Business Facilitation Advisory Committee
Retail Task Force

Response to Concern of the Proprietary Chinese Medicine Trade - February 2007

Trade's concern	Improvement proposal	Response by Department of Health
(A) Technical difficulties and high costs involved in meeting requirements for product specifications and general stability		
(I) There is no standard testing methodology for such attributes of proprietary Chinese medicine (pCm) in China or other places. The Administration had not assessed the capability of the trade in meeting the full registration requirements which are more stringent than other countries e.g. Singapore, Taiwan, Macau and Malaysia.	(a) To allow full registration of transitional pCms on basis of safety test result only. (b) To allow provisional registration of non-transitional pCms on basis of safety test result only. Products that satisfy the additional test results can be given accreditation for recognition. (c) For full registration of non-transitional pCms – • to accept basic information on product stability instead of testing reports for the two attributes; and/or • to categorise pCms into different classes with different regulatory requirements such that a particular test is required only of a class of pCms.	• In determining an application for registration of a pCm, the Medicines Board (CMB) shall follow Section 122 of the Chinese Medicine Ordinance. The CMB shall in particular take into consideration the safety, quality and the efficacy of the pCm. • In developing the registration requirements, the CMB had made reference to international control measures of Chinese medicines and herbal medicines. Chinese medicines experts were invited to participate in meetings and extensive consultations with the Chinese medicines traders and laboratory representatives with over 30 consultation sessions held. • PCm are categorized into "**Established medicines**", "**Non-established medicines"** and " **New medicines**", each category is further divided into Groups I, II and III. The evidence required to substantiate safety and efficacy are different depending on the classification.

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(II) The testing cost is high. Test results can also fail the registration requirements. The tests pose huge hurdle in the development of new pCm and drive SMEs in the industry out of business.	(a) To collaborate with academic institutions and other relevant organizations in subsidizing laboratory tests for pCm. (b) To eliminate duplicate tests for different brands of pCm of the same prescription. (c) To allow registration of multiple names for a particular pCm. (d) To accept test results performed by Chinese laboratories other than those produced by the Municipal testing laboratories recommended by the State Food and Drug Administration. (e) To accept test results meeting the Good Manufacturing Practice (GMP) standard.	(a) Trade Development Council may provide assistance in this area. (b) To alleviate the trade's costs of testing of pCm, the CMB would consider accepting test reports covering a number of products of the same formulation. (c) Under the Chinese Medicine Ordinance, product name is one of the particulars to be registered. One pCm registration shall only have one registered product name, and variation of such name, under section 124 of the Ordinance, is not allowed. However, CMB would consider accepting the reports covering a number of products of the same formulation. (d) Apart from the accepted municipal Institutes for Drug Control in China, other laboratories complied with the following are also accepted: (i) The scope of (ISO/IEC 17025) accreditation of that laboratory is relevant to proprietary Chinese medicine *(e.g. Chinese Proprietary Medicine Product, Chinese Medicine & Related Products, or Traditional Medicine)*; and

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		(ii) The relevant test(s), e.g. Heavy Metals and Toxic Element Test, Pesticide Residues Test and Microbial Limit Test, of that laboratory is/are accredited; and (iii) Testing method(s) is/are complied with requirement(s) stipulated by the CMB in the technical guidelines. (e) For acceptance of stability test report relevant to GMP manufacturer, the stability test of at least the first batch of product should be conducted in test laboratory which has been granted ISO/IEC 17025 accreditation of the three basic tests, namely Heavy metals and toxic element test; Pesticide residues test; and Microbial limit test. The stability tests for the remaining batch(es) can be conducted by the manufacturer of the product which have met the requirements of Good Manufacturing Practice (GMP) in respect of the manufacturing and quality control of pCm. Nevertheless, the CMB emphasizes there are differences between the accreditation requirements for GMP and ISO/IEC 17025 or GLP. Therefore she does not recognize that the accreditation of GMP is equivalent to ISO/IEC 17025 or GLP. The current arrangement is only made in consideration of the burden on traders and infrastructure at present.

