Business Facilitation Advisory Committee
Retail Task Force

Registration System for Proprietary Chinese Medicines

Introduction

This paper serves to brief members of the Retail Task Force on the registration system for proprietary Chinese medicines (pCm) in Hong Kong and addresses concerns raised some Chinese medicines traders.

Background

2. The Chinese Medicine Ordinance (Cap.549 of the Laws of Hong Kong) (CMO) was enacted in 1999. A statutory body, the Chinese Medicine Council (CMC), was established in September 1999 and it is responsible for the regulation of Chinese medicine practitioners, licensing of Chinese medicine traders and registration of proprietary Chinese medicines. All pCm manufactured or sold, in Hong Kong must be registered.

Definition of pCm

3. Under the CMO, " pCm" means any proprietary product -

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

(i) any Chinese herbal medicines; or

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

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

(b) formulated in a finished dose form; and

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

4. For pCm manufactured in Hong Kong, the application for registration should be submitted by the local manufacturers. For pCm manufactured outside Hong Kong, the application for registration should be submitted by the importers or the local representatives/ agents.

Transitional arrangement

5. The registration system for pCm commenced on 19 December 2003. To enable the continual sale of pCms that have been on the market for a long time, a transitional arrangement has been provided in the Ordinance for pCms which have been manufactured or sold in Hong Kong on 1st March 1999. These products are eligible for transitional registration and the relevant manufacturer or importer / agent were required to submit the application before 30 June 2004. By the deadline of end June 2004, a total of about 14,000 applications for transitional registration and 2,000 non-transitional registration were received by the Chinese Medicines Board (CMB) of the CMC.

Registration requirement

6. In assessing an application for pCm registration, the CMB will take into consideration the safety, quality and efficacy of the pCm.

7. In developing the registration requirements, the CMB had made reference to international control measures of Chinese medicines and herbal medicines. Chinese medicine experts were invited to participate in meetings and extensive consultations with the Chinese medicines traders and laboratory representatives with over 30 consultation sessions held.

8. All pCm have to fulfill five basic registration requirements, namely:

(a) Not exceeding the limits of heavy metals and toxic element;

(b) Not exceeding limits of pesticide residues;

(c) Not exceeding limits of microbes;

(d) No adulteration with western medicine; and

(e) Compliance with the Animals and Plants (Protection of Endangered Species) Ordinance.

Classification of pCm

9. Having regard to the unique nature of traditional Chinese medicine, pCm is divided into the following three categories, taking into account the formulation, usage history and indications of pCm:

i) established medicines;

ii) non-established medicines; and

iii) new medicines.

10. Please refer to the Annex for the detailed classification.

11. Depending on the category of the pCm, the applicant is required to submit different levels of documents in order to prove the safety, quality and efficacy of the product For example, for established medicines, references from Chinese medicines bibliography, Pharmacopoeia or any other National Standards of the People's Republic of China would be sufficient for product efficacy. For new medicines, reports on product efficacy and clinical trials are required.

Concerns of Traders

Progress

12. Since the commencement of the registration system from 19.12.2003, over 16,100 applications *(including about 14,000 for transitional registration and about 2,100 for non-transitional registration)* have been received.

13. For transitional registration, applicants were required to submit documentary proof to show that the pCm was manufactured or on sale on 1 March 1999 at the time of application. Applicants for transitional registration were allowed to submit their safety test reports *(including heavy metals and trace element, pesticide residues and microbial limit)* by 30 June 2005. As at today, about 4,000 transitional applications have not yet provided satisfactory test reports and these products are not issued entry permit until they provide a report to CMB.

14. As at end November 2006, the CMB has completed processing 3,477 cases. It is estimated that all applications for transitional registration will be completed by the end of 2007. The progress is uploaded onto the website of the CMC at www.cmchk.org.hk.

15. After consultation with the trade, the CMB has decided that the registration certificates will be issued in one lot when processing of all the applications is completed. Meanwhile, the pCms are allowed to be manufactured/ sold/ imported/ exported and a letter will be issued by Department of Health to the traders to facilitate their export in fulfillment of other countries' requirement if necessary.

Requirements for Laboratory

16. Laboratories performing the tests for pCm registration should meet requirements set by the International Standardization Organization (i.e. ISO/IEC 17025) or Good Laboratories Practice (GLP). Recognizing the limited capacity of local laboratories and the fact that many pCm were produced in the Mainland, CMB had also accepted 16 Municipal testing laboratories recommended by the State Food & Drug Administration. This gives more option for Chinese medicines traders and avoids additional costs for repeated testing for pCm manufactured in the Mainland.

