical Service of its role to keep the Chinese Medicine Division informed of its market surveillance findings on registered pCms;**
- (c) **make use of the market surveillance programme to monitor the sale of unregistered pCms in the market; and**
- (d) **in connection with (c), remind the Chinese Medicine Division to keep the Inspection and Licensing Section informed of any rejected pCms.**

Response from the Administration

4.11 The **Director of Health** accepts the audit recommendations. He has said that:

- (a) the DH has all along been providing secretariat and executive support to the CMB, and will continue to follow the procedures laid down by the CMB when discharging its functions. The DH will report investigation findings to the CMB for consideration of de-registration of the problematic pCms, or rejection of their registration applications; and
- (b) the surveillance systems for western and Chinese medicines are in different stages of development. A coordinated regime for pCm surveillance between the Pharmaceutical Service and the Chinese Medicine Division is being developed.

Web surveillance

4.12 To keep track of public health incidents relating to Chinese medicines in other regions, the Chinese Medicine Division has a programme to monitor international websites for adverse drug reaction reports and announcements issued by health authorities. The Division has included 81 websites of 50 international food and drug regulatory agencies in its daily surveillance list. The daily surveillance is to identify news items relating to quality or safety problems of Chinese medicines (such as counterfeit or adulteration). As regards news relating to pCms, the Division will ascertain whether they have registration records in Hong Kong and seek the assistance of the Pharmaceutical Service in checking the import licence record (see para. 1.7).

Audit observations and recommendations

4.13 In 2008, the Chinese Medicine Division screened 107,236 news items through its web surveillance. Some 660 news items relating to pCms with quality or safety problems in other places were identified (Note 18). Four problematic pCms were found to have registration records in Hong Kong (see Cases 2 to 5 in Table 5 for details).

Table 5
Web surveillance results in 2008

Case	Date of news item	Problem identified by overseas health authorities	Type of registration (Note)	Import licence record
2	January and December 2008	Counterfeit	Non-transitional	Yes (in 2001)
3	June 2008	Counterfeit	Transitional	Yes (in 2004)
4	September 2008	Illegal production	Non-transitional	No
5	November 2008	Substandard quality	Non-transitional	No

Source: DH records

Note: The pCms of Cases 2, 4 and 5 were issued with Non-transitional Registration Notices and that of Case 3 was issued with Transitional Registration Notice.

Note 18: In 2008, no news items relating to problematic Chinese herbal medicines were identified.

4.14 Audit reviewed the DH's follow-up action on the above four cases and found that there was room for improvement:

- (a) after ascertaining that Cases 2 and 3 had import licence records, neither the Pharmaceutical Service nor the Chinese Medicine Division had taken any further action (such as investigation to ascertain if there were similar problems in Hong Kong). There was no documentation of the reason for not taking follow-up action;
- (b) in September 2008, at the request of the Mainland authority to conduct an investigation into Case 4, the DH visited the relevant Hong Kong importer. The DH found a small quantity of the pCm in question. Upon the DH's advice, the importer subsequently returned the pCm stock to the Mainland manufacturer. However, the DH had not referred this case to the Customs and Excise Department for investigation although there was prima facie evidence that the pCm was imported without a licence (see Table 5); and
- (c) notwithstanding its finding of Case 4 in (b) above, the DH had not sought confirmation from the trader concerned for Case 5 (i.e. the other case without import licence records) that the pCm in question had not been imported for sale in Hong Kong.

Audit recommendations

4.15 **Audit has recommended that the Director of Health should ensure that proper follow-up action is taken on Chinese medicines identified to have quality or safety problem by web surveillance, by stipulating that:**

- (a) **in respect of a registered pCm with import licence records, arrangements should be promptly made with the importer concerned for any necessary recall of the product from the market, and where there are valid reasons for not taking follow-up action, they should be properly documented;**
- (b) **any suspected case of import of pCm without a licence should be promptly referred to the Customs and Excise Department for investigation; and**
- (c) **in respect of a registered pCm without import licence records, the importer concerned should be contacted to confirm that no such pCm has been imported.**

Response from the Administration

4.16 The **Director of Health** agrees with the audit recommendations.

PART 5: REGULATION OF UNDESIRABLE MEDICAL ADVERTISEMENTS

5.1 This PART examines the DH's measures in regulating undesirable medical advertisements.

Enforcement of Undesirable Medical Advertisements Ordinance

5.2 The UMAO prohibits the advertisements of medicines (Note 19), surgical appliances or treatments for prevention or treatment of certain diseases or conditions in human beings as specified in Schedules 1 and 2 of the Ordinance (Note 20). The purpose is to protect the public from being induced by advertisements to seek improper self-medication instead of consulting medical practitioners. Improper self-medication may result in inappropriate or delayed treatment, thereby endangering the life of patients.