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(B) Slow progress in processing applications for registration		
(III) Out of the 16,000 applications received since the commencement of the registration system in December 2003, DH has just completed processing of less than 4,000 applications.	• To process applications with initial focus on the attribute of safety. For pCms that have satisfied the safety requirements, transitional and non-transitional ones can be granted full and provisional registration respectively in one lot.	• It is estimated that all applications for transitional registration will be completed by the end of 2007. When processing of all the applications is completed, the "Notice of transitional registration of pCm" will be issued in one lot to pCm which fulfilled the fundamental safety requirements. • For non-transitional applications, CMB will issue the applicant "Certificate of registration of pCm" when CMB satisfies with the safety, quality and efficacy documents submitted by the applicant.
(IV) DH does not process application for registration submitted after December 2003 until the backlog of 16,000 applications have been cleared. In the interim, new pCm cannot be registered.	• To allow provisional registration of new pCm on basis of safety test result only.	• In determining non-transitional application for registration of a pCm, CMB shall, in accordance with the Chinese Medicine Ordinance, take into consideration the safety, quality and efficacy of the pCm. • The CMB is processing applications submitted before June 2004. For new applications received after June 2004 which have submitted satisfactory safety reports, they are continued to be granted import permit.

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(V) There is not sufficient qualified laboratories for performing the tests for pCm registration.	• To increase the number of recognized laboratories in Hong Kong and Mainland for conducting tests.	• The number of accredited laboratories in Hong Kong is growing. There are currently eight locally accredited laboratories. • Laboratories performing the tests for pCm registration should meet requirements set by the International Standardization Organization (i.e. ISO/IEC17025) 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. • Laboratories are encouraged to apply for ISO/IEC17025 accreditation to provide services to traders. • Regular dialogue is maintained with Mainland to update the list of recommended Municipal testing laboratories for CMB consideration.
(VI) There is no enquiry service for the trade to track the position of their application.	(a) To provide processing status for application on the web. (b) To set up an enquiry service.	• Applicants can use CMD telephone enquiry service to enquire matters related to their applications.

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(C) Lack of control over pCm that do not have intention to register		
(VII) Before DH can complete processing all the registration applications, pCms that have not applied for registration can be sold freely in the market. Many of these have not been tested and the Administration cannot take action against them. Those pCms that applied for registration through the proper channel are not differentiated from pCms that have no intention to apply for registration	• To publish and publicise list of pCms that have applied for registration.	• This recommendation will be brought up to the CMB for discussion.
(D) Dual requirements and inadequate support for export of pCm		
(VIII) PCms for export have to meet requirements of both local and importing countries. At times, they may be different and contradicting.	• To exempt export pCm from registration.	• Under section 119 of the Chinese Medicine Ordinance, no person shall sell; or import; or possess any pCm unless the pCm is registered. Hence, pCm for export could not be exempted from registration.
(IX) The same pCm for export under different names requires registration for each of the names.	• To allow registration of multiple names for a particular export pCm.	• Under the Chinese Medicine Ordinance, product name is one of the particulars to be registered. One pCm registration shall only have one registered product name, and variation of such name, under section 124 of the Ordinance, is not allowed.

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(X) The long lead time in obtaining GMP deprives export pCms from obtaining GMP favourable treatment of the importing countries	(a) To improve the GMP approval system for faster approval. (b) To improve communication with overseas countries and explain the current process time for obtaining GMP.	• To facilitate certification system of GMP, the CMB had delegated the function of approval to the Chinese Medicines Traders Committees (CMTC). The CMTC will base on the technical report submitted by GMP auditor to approve or reject the application. • With reference to other international practice on how to process GMP application, GMP auditor will first evaluates all necessary documents such as basic information of manufacturer, personnel information, premises and facilities information, equipment information, brief description of documentation system, manufacturing management information, quality control information, complaint handling and product recall information, self-inspection program and contract manufacture and test information (if any) when the application is submitted. The applicant and key personnel may be interviewed for clarification and modification of application issues. For better arrangement, site inspection will be notified and conducted by GMP auditor and other relevant experts if necessary. If there are non-conformances found during the inspection, time will be allowed the applicant for rectification.

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		• According to our experiences of handling GMP applications, the time spending most in processing the application are vetting documents, clarification of GMP requirement with the applicant, renovation of manufacturing plant, etc. In order to speed up the process, arrangement had already been made to interview or contact manufacturer who intends to apply for GMP certification initially, so that the manufacturer can has better understanding of GMP principles and requirements before implementation.
(XI) There is no free sale certificate (FSC) for pCms. The certification letter issued by DH cannot replace the FSC and export pCms are not accepted in most countries.	(a) To implement the improvement proposals under the section on "Slow progress in processing applications for registration". (b) To include more description of the pCm registration progress and the marketing history of the pCm in question.	(a) Since the provision of service for issuance of free sale letters by DH to facilitate traders to export their products, there has not been any major report related to the acceptance of the letter by other countries. Traders are welcome to contact DH if they encounter such problem. (b) Since the provision of this service, the contents of the letters has been reviewed and updated to reflect the current requirement of the traders. The contents will be amended when needed. Traders are welcome to contact DH if they encounter problem on the acceptance of this letter by other countries.