17. Technical guidelines have been prepared and published, and regular dialogue is maintained with both the local laboratories and the ones in Mainland, in respect of the technical requirements for pCm testings.

Time table for submission of product specification documents and general stability reports for transitional registrations

18. In response to concerns raised by traders on the technical difficulties and costs involved in preparing product specifications and general stability, the CMB has agreed to allow more time for submission of product specification documents and general stability reports for all transitional registrations.

19. For pCms under transitional registration that already had defined product specifications, e.g., those documented in the Pharmacopoeia of the People's Republic of China or the National Drug Standards of the People's Republic of China , the quality report and stability test reports for the first batch should be submitted by end June 2009. The reports for the second and third batches should be submitted by 2015.

20. For pCm which do not belong to the aforementioned category, the applicant should submit the quality reports by end June 2009. The stability test reports for the first batch should be submitted by end June 2013 and the remaining two batches by 2015.

21. The major trade associations were invited to attend briefings on the latest arrangement in June and July 2006 and a letter has been issued to all applicants.

Compliance with the Animals and Plants (Protection of Endangered Species) Ordinance

22. For Chinese herbs that are listed in Convention on International Trade in Endangered Species (CITES) Appendix II, [e.g., Gastrodia (天麻), Moschus (麝香)], they can still be used in pCm as long as the law is complied with by possessing the required permit for import.

23. In the case of, for example, "Natural Moschus(麝香)", the Mainland has issued official guideline that except for four types of pCm, namely, "Angong Niuhuang Wan (安宮牛黃丸)", " Luishen Wan (六神丸)", "Babao Dan (八寶丹) " and "Pianzai Huang (片仔癀)" manufactured by authorized enterprises, " Natural Mochus" in the prescriptions of pCm should be substituted by " Artificial Moschus" Therefore, for pCm manufactured in the Mainland, their eligibility for transitional registration will not be affected if the "Natural Moschus" in the prescription has to be substituted by " Artificial Moschus" in accordance with the Mainland regulatory requirements.

24. All applications will be examined on a case to case basis and CMB cannot accept the exclusion of these herbs without considering the overall affect on the efficacy of the pCm.

Change of Dose Form

25. Under the CMO any change of the dose form for a registered pCm would render it a new application. This applies to the change of dose form from pills to tablets or tablets to capsules. As under these circumstances, the specification of the pCm will totally be different and the quality of the pCm will be changed with the change of dose form.

26. However, for some dose forms, they are further divided into "subtypes". There are honeyed pills (蜜丸), water-honeyed pills (水蜜丸), watered pills (水丸) and concentrated pills(濃縮丸) for pills; and there are sugar-coated tablets (糖衣片), film-coated tablets (薄膜衣片) and enteric-coated tablets(腸溶衣片) for tablets.

27. The change of these subtypes will be considered on a case to case basis. For example, if a tablet with sugar-coating is changed to film-coating, the mere change of the coating of the pCm might not affect the quality of the tablets with the principal manufacturing method remains unchanged. Under such circumstances CMB might consider the change to be acceptable and will not affect the eligibility of the pCm. On the other hand, if a pCm is changed from honeyed pills to concentrated pills, the pills will be made of herbs extraction instead of herbs powder. The overall quality of the pCm will be different and the principal manufacturing method is not the same. Hence, such pCm will be considered to be a different product.

Undesirable Medical Advertisement Ordinance (UMAO)

28. The UMAO (Cap. 231) prohibits the advertising of medicine, surgical appliance or treatment for prevention or treatment of certain diseases or conditions in human beings as specified in Schedule 1 and 2 of the Ordinance in order to prevent the adverse effects of improper self-medication by members of the public.

29. To assist the trade to understand the UMAO better, a set of guidelines was issued and uploaded onto the website of the Pharmaceutical Service at www.psdh.gov.hk. In addition, briefing workshops with the Chinese Medicines traders had been organized, recently on 24 and 25 October 2006.

Samples of unregistered pCm and herbs not allowed to be imported for display in Hong Kong trade shows

30. Discussions had been held with the Trade Development Council since about 2 years ago on the arrangement for display of imported pCms or herbs at Hong Kong trade fairs. The organizers have been advised to obtain a wholesaler licence and apply for the import of the unregistered pCm samples for display only after which the entire stock would be exported to the country of origin by the importer after exhibition. The CMB and DH will continue liaise with TDC and the trade on how to facilitate exhibition on Chinese medicine.