5.3 The DH has laid down the following procedures for enforcing the UMAO:

- (a) a team of screeners (comprising 6 dispensers and 2 other supporting staff) are responsible for screening advertisements appearing on different media, namely printed media (i.e. newspapers and magazines), outdoor media (i.e. pamphlets, posters and signboards) and electronic media (i.e. the Internet, television and radio). They are guided by an Operation Manual in conducting the screening, issuance of warnings and identification of cases for referral to the Police for investigation and prosecution;
- (b) if an advertisement is suspected to have contravened the UMAO, the DH will issue a warning letter to the publisher and medicine distributor, advising them that if the same advertisement is found again, prosecution action may be taken without further notice; and
- (c) if the publisher/distributor disregards the warning and continues to publish the relevant advertisement, the DH will refer the case to the Police for investigation and prosecution.

Note 19: *Medicine is defined in the UMAO as any kind of medicament or other curative or preventive substance, regardless of whether it is a proprietary medicine, a patent medicine, a Chinese herbal medicine, a pCm, or purported natural remedy.*

Note 20: *Under Schedule 1, there are 14 diseases or conditions (e.g. any benign/malignant tumour) in respect of which advertisements are prohibited or restricted, except for some specified purposes (e.g. symptomatic relief of headaches). Under Schedule 2, there are three purposes (e.g. the promotion of sexual virility) that are prohibited.*

5.4 Table 6 shows the UMAO enforcement statistics from 2006 to 2008.

Table 6
UMAO enforcement statistics
(2006 to 2008)

	2006	2007	2008
(a) Advertisements screened			
• Printed media	50,020 (97.7%)	51,028 (98.4%)	53,480 (96.9%)
• Outdoor media	962 (1.9%)	759 (1.5%)	1,694 (3.0%)
• Electronic media	226 (0.4%)	37 (0.1%)	32 (0.1%)
Total	51,208 (100%)	51,824 (100%)	55,206 (100%)
(b) Warning letters issued	1,642	1,032	1,491
(c) Referrals to the Police	48	24	17
(d) Prosecutions instituted	38	23	13
(e) Convictions	37	20	12

Source: DH records

Audit observations and recommendation

Screening advertisements on electronic media

5.5 According to the DH's Operation Manual, with the exception of advertisements on television/radio (Note 21), advertisements on the Internet should be regularly screened. Each screener should spend one hour per week to screen for undesirable medical advertisements on the Internet. Three types of websites should be targeted, namely websites with warning letters issued, websites of health products and medicine companies/manufacturers (to be identified using search engines on the Internet) and websites appearing on newspaper or magazine advertisements.

Note 21: *The Operation Manual only requires screening of advertisements on television/radio upon receipt of a complaint. According to the DH, the Television and Entertainment Licensing Authority would screen advertisements on television/radio and refer suspected contravening cases to the DH for investigation.*

5.6 Table 6 shows that less than 1% of the advertisements screened were on electronic media. Moreover, the number of advertisements screened on electronic media had decreased from 226 in 2006 to 32 in 2008. Of these 32 advertisements, 29 were on the Internet (relating to 20 websites) and 3 on television/radio. About 90% of the advertisements were screened as a follow-up action on complaints/referrals received by the DH. **The DH needs to consider increasing the screening of advertisements on the Internet.**

Undesirable medical advertisements on websites located outside Hong Kong

5.7 Based on the DH's Operation Manual, the UMAO provisions do not apply to advertisements on the Internet when the relevant server company and the website registrant are located outside Hong Kong. In this connection, since 2006, the DH had not taken follow-up actions on five undesirable medical advertisements found on the Internet because both the server companies and the website registrants for the relevant advertisements were located outside Hong Kong. In February 2009, in response to the Food and Environmental Hygiene Department's referral of a suspected undesirable medical advertisement, the DH also said that no further action would be taken as the server company and the website registrant were located in the United States. According to the DH, while no further action was taken against the advertisement on the Internet in this case, the DH had taken enforcement actions against related advertisements published in other media in Hong Kong.

5.8 Among the five undesirable medical advertisements mentioned in paragraph 5.7, one pCm advertisement was found in 2008 to contain claims relating to treatment of venereal disease (which were prohibited under the UMAO). After the receipt of a warning letter from the DH, the licensed pCm manufacturer concerned relocated his website outside Hong Kong. As a result, the DH took no further action. Apparently, in this case, the manufacturer had sought to circumvent the UMAO restrictions by relocating his website outside Hong Kong.