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(XII) PCms registered in Hong Kong have to be registered again in China and vice versa. The requirements hinder the development of both local and the Chinese markets.	• To initiate discussion with the Mainland for mutual recognition of pCm registration.	• DH has been participating in The Forum on Harmonization of Herbal Medicines (FHH) which is a technical forum involving drug regulatory authorities of founding member parties (Australia, China, Hong Kong, Japan, Republic of Korea, Singapore and Vietnam). The role of the FHH is to provide technical documents and consensus on technical issues related to safety, efficacy and quality of herbal medicine. The expected outcome of harmonization would be the development and commitment to common technical guidelines, which are not only acceptable to Mainland, but also to other neighbouring countries.
(XIII) Overseas markets present a principal revenue source of the trade. Assistance is needed to enhance business in this area.	• To assist the trade to develop overseas markets, leveraging on the edges of business and research institutes.	• Trade Development Council may provide assistance in this area.
(E) Unclear distinction of pCm and health food		
(XIV) Some officers of Customs and FEHD are not good at making distinctions between pCm and health food. Some of them detain goods for classification. The delay due to classification may cause severe damage to traders.	(a) To refine the definition of pCm and health food and regulate the two classes differently. (b) To improve communication with relevant departments and trade on how to determine if a product requires registration. The provision of self-explanatory guidelines could be useful.	(a) The term pCm is defined and regulated under the Chinese Medicine Ordinance. (b) Meetings were held among DH, Customs & Excise and FEHD on the issue and clear communication channels have been established. Considering a lot of the products with no medicinal claims can be regarded as food, the criteria for render a product to be regarded as "food" are already published in

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	(c) To publish and publicise list of ingredients that must or need not register.	the "Application Handbook for Registration of Proprietary Chinese Medicines". This handbook is updated regularly to reflect the latest registration requirements and concerns from traders. (c) DH will consider publishing a list of materials which, when included as an active ingredient in a product, may render the product to be not a pCm, i.e., non- Chinese herbs or materials.
(F) Enhance communication with trade		
(XV) Different DH officers gave different answers to the same question, causing much confusion to the trade.	• To enhance internal communication among staff on matters that are of interest to the trade.	• Frontline staffs are frequently updated with the latest information for answering public enquiry and they should all be replied according to the latest principle and policy set out by the CMB. Nevertheless, the traders are encouraged to send in written enquiry with the complete picture of the case, so a comprehensive written reply can be given to the inquirer.
(XVI) Representation on the Chinese Medicine Board is not broad enough. Members are not actually engaged in the trading of pCm and some do not seem to be well versed in the subject of pCm.	• To include members of relevant trade and subject onto the Board.	• Under section 14 of the Chinese Medicine Ordinance, the CMB consists of 5 persons from the trade of Chinese medicines. Currently, the 5 persons include representatives from Chinese herbal medicines and pCm traders as well as pCm manufacturer. • Besides, continuous dialogue is maintained with the trade and briefing sessions are arranged to promote communication between the CMB and the trade..

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(G) Complicated and inflexible pCm registration requirements		
(XVII) The registration guide was too complicated to follow.	• To review and trim the requirements and associated guide.	• Besides the "Application Handbook for Registration of Proprietary Chinese Medicines" which lays out the registration requirement in details, there are also many frequently asked questions (FAQ) uploaded to the website of Chinese Medicine Council for the convenience of the traders.
(XVIII) Applicant for registration of transitional pCm cannot pass ownership to another person.	• To allow change in ownership during the processing of an application for registration.	• After receiving "Notice of transitional registration of pCm", applicant could apply for change of registration particulars such as holder of the certificate of registration.
(XIX) With the operation of the Protection of Endangered Species of Animals and Plants Ordinance, traders wish to delete or replace ingredients derived from endangered species under the premise that no change would be made to the original characteristics and efficacy of the medicines. DH insists that any deletion or amendment to the prescription will be regarded as a new product that requires a separate application for registration.	• To adopt a principle that deletions and replacement of ingredients derived from endangered species would not constitute a new product when there is no change to the original characteristics and efficacy of the medicine.	• For materials that are listed in Convention on International Trade in Endangered Species (CITES) Appendix II, they can still be used in pCm as long as the law is complied with by possessing the required permit for import. • If an ingredient of a pCm is changed due to the Protection of Endangered Species of Animals and Plants Ordinance (ingredient listed in Convention on International Trade in Endangered Species (CITES) Appendix I), the product information including the product's function and indication should be amended accordingly. In this circumstance and subject to the overall assessment of the product, the CMB may consider allowing the pCm to retain its original registration.

