

**Business Facilitation Advisory Committee
Retail Task Force**

***Response to Concern of the Proprietary Chinese Medicine Trade
- May 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		
<p>(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. <i>[February 2007]</i></p> <p>PCms applying for transitional registration have been put up for sale in the market for a period of time and their efficacy and quality have already been recognized by the general public. <i>[March 2007]</i></p> <p>Existing definition of pCms is too broad for targeted regulation according to actual market operation. <i>[March 2007]</i></p>	<p>(a) To allow full registration of transitional pCms on basis of safety test result only. <i>[February 2007]</i></p> <p>(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. <i>[February 2007]</i></p> <p>(c) For full registration of non-transitional pCms –</p> <ul style="list-style-type: none"> • 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. <i>[February 2007]</i> 	<p>(a)(b)(c)</p> <ul style="list-style-type: none"> • Section 122 of the Chinese Medicine Ordinance (CMO) provides that the Chinese Medicines Board (CMB), in determining an application for registration of a pCm, shall take into consideration the safety, quality and the efficacy of the pCm. The CMB has exercised discretion in accordance with relevant provisions in the CMO to facilitate the applicants in fulfilling the requirement. Therefore, a pCm can be applied for registration under different arrangement (transitional or non-transitional) according to the history of sale, the composition, the claim of the pCm. Furthermore, for non-transitional registration, pCms 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 of category and registration group. Applicants are required to submit registration

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	<p>(d) To issue certificates of registration in one go to all applications submitted with full set of safety test reports before 30 June 2004 and to allow submission of bits of non-safety related information as supplementary after transitional registration. <i>[March 2007]</i></p> <p>(e) To classify pCms into the “Medicines category” and the “Health-preserving category” and to develop appropriate regulatory standards and rule. <i>[March 2007]</i></p>	<p>documents according to the classification chosen by them. For pCms under Group I, applicants usually only required to submit basic documents in respect of safety, efficacy and quality of the medicine for the application, while for the pCms under Group II, they are required to submit further documents. The requirement for Group III is most stringent which required the comprehensive documents in all 3 aspects. Moreover, we will keep in view of the latest scientific development so as to keep in pace with the grow of industry. <i>[May 2007]</i></p> <p>(d) For transitional registration, we have adopted an arrangement alike the improvement proposal. Taking into the consideration of “long history of usage”, the applicants are allowed to submit the reports by phases. For instance, subject to provision of the full set of safety test reports, the applicants for transitional registration are allowed to submit other non-safety related information such as product specification documents and general stability reports at a later date. For non-transitional registration, the CMB has already promulgated that for pCm which were on the market on and before 19.12.2003, their stability reports can be submitted at a later date.</p>

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		<p>It is expected that all applications for transitional registration would be completed by the end of 2007. In response to the request of the Chinese medicines traders, the Chinese Medicines Board has decided to issue the certificates for transitional registration in one lot upon completion of the transitional registration exercise. <i>[May 2007]</i></p> <p>(e) Health preserving products are already classified into the "Non-established Medicines" category. Applicants should submit registration documents according to the classification of category and registration group chosen by them. For products that are basically used in the form of food without any proposed dosage, any curative or health claim, and whose ingredients are Chinese herbs that are generally accepted as food, they are classified as food and regulated under the Public Health and Municipal Services Ordinance (Cap. 132) This kind of product is not required to submit pCm registration and can be freely sold in HK. For details of the registration, please refer to the Application Hand book for Registration of pCms. <i>[May 2007]</i></p>