5.9 As early as 1999, the DH had referred to the Police for investigation an advertisement on a website located outside Hong Kong which was suspected to have contravened the UMAO. After seeking legal advice, the Police informed the DH that there were difficulties in proceeding with prosecution in this case because they were unable to identify the location where the files of the website were uploaded. If the uploading occurred outside Hong Kong, the offence was committed outside the jurisdiction of Hong Kong. **Nevertheless, the Police issued a warning letter to the local trader concerned for publishing the advertisement.**

5.10 In September 2009, in response to Audit's enquiry, the DH said that:

- (a) the DH would take enforcement actions whenever there was sufficient evidence suggesting that an advertisement had contravened the UMAO. According to the DH's understanding, the jurisdiction of the UMAO was limited to Hong Kong. There would be legal uncertainties about taking any enforcement actions involving entities or activities outside the local jurisdiction. There would also be difficulties in collecting evidence overseas;
- (b) prosecution against advertisements suspected to have contravened the UMAO on websites located overseas, even if they contained information of local traders, might not be warranted from the legal point of view; and
- (c) the DH would seek advice from the Department of Justice and assistance from the Police on individual cases as appropriate.

Audit recommendation

5.11 **Audit has recommended that the Director of Health should consider increasing the screening of advertisements on the Internet.**

Response from the Administration

5.12 The **Director of Health** accepts in principle the audit recommendation. He has said that the DH has an established protocol for enforcing the UMAO, which was developed in compliance with the International Organisation for Standardisation 9001:2000 quality management systems requirement. Advertisements screened are prioritised by risk and public health impact. In Hong Kong, printed materials have a wider distribution and hence a more significant public implication. The DH will consider allocating more resources targeting Internet advertisements based on risk.

Undesirable Medical Advertisements (Amendment) Ordinance 2005

5.13 Since the early 2000's, there has been an increasing number of orally consumed products (e.g. "health foods" and "dietary supplements") found in the local market. Many of these products are not classified as medicines and are therefore not subject to the regulation of the CMO and the PPO. They may, however, be labelled or advertised with claims of specific beneficial health effects which may exist in the domain of drugs, but are not explicitly prohibited under the UMAO. This causes confusion among the public on the medical effects of these products. There have been complaints about misleading or exaggerated claims of these products from the general public, who has called for the regulation of these irresponsible claims.

5.14 In 2002, the Administration set up an Expert Committee (Note 22) to study and recommend a list of health claims to be prohibited in orally consumed products. The Expert Committee reviewed 13 types of health claims and recommended that 9 types should be prohibited. In 2003, a public consultation was conducted on the Committee's recommendations. Taking into account the views collected, the Administration decided to first introduce regulation on 6 types of claims with higher risks. In June 2005, the UMA (Amendment) Ordinance was enacted to set out the 6 types of undesirable health claims which are subject to two levels of restriction (see Table 7 for details).

Table 7
Restrictions on 6 types of undesirable health claims

Health claims	Restriction imposed
(i) Prevention, elimination or treatment of breast lumps	Level 1 restriction: The advertising of these three most risky claims is not allowed under any circumstances.
(ii) Regulation of function of genitourinary system	
(iii) Regulation of endocrine system	
(iv) Regulation of body sugar	Level 2 restriction: For these items, the advertising of certain prescribed claims is allowed (e.g. "The product is suitable for people concerned about blood sugar"). However, for products not registered under the CMO or the PPO, a disclaimer must be clearly put in the advertisement to inform consumers that they are not products registered under the CMO or the PPO.
(v) Regulation of blood pressure	
(vi) Regulation of blood lipids or cholesterol	

Source: UMA (Amendment) Ordinance

5.15 In June 2005, during the LegCo session for the Second Reading of the UMA Amendment Bill, the Secretary for Food and Health informed Members that, when the pCm registration system was well on track, the Administration would consider further regulating

Note 22: The Expert Committee consisted of representatives from the Consumer Council, Chinese medicine practitioners, medical practitioners, pharmacists and a nutritionist.

other health claims. They included three types of claims relating to slimming, promotion of detoxification and regulation of immune system which were recommended by the Expert Committee but excluded from the 2005 Amendment Ordinance (see para. 5.14).

Audit observations and recommendation

UMA (Amendment) Ordinance not yet commenced

5.16 The UMA (Amendment) Ordinance has provided that the Secretary for Food and Health shall appoint a day for the commencement of the new regulatory requirements under the Ordinance. This is to give the trade and industry a grace period of at least 18 months to prepare for the new regulation. In December 2005, the Administration informed the Health Panel that the Amendment Ordinance would come into full operation in 2007. **However, up to September 2009 (over 2 years after the expected commencement date), the UMA (Amendment) Ordinance had not come into operation.**

5.17 The main reason for the delay in implementing the Amendment Ordinance was that for products making permissible claims under the Level 2 restriction (see items (iv) to (vi) in Table 7), a disclaimer must be put in the advertisement to inform consumers that they are not products registered under the CMO or the PPO. As the registration of pCms was still in progress (see para. 2.11), the Secretary for Food and Health has not yet appointed a day for commencing the UMA (Amendment) Ordinance.