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(XX) Restrictions on dose form are too rigid for trade to react to changing market conditions.	• To allow alteration of dose form appropriately while maintaining the original category for registration and / or the eligibility for "transitional" registration of such products.	• 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. • 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. 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.

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(XXI) The requirement of conducting acute poisoning test for pCms that have been on sale for some time is redundant.	• To waive the requirement for products that have been in the market for some time.	• Acute toxicity test plays an important role in assessing pCm safety. The requirement for pCm with a long history of usage will be put up to the CMB for further discussion.
(H) Regulation on medical advertisements		
(XXII) Restrictions under the Undesirable Medical Advertisements Ordinance are outdated or too rigid. They curtail consumers' right to information and may result in more cases of inappropriate use of medicines.	• To review the existing Ordinance with participation from the trade.	• The Undesirable Medical Advertisements Ordinance (UMAO), Cap. 231 prohibits the advertisement of medicines, surgical appliances, or treatment for prevention or treatment of certain diseases or bodily conditions as specified in its Schedules. The purpose is to protect the public from being induced by advertisements to seek improper self-medication or treatment instead of consulting medical practitioners. Improper self-medication or treatment may result in inadequate, inappropriate or incorrect treatment, no supervision of treatment outcome, no monitoring for adverse effects and delayed treatment, thereby endangering the health of the patients. • There was public consultation before the Undesirable Medical Advertisements (Amendment) (No. 2) Bill 2004 ("the Bill") was introduced to the LegCo in 2004. The Bill was passed in June 2005. The new Schedule 4 of UMAO listed 6 higher risk health claims to be prohibited in orally consumed products. At the same time, restrictions on certain diseases or disease conditions have been suitably lessened in Schedule 1.

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		• To assist the trade to understand the UMAO better, DH has issued a set of guidelines on the Ordinance, which can be downloaded from www.psdh.gov.hk. • On 24 and 25 October 2006, DH organized workshops on the Ordinance and traders from the Chinese Medicines Sector had also been invited. After the workshops, many participants commented that the workshops were very useful and informative for understanding the Ordinance. • We do not have immediate plans to review the provisions in the UMAO at this stage.
(I) Limited sales channels		
(XXIII) PCms have been for retail only in the local market. The sales of most pCm products are persistently low. This hampers the development of the industry as a whole.	• To include pCms for use in the public medical sector and to speed up the setting up of Chinese medicine out-patient clinics.	• DH strongly supports the use of Chinese medicine. The current regulatory regime governing pCm was set up with a view to safeguarding public safety and ensuring the availability of good quality, safe and effective medicines to the people of Hong Kong. The DH is open to views from the trade and would continue to explore possible ways to facilitate the trade and resolve technical problems without compromising the public interest.

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(J) Inadequate support for the pCm industry		
(XXIV) The trade is loaded with stringent regulations and difficulties in operation. To improve the business environment, the trade would need support from the Administration.	(a) To step up the promotion of services provided for the pCm trade by various institutions, e.g. Trade Development Council, Jockey Club Institute of Chinese Medicine, centres of Chinese medicine of higher learning institutes. (b) To expand the coverage of subsidy funds, simplify their application procedures and relax the approval criteria.	• The DH will continue to explore possible ways to facilitate the trade and resolve technical problems without compromising the public interest.
(XXV) Samples of unregistered pCms and herbs are not allowed to be imported for display at trade shows. The trade opines that photos and brochures often cannot replace actual product samples in making a business deal.	• To allow small quantities of pCms and herbs to be imported without licensing for display-purpose only in trade shows after securing the authority's prior approval.	• Discussions had been held with the TDC since about 2 year 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. • DH has recently discussed with TDC and some trade fairs organizers again on how to facilitate exhibition involving Chinese herbs. DH will work out the system with CMB and revert to TDC.

Department of Health

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