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<p>(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. <i>[February 2007]</i></p>	<p>(a) To collaborate with academic institutions and other relevant organizations in subsidizing laboratory tests for pCm. <i>[February 2007]</i></p> <p>(b) To eliminate duplicate tests for different brands of pCm of the same prescription. <i>[February 2007]</i></p> <p>(c) To allow registration of multiple names for a particular pCm. <i>[February 2007]</i></p> <p>(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. <i>[February 2007]</i></p> <p>(e) To accept test results meeting the Good Manufacturing Practice (GMP) standard. <i>[February 2007]</i></p>	<p>(a) Trade Development Council may provide assistance in this area. <i>[February 2007]</i></p> <p>(b)(c)</p> <ul style="list-style-type: none"> • 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. To alleviate the trader's costs of testing of pCm, the trader could submit one test report covering a number of products of the same formulation for consideration of the CMB. <i>[May 2007]</i> <p>(d) Apart from the accepted municipal Institutes for Drug Control in China, other laboratories complied with the following are also accepted:</p> <ul style="list-style-type: none"> (i) The scope of (ISO/IEC 17025) accreditation of that laboratory is relevant to proprietary Chinese medicine (<i>e.g. Chinese Proprietary Medicine Product, Chinese Medicine & Related Products, or Traditional Medicine</i>); and (ii) The relevant test(s), <i>e.g. Heavy Metals and Toxic Element Test, Pesticide Residues Test and Microbial Limit Test</i>, of that laboratory is/are accredited; and

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		<p>(iii) Testing method(s) is/are complied with requirement(s) stipulated by the CMB in the technical guidelines. <i>[February 2007]</i></p> <p>(e) CMB recognizes the traders' concern of high testing cost. Therefore, Good Manufacturing Practice (GMP) in-house testing laboratories are accepted to conduct up to 2 out of 3 batches of stability tests. This measure is aimed at reducing the burden of traders. Nevertheless, the CMB emphasizes there are differences between the accreditation requirements for GMP and ISO/IEC 17025 or GLP. So, the accreditation of GMP is not considered as equivalent to ISO/IEC 17025 or GLP. <i>[May 2007]</i></p>
<p>(B) Slow progress in processing applications for registration</p>		
<p>(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. <i>[February 2007]</i></p>	<ul style="list-style-type: none"> 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. <i>[February 2007]</i> 	<ul style="list-style-type: none"> 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. <i>[February 2007]</i>

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		<ul style="list-style-type: none"> • 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. <i>[February 2007]</i> • Applicants will be given enough time and opportunity to make remedial action and recall their products, if necessary, before the commencement of section 119 of CMO. <i>[May 2007]</i>
<p>(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. <i>[February 2007]</i></p> <p>Granting of import permit to applications submitted after June 2004 has not been publicized and the approval criteria for the issue of permit are also unknown to the trade. The policy is unfair to local pCm manufacturers. <i>[March 2007]</i></p>	<ul style="list-style-type: none"> • To allow provisional registration of new pCm on basis of safety test result only. <i>[February 2007]</i> • To discuss with trade on the policy and criteria on granting import permit to applications submitted after June 2004. <i>[March 2007]</i> 	<ul style="list-style-type: none"> • 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. <i>[February 2007]</i> • 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. <i>[February 2007]</i> • For those pCms for which an application for registration is made after 30 June 2004, the applicant has to submit all the required documents before the application can be processed. Upon the request of the traders on granting import permit for these pCms, CMB has adopted the following arrangement to facilitate the trade during the assessment

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		<p>period –</p> <p>“Provided that all the submitted safety reports are found to be satisfactory, the product may be allowed to import into Hong Kong and export from Hong Kong until</p> <p>(a) the refusal of the application for registration of that pCm under section 121(4); or</p> <p>(b) the commencement of section 119 of CMO, whichever is the earliest.”</p> <p><i>[May 2007]</i></p> <ul style="list-style-type: none"> • The above arrangement will also facilitate local pCm manufacturers as their products can be exported from Hong Kong during the assessment period, provided that they have submitted satisfactory safety reports. <i>[May 2007]</i>
<p>(V) There is not sufficient qualified laboratories for performing the tests for pCm registration. <i>[February 2007]</i></p>	<ul style="list-style-type: none"> • To increase the number of recognized laboratories in Hong Kong and Mainland for conducting tests. <i>[February 2007]</i> 	<ul style="list-style-type: none"> • The number of accredited laboratories in Hong Kong is growing. There are currently eight locally accredited laboratories. <i>[February 2007]</i> • 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