Difficulties to regulate undesirable medical advertisements

5.18 Without the legislative backing of the UMA (Amendment) Ordinance, the DH had difficulty taking enforcement action against undesirable medical advertisements, as follows:

- (a) Audit reviewed all the 62 complaints on undesirable medical advertisements of orally consumed products received by the DH in 2008. Audit found that, of these 62 complaints, 14 (23%) related to health claims which might not meet the Amendment Ordinance requirements. The DH could not take action on these complaints because the Amendment Ordinance was not yet in operation; and
- (b) Audit selected two newspapers and two weekly magazines (one of their daily/weekly issues for each week of March 2009) for screening advertisements relating to orally consumed products. Audit found that, of the 244 advertisements screened, 56 (23%) contained claims which might not meet the Amendment Ordinance requirements. Owing to the same reason as stated in (a) above, the DH also could not take action on these advertisements.

5.19 To safeguard public health, the DH should expedite action to complete the pCm registration so that the UMA (Amendment) Ordinance can be put into operation as soon as possible for the effective control of undesirable medical advertisements.

5.20 **Publicity.** Following the enactment of the UMA (Amendment) Ordinance, in 2006 the DH developed guidelines on complying with the new regulation, organised three seminars for the trade, and issued letters to publishers to inform them of the new requirements. In September 2009, in response to Audit's enquiry, the DH said that it had planned to further step up publicity before the commencement of the Amendment Ordinance.

Audit recommendation

5.21 Audit has *recommended* that the Director of Health should expedite action to complete the pCm registration so that the UMA (Amendment) Ordinance can be put into operation as soon as possible for the effective control of undesirable medical advertisements.

Response from the Administration

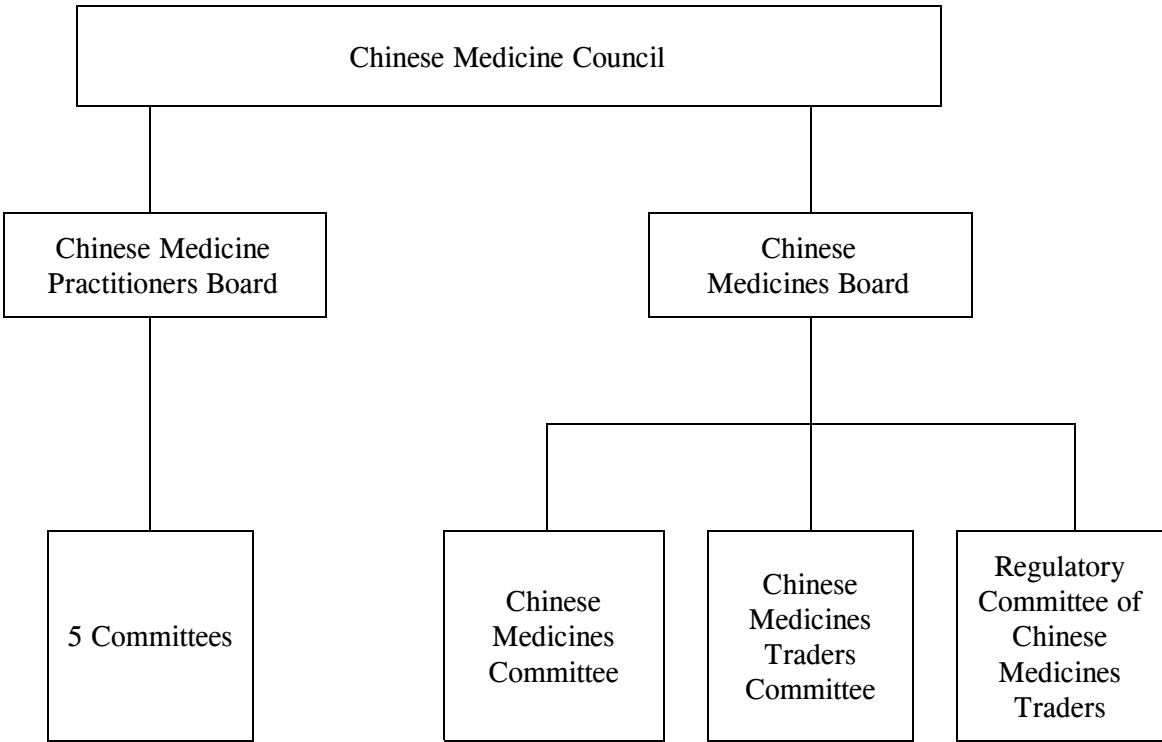
5.22 The **Director of Health** agrees with the audit recommendation.

Chronology of key events in implementing the Chinese Medicine Ordinance

July 1999	The CMO was enacted.
September 1999	The CMC was established.
30 April 2003	The provisions for licensing of Chinese medicines traders (retailers and wholesalers of Chinese herbal medicines, and wholesalers and manufacturers of pCms) commenced.
15 July 2003	Application period for transitional licensing of Chinese medicines traders commencing 5 May 2003 came to an end.
19 December 2003	The provisions for registration of pCms commenced.
30 June 2004	Application period for transitional registration of pCms commencing 19 December 2003 came to an end.
30 June 2005	Second Phase supporting documents under pCm transitional registration were due.
11 January 2008	Sections 109, 110, 111, 131 and 134 of the CMO (requiring that no person shall engage in the Chinese medicine trade without a licence) came into effect.
30 June 2009	Third Phase supporting documents under pCm transitional registration were due.