Department of Health
December 2006

Annex

Classification of proprietary Chinese medicines (中成藥)

Proprietary Chinese medicines (pCm) are categorized into "Established medicines", "Non-established medicines", and "New medicines".

Established medicines (固有藥)

2. Except for Chinese medicine injections, pCm that fulfills any of the following shall be regarded as "Established medicines":-

(a) Its prescription is:

i. an ancient prescription *(which is documented in Chinese medicines bibliography in, or before, the Qing dynasty)*; or

ii. a modified ancient prescription *(the prescription of which is based on an ancient prescription with reasonable and rational modifications)*; or

iii. a pharmacopoeia prescription *(which has been documented in the Pharmacopoeia of the People's Republic of China)*; or

iv. any other prescriptions originated from the National Drug Standards of the People's Republic of China and accepted by the Chinese Medicines Board.

The original dose form of the prescription should not be changed; otherwise the pCm will be regarded as "New medicines category". *(except for those ancient prescriptions provided that their principal manufacturing method remains unchanged).*

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

3. The Chinese Medicines Board will adopt the following principles in deciding whether to accept a prescription originated from the National Drug Standards of the People's Republic of China as "Established medicines" -

(a) Accept only the latest promulgated standard of the prescription. For example, if a prescription is both documented in the Drug Standard of the Ministry of Health and the Pharmacopoeia of the People's Republic of China, the Chinese Medicines Board will only accept the one in current edition of the Pharmacopoeia.

(b) Consider the current use of the prescription. For example the Chinese Medicines Board will not accept the Drug Registration Standards that have been withdrawn due to safety concerns.

(c) The product specification of the pCm must fulfill the requirements imposed by the Chinese Medicines Board.

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

(a) The amendment is according to the requirement or regulation of the country /district for sale,

(b) The amendment is made to the prescription for a pCm that is qualified for transitional registration, transitionally registered or registered; and

(c) The amendment does not affect the pharmacodynamic and pharmacological effects of the product. For example, the principle and assistant drug(s) shall not be changed.

Non-established medicines (非固有藥)

5. 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.

6. "Single Chinese medicine granules" are those granules that fall within the definition of pCm, and are made from single Chinese herbs, and their claimed indications and functions are the same as those of their crude drugs.

New medicines (新藥)

7. PCms that meet any of the following descriptions shall be regarded as "New medicines":-

(a) Its prescription comprises any one (or several) of the following:

(i) a newly discovered Chinese herb [(1)] ;

(ii) a new medicinal part of a Chinese herb [(2)] ;

(iii) an active group extracted from Chinese herb [(3)] ;

(iv) a set of active groups extracted from a compound prescription;

(b) Chinese medicine injection [(4)] ;

(c) preparation of a new Chinese medicine prescription [(5)] ;

(d) pCm with altered route of administration [(6)] ;

(e) pCm with new indication [(7)] ;

(f) pCm with altered dose form [(8)].

Notes :

(1) A newly discovered Chinese herb refers to species that is not documented in any Chinese medicines bibliography or the Pharmacopoeia of the People's Republic of China.

(2) A new medicinal part of a Chinese herb refers to the part of Chinese herb that is not documented in any Chinese medicines bibliography or the Pharmacopoeia of the People's Republic of China.

(3) An active group refers to a non-isolated chemical constituent extracted from Chinese herb, e.g.: flavones

(4) Chinese medicine injection refers to a Chinese medicine prescription in the form of injection. It can be a non-isolated chemical constituent, single herb prescription or compound prescription preparation.

(5) New Chinese medicine prescription preparation refers to preparation that is not formulated based on an ancient prescription, a pharmacopoeia prescription, a modified ancient prescription, and any other prescriptions originated from the National Drug Standards of the People's Republic of China as approved by the Chinese Medicines Board.

(6) An example of altered route of administration: from oral administration to application to mucous membrane.

(7) New indication refers to indication that is additional to the already documented indications of the registered pCm, the ancient prescription or the pharmacopoeia prescription.

(8) Altered dose form refers to those, which are different from the dose form of the registered pCm, the ancient prescription (except those without changing the principle manufacturing process), the pharmacopoeia prescription, or any other prescriptions originated from the National Drug Standards of the People's Republic of China.