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		<p>accepted 16 Municipal testing laboratories recommended by the State Food & Drug Administration. <i>[February 2007]</i></p> <ul style="list-style-type: none"> ● Laboratories are encouraged to apply for ISO/IEC17025 accreditation to provide services to traders. <i>[February 2007]</i> ● Regular dialogue is maintained with Mainland to update the list of recommended Municipal testing laboratories for CMB consideration. <i>[February 2007]</i>
<p>(VI) There is no enquiry service for the trade to track the position of their application. <i>[February 2007]</i></p> <p>The existing telephone enquiry service is restricted to answering simple questions. The trade is mainly concerned with testing items and the methods to conduct quality and standard tests. It would like to make enquiries to and seek prior confirmation of the CMB on such matters. <i>[March 2007]</i></p>	<p>(a) To provide processing status for application on the web. <i>[February 2007]</i></p> <p>(b) To set up an enquiry service. <i>[February 2007]</i></p> <p>(c) To set up a dedicated unit to provide the enquiry service needed by the trade. <i>[March 2007]</i></p>	<ul style="list-style-type: none"> ● Applicants can use CMD telephone enquiry service to enquire matters related to their applications. <i>[February 2007]</i> ● There are designated case officers to handle individual applications. Applicants may contact their case officers if they have any questions regarding their applications. <i>[May 2007]</i> ● Other than calling the enquiry hotline, the Chinese medicines traders may make appointment to have face-to-face interviews with the duty officers who are professional staff of the DH. <i>[May 2007]</i> ● Applicants may contact their case officers if they have any questions on conducting chemical assay on their products. DH will continue to explore possible ways to facilitate the trade and resolve technical problems

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		<p>without compromising the public interest. <i>[May 2007]</i></p> <ul style="list-style-type: none"> • Due to the complexity of pCm testing, the applicants are encouraged to send in the technical enquires in writing, so that more in-depth evaluation of their applications can be conducted. <i>[May 2007]</i> • DH will continue to explore possible ways to facilitate the trade. <i>[May 2007]</i>
(C) Lack of control over pCm that do not have intention to register		
<p>(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 <i>[February 2007]</i></p>	<ul style="list-style-type: none"> • To publish and publicise list of pCms that have applied for registration. <i>[February 2007]</i> 	<ul style="list-style-type: none"> • This recommendation will be brought up to the CMB for discussion. <i>[February 2007]</i>

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(D) Dual requirements and inadequate support for export of pCm		
<p>(VIII) PCms for export have to meet requirements of both local and importing countries. At times, they may be different and contradicting. <i>[February 2007]</i></p> <p>There is exemption to the possession of not-for-sale western medicines under the ordinance governing western medicines. <i>[March 2007]</i></p>	<ul style="list-style-type: none"> • To exempt export pCm from registration. <i>[February 2007]</i> • To provide exemption for the possession of not-for-sale pCms. <i>[March 2007]</i> 	<ul style="list-style-type: none"> • Under section 119 of the Chinese Medicine Ordinance (CMO), 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. <i>[February 2007]</i> • The requirement is in line with the World Health Organization's recommendation that the manufacturing country should properly control the quality of its pharmaceutical products. <i>[May 2007]</i> • The exemptions for section 119 are provided under section 158 (5) and (6) of CMO. A pCm may be exempted from registration if it is: imported by a wholesaler of pCms for the purpose of re-exporting by the same wholesale dealer; or imported by a holder of a valid certificate for clinical trial and medical test and is to be used for the purposes of the clinical trial and medical test to which the certificate relates; or compounded by or under the supervision of registered Chinese medicines practitioner (CMP) or a listed CMP at the premises where he practices and only if such pCm used for administering or supplying to a patient under his direct care; or individually prepared or compounded for one patient by a