Source: DH records

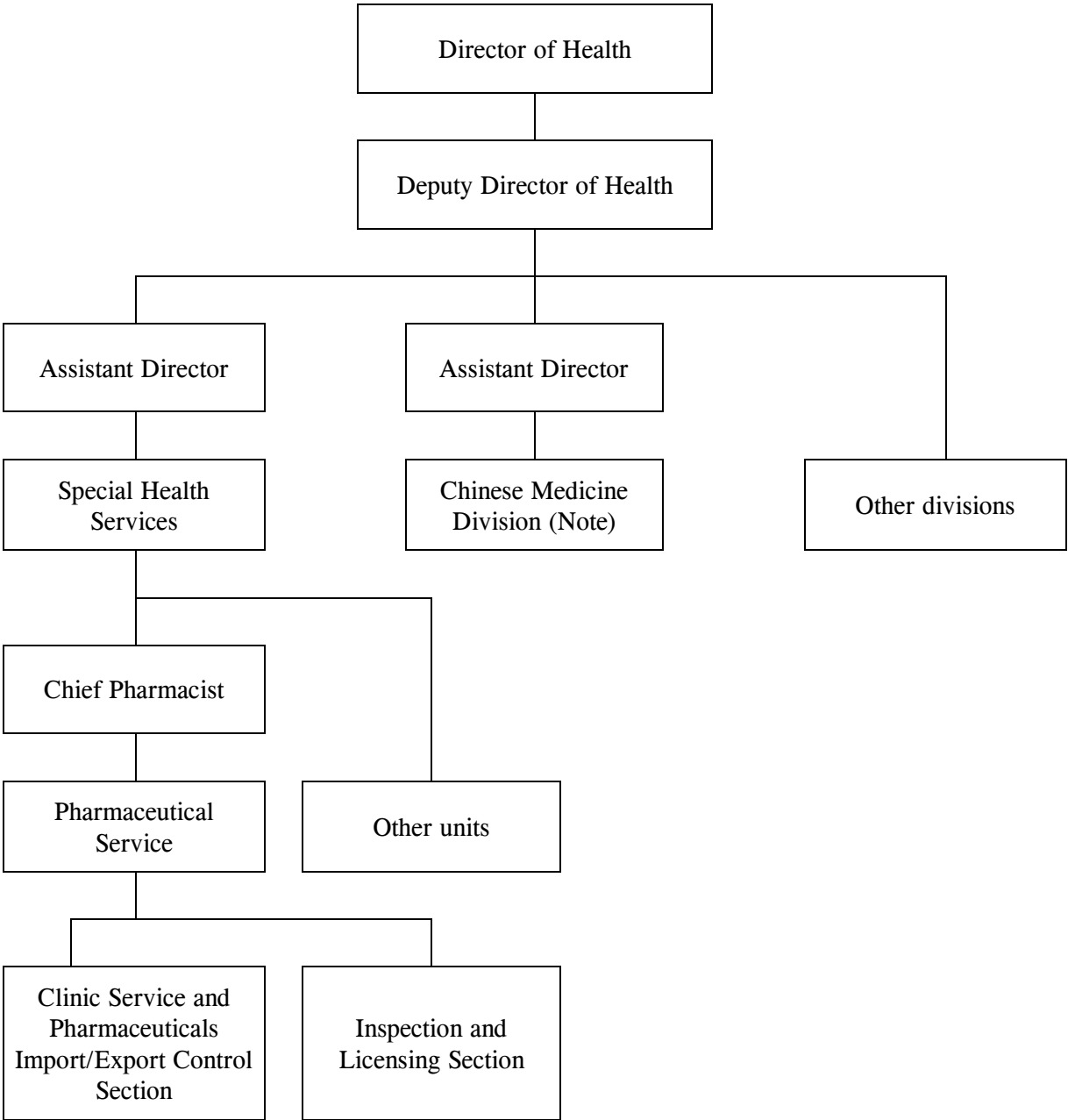
Chinese Medicine Council
Council structure
(1 August 2009)



Source: DH records

Remarks: The CMC consists of the Director of Health as an ex-officio member and 18 other members (including the Chairman) appointed by the Chief Executive.

Department of Health
Organisation chart (extract)
(1 August 2009)



Source: DH records

Note: There were 4 Senior Pharmacists (including 1 supernumerary post for a period of 12 months), 22 Pharmacists (16 on civil service terms and 6 on contract terms), 1 Senior Medical and Health Officer and 1 Medical and Health Officer working in the division.

Classification categories of proprietary Chinese medicines

1. The classification categories of pCms include the “Established medicines”, “Non-established medicines”, and “New medicines”.

Established medicines

2. Except for Chinese medicine injections, a pCm that fulfils any of the following shall be regarded as an established medicine. Its prescription is:

- (a) an ancient prescription (which has been documented in Chinese medicines bibliography in, or before, the Qing Dynasty); or
- (b) a modified ancient prescription (the prescription of which is based on an ancient prescription with reasonable and rational modifications); or
- (c) a pharmacopoeia prescription (which has been documented in the Pharmacopoeia of the People’s Republic of China); or
- (d) any other prescriptions originating from the National Drug Standards of the People’s Republic of China and accepted by the CMB.

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

3. The CMB 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 an established medicine:

- (a) accept only the latest promulgated standard of the prescription. For example, if a prescription is both documented in the Drug Standard of the Ministry of Health and the Pharmacopoeia of the People’s Republic of China, the CMB will only accept the one in current edition of the Pharmacopoeia;
- (b) consider the current use of the prescription. For example, the CMB will not accept the Drug Registration Standards that have been withdrawn due to safety concerns; and
- (c) the product specification of the pCm must fulfil the requirements imposed by the CMB.

Non-established medicines

4. Except for Chinese medicine injections, any pCms, 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 Chinese herb, new medicinal part(s) of Chinese herb, active group extracted from Chinese herb or set of active groups extracted from compound prescription. Otherwise, the pCm will be required for registration under the new medicines category.

5. Single Chinese medicine granules are those granules that fall within the definition of pCm, and are made from one kind of Chinese herb, and their claimed indications and functions are the same as those of their crude drugs.

New medicines

6. A pCm that meets any of the following descriptions shall be regarded as a new medicine:

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

Source: DH records

Appendix E
(paras. 2.4(b)(ii), 2.5 and
2.18 refer)

Documents required for proprietary Chinese medicine registration

	Group I	Group II	Group III
(A) General documents			
1. Completed application form and appropriate checklist	✓	✓	✓
2. Personal information of the person-in-charge of the company	✓	✓	✓
3. Documentary proofs of manufacturer or sales history of the product	✓	✓	✓
4. Copy of manufacturing authorisation issued by the country of origin (if applicable)	✓	✓	✓
5. Copy of free sale documentation issued by the country of origin (if applicable)	✓	✓	✓
6. Product sample and prototype sales pack	✓	✓	✓
7. Label and package insert that have complied with the laws	✓	✓	✓
8. Master formula	✓	✓	✓
(B) Product safety documents			
1. Heavy metals and toxic element test report	✓	✓	✓
2. Pesticide residues test report	✓	✓	✓
3. Microbial limit test report	✓	✓	✓
4. Acute toxicity test report	✓	✓	✓
5. Long-term toxicity test report	✓ (*)	✓	✓
6. Local toxicity test report	✓ (*)	✓ (*)	✓ (*)
7. Mutagenicity test report	×	✓ (*)	✓ (*)
8. Carcinogenicity test report	×	✓ (*)	✓ (*)
9. Reproductive and development toxicity test report	×	✓ (*)	✓ (*)
10. Summary report on product safety documents	✓	✓	✓

Appendix E
(Cont'd)
(paras. 2.4(b)(ii), 2.5 and
2.18 refer)

	Group I	Group II	Group III
(C) Product efficacy documents			
1. Interpretation and principle of formulating a prescription	✓ (*)	✓ (*)	✓ (*)
2. Reference materials on product efficacy	✓	✓	✓
3. Principal pharmacodynamic studies report	×	×	✓
4. General pharmacological studies report	×	×	✓ (*)
5. Clinical trial protocol and summary report	×	×	✓
6. Summary report on product efficacy documents	✓	✓	✓
(D) Product quality documents			
1. Manufacturing method	✓	✓	✓
2. Physicochemical properties of crude drugs	✓	✓	✓
3. Product specification, method and certificate of analysis	✓ (*)	✓ (*)	✓ (*)
4. Accelerated stability test report or general stability test report	✓ (*)	×	×
5. Real-time stability test report	×	✓ (*)	✓ (*)

Legend: ✓ Required

× Not required

* For details of the application and exception to these items, please see the “Application Handbook for Registration of pCms” which is available on the CMC website (www.cmchk.org.hk).