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		<p>person nominated under CMO or under such person's supervision, at the premises in respect of which a retailer license is in force and in accordance with the prescription given by a registered CMP or a listed CMP. <i>[May 2007]</i></p>
<p>(IX) The same pCm for export under different names requires registration for each of the names. <i>[February 2007]</i></p>	<ul style="list-style-type: none"> • To allow registration of multiple names for a particular export pCm. <i>[February 2007]</i> 	<ul style="list-style-type: none"> • 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. <i>[February 2007]</i> • Notwithstanding the above, CMB would accept one test report covering multiple names' products of the same formulation under different applications. <i>[May 2007]</i>
<p>(X) The long lead time in obtaining GMP deprives export pCms from obtaining GMP favourable treatment of the importing countries. <i>[February 2007]</i></p>	<ul style="list-style-type: none"> (a) To improve the GMP approval system for faster approval. <i>[February 2007]</i> (b) To improve communication with overseas countries and explain the current process time for obtaining GMP. <i>[February 2007]</i> 	<ul style="list-style-type: none"> • 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. <i>[February 2007]</i> • 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,

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		<p>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. Once informed by the applicant that the factory is ready for inspection, GMP auditor will arrange site inspection as soon as practicable. 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. <i>[February & May 2007]</i></p>

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		<ul style="list-style-type: none"> ● 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. <i>[February 2007]</i> ● Application form and related documents for applicant of GMP certificate can be downloaded from the CMCHK website. Information on local manufacturers with GMP certification can also be found in the website. <i>[May 2007]</i>
<p>(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. <i>[February 2007]</i></p>	<p>(a) To implement the improvement proposals under the section on “Slow progress in processing applications for registration”. <i>[February 2007]</i></p> <p>(b) To include more description of the pCm registration progress and the marketing history of the pCm in question. <i>[February 2007]</i></p>	<p>(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. <i>[February 2007]</i></p>

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		<p>(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. <i>[February 2007]</i></p>

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<p>(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. <i>[February 2007]</i></p>	<ul style="list-style-type: none"> To initiate discussion with the Mainland for mutual recognition of pCm registration. <i>[February 2007]</i> 	<ul style="list-style-type: none"> 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. <i>[February 2007]</i> Due to the one-country-two-system policy, pCm registered in Mainland cannot gain automatic registration in Hong Kong. However, the CMB accepts pCm with prescription originated from the "National Drug Standards" of the People's Republic of China as "Established medicines", and a lot of the tests like clinical trial studies and long-term toxicity studies can be exempted,. <i>[May 2007]</i> Apart from the international forum, DH has regular dialogue with the Mainland to continue communication and explore the feasibility of further collaboration. <i>[May 2007]</i>

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<p>(XIII) Overseas markets present a principal revenue source of the trade. Assistance is needed to enhance business in this area. <i>[February 2007]</i></p>	<ul style="list-style-type: none"> • To assist the trade to develop overseas markets, leveraging on the edges of business and research institutes. <i>[February 2007]</i> 	<ul style="list-style-type: none"> • Trade Development Council may provide assistance in this area. <i>[February 2007]</i>
<p>(E) Unclear distinction of pCm and health food</p>		
<p>(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. <i>[February 2007]</i></p>	<ul style="list-style-type: none"> (a) To refine the definition of pCm and health food and regulate the two classes differently. <i>[February 2007]</i> (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. <i>[February 2007]</i> (c) To publish and publicise list of ingredients that must or need not register. <i>[February 2007]</i> 	<ul style="list-style-type: none"> (a) The term pCm is defined and regulated under the Chinese Medicine Ordinance. <i>[February 2007]</i> (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 the “Application Handbook for Registration of Proprietary Chinese Medicines”. This handbook is updated regularly to reflect the latest registration requirements and concerns from traders. <i>[February 2007]</i> (c) DH will publish 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. Work on the list is in progress. <i>[February 2007]</i>