Source: DH records

Appendix F
(Table 1 in para. 2.6 and
2.22 refer)

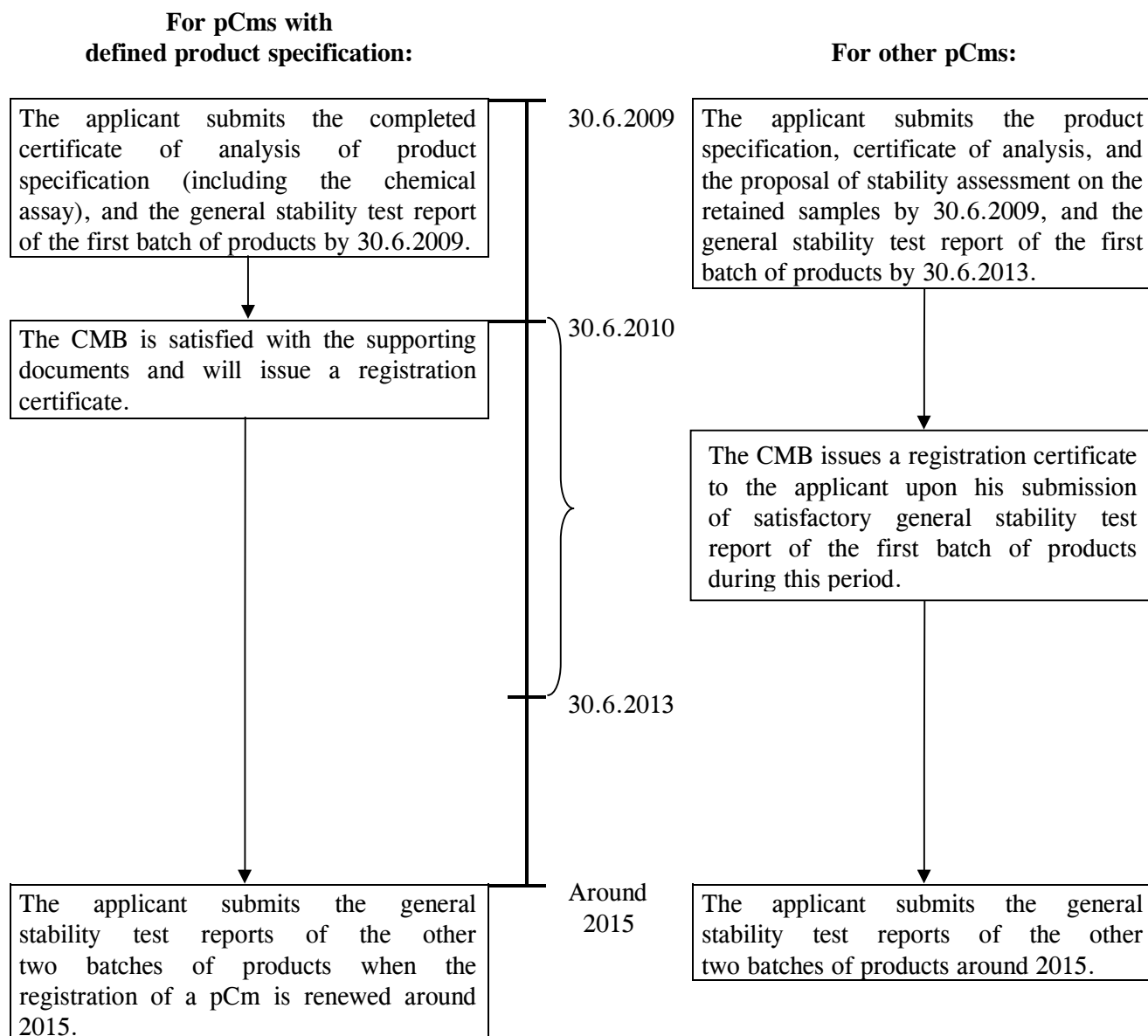
Third Phase supporting documents due on 30 June 2009

	Group I	Group II	Group III
Product safety documents			
1. Acute toxicity test report	×	✓	✓
2. Long-term toxicity test report	×	✓	✓
3. Local toxicity test report (*)	×	✓	✓
4. Mutagenicity test report (*)	×	✓	✓
5. Carcinogenicity test report (*)	×	✓	✓
6. Reproductive and development toxicity test report (*)	×	✓	✓
7. Summary report on product safety documents	✓	✓	✓
Product efficacy documents			
8. Principal pharmacodynamic studies report	×	×	✓
9. General pharmacological studies report (*)	×	×	✓
10. Clinical trial protocol and summary report	×	×	✓
11. Summary report on product efficacy documents	✓	✓	✓
Product quality documents			
12. Product specification, method and certificate of analysis	✓	✓	✓
13. Accelerated stability test report or general stability test report (*)	✓	✓	✓
14. Real-time stability test report	×	✓	✓

Legend: ✓ Required
 × Not required
 * For details of the application of these items, please see “Transitional registration checklist (C) (Amended version)” on the CMC website (www.cmchk.org.hk).

Source: DH records

Extended time for submitting certain Third Phase documents



Source: DH records

Qualification for supervising medicine dispensing and manufacturing

(A) Dispensing of Chinese herbal medicines

A person to be responsible for the supervision of the dispensing of Chinese herbal medicines and not more than two deputies shall be nominated (Note). Each responsible person (i.e. the nominated person and his deputies) in the application complies with any of the following minimum requirements regarding knowledge and experience:

	Professional qualification	Academic qualification	Working experience
(a)	—	(1) holding a bachelor's degree in Chinese medicine awarded by a university in Hong Kong; or (2) having a qualification which, in the opinion of the CMB, is equivalent to that mentioned in subparagraph (1) above	Having six months' practical experience in dispensing Chinese herbal medicines in Hong Kong
(b)	—	(1) holding a diploma in Chinese medicines awarded by a university in Hong Kong; or (2) holding a diploma in Chinese medicines awarded by the Vocational Training Council; or (3) having a qualification which, in the opinion of the CMB, is equivalent to that mentioned in subparagraph (1) or (2) above	Having one year's practical experience in dispensing Chinese herbal medicines in Hong Kong
(c)	Registered/ Listed Chinese Medicine Practitioner	—	Having six months' practical experience in dispensing Chinese herbal medicines in Hong Kong
(d)	Registered Pharmacist	(1) holding a postgraduate certificate in Chinese medicines awarded by a university in Hong Kong; or (2) having a qualification which, in the opinion of the CMB, is equivalent to that mentioned in subparagraph (1) above	Having one year's practical experience in dispensing Chinese herbal medicines in Hong Kong

Appendix H
(Cont'd)
(Table 2 in para. 3.4 refers)

	Professional qualification	Academic qualification	Working experience
(e)	—	(1) holding a certificate in Chinese medicines awarded by a university in Hong Kong on completion of a 120-hour course; or (2) holding a certificate in Chinese medicines awarded by Vocational Training Council on completion of a 120-hour course; or (3) having a qualification which, in the opinion of the CMB, is equivalent to that mentioned in subparagraph (1) or (2) above	Having three years' practical experience in dispensing Chinese herbal medicines in Hong Kong
(f)	—	—	Having five years' practical experience in dispensing Chinese herbal medicines in Hong Kong

(B) Manufacturing of pCms

A person to be responsible for the supervision of the manufacture of pCms and not more than two deputies shall be nominated. Each responsible person (i.e. the nominated person and his deputies) in the application complies with any of the following minimum requirements regarding knowledge and experience:

	Professional qualification	Academic qualification	Working experience
(a)	—	(1) holding a bachelor's degree in Chinese medicine awarded by a university in Hong Kong; or (2) having a qualification which, in the opinion of the CMB, is equivalent to that mentioned in subparagraph (1) above	Having six months' practical experience in manufacturing pCms in Hong Kong
(b)	—	(1) holding a diploma in Chinese medicines awarded by a university in Hong Kong; or (2) holding a diploma in Chinese medicines awarded by the Vocational Training Council; or	Having one year's practical experience in manufacturing pCms in Hong Kong

Appendix H
(Cont'd)
(Table 2 in para. 3.4 refers)

	Professional qualification	Academic qualification	Working experience
		(3) having a qualification which, in the opinion of the CMB, is equivalent to that mentioned in subparagraph (1) or (2) above	
(c)	Registered/ Listed Chinese Medicine Practitioner	—	Having six months' practical experience in manufacturing pCms in Hong Kong
(d)	Registered Pharmacist	(1) holding a postgraduate certificate in Chinese medicines awarded by a university in Hong Kong; or (2) having a qualification which, in the opinion of the CMB, is equivalent to that mentioned in subparagraph (1) above	Having six months' practical experience in manufacturing pCms in Hong Kong
(e)	—	(1) holding a certificate in Chinese medicines awarded by a university in Hong Kong on completion of a 120-hour course; or (2) holding a certificate in Chinese medicines awarded by Vocational Training Council on completion of a 120-hour course; or (3) having a qualification which, in the opinion of the CMB, is equivalent to that mentioned in subparagraph (1) or (2) above	Having three years' practical experience in manufacturing pCms in Hong Kong
(f)	—	—	Having five years' practical experience in manufacturing pCms in Hong Kong

Source: DH records

Note: If the application states that no Chinese herbal medicine is to be dispensed in the premises to which the application relates, then there will be no need to nominate persons to be responsible for the supervision of the dispensing of Chinese herbal medicines.

Acronyms and abbreviations

Audit	Audit Commission
CMB	Chinese Medicines Board
CMC	Chinese Medicine Council
CMO	Chinese Medicine Ordinance
CMR	Chinese Medicines Regulation
DH	Department of Health
FHB	Food and Health Bureau
GMP	Good Manufacturing Practice
Health Panel	Panel on Health Services
LegCo	Legislative Council
pCm	Proprietary Chinese medicine
PI	Pharmacist Inspector
PPO	Pharmacy and Poisons Ordinance
UMAO	Undesirable Medical Advertisements Ordinance
UMA (Amendment) Ordinance	Undesirable Medical Advertisements (Amendment) Ordinance 2005