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(F) Enhance communication with trade		
<p>(XV) Different DH officers gave different answers to the same question, causing much confusion to the trade. <i>[February 2007]</i></p>	<ul style="list-style-type: none"> To enhance internal communication among staff on matters that are of interest to the trade. <i>[February 2007]</i> 	<ul style="list-style-type: none"> 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. <i>[February 2007]</i>
<p>(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. <i>[February 2007]</i></p>	<ul style="list-style-type: none"> To include members of relevant trade and subject onto the Board. <i>[February 2007]</i> 	<ul style="list-style-type: none"> 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. <i>[February 2007]</i> Besides, continuous dialogue is maintained with the trade and briefing sessions are arranged to promote communication between the CMB and the trade. Trade representatives are all welcome to join the discussion and briefing sessions. <i>[February and May 2007]</i>

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(G) Complicated and inflexible pCm registration requirements		
(XVII) The registration guide was too complicated to follow. <i>[February 2007]</i>	<ul style="list-style-type: none"> To review and trim the requirements and associated guide. <i>[February 2007]</i> 	<ul style="list-style-type: none"> 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. <i>[February 2007]</i>
(XVIII) Applicant for registration of transitional pCm cannot pass ownership to another person. <i>[February 2007]</i>	<ul style="list-style-type: none"> To allow change in ownership during the processing of an application for registration. <i>[February 2007]</i> To adopt a more flexible approach in processing registration and allow the applicants to make alterations in the registration process. <i>[March 2007]</i> 	<ul style="list-style-type: none"> After receiving “Notice of transitional registration of pCm”, applicant could apply for change of registration particulars such as holder of the certificate of registration. <i>[February 2007]</i> Section 121 and section 128 of CMO provide for registration of pCm and transitional registration of pCm, respectively. Variation of registered particulars of registered pCm is under the provision of section 124. In accordance with section 124, the holder of a certificate of registration may apply to the Chinese Medicines Board (CMB) to vary the registered particulars of the pCm except (a) the product name; (b) the dose form; and (c) the name and quantity of any active ingredient. It also provides that the CMO may approve the variation if the proposed variation will not adversely affect the safety, efficacy and quality of the pCm. The CMB understands that the trade is concerned about the

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		<p>transitional eligibility and cost of tests for a new application. Taking into account the justifications provided by individual applicants, the CMB will exercise discretion in accordance with the relevant provisions in CMO in considering the applications. <i>[May 2007]</i></p>
<p>(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. <i>[February 2007]</i></p>	<ul style="list-style-type: none"> • 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. <i>[February 2007]</i> • To allow medicine traders to replace endangered species with other ingredients and retain their transitional registration under the established medicines category. <i>[March 2007]</i> 	<ul style="list-style-type: none"> • 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. <i>[February 2007]</i> • If the ingredients of a pCm have to be changed in order to comply with the Protection of Endangered Species of Animals and Plants Ordinance, 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. The applicants are encouraged to write in their proposal to CMB for consideration. <i>[May 2007]</i>

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<p>(XX) Restrictions on dose form are too rigid for trade to react to changing market conditions. <i>[February 2007]</i></p>	<ul style="list-style-type: none"> To allow alteration of dose form appropriately while maintaining the original category for registration and / or the eligibility for “transitional” registration of such products. <i>[February 2007]</i> 	<ul style="list-style-type: none"> 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. <i>[February 2007]</i> 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

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		same. Hence, such pCm will be considered to be a different product. <i>[February 2007]</i>
(XXI) The requirement of conducting acute poisoning test for pCms that have been on sale for some time is redundant. <i>[February 2007]</i>	<ul style="list-style-type: none"> • To waive the requirement for products that have been in the market for some time. <i>[February 2007]</i> 	<ul style="list-style-type: none"> • 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. <i>[February 2007]</i>
(H) Regulation on medical advertisements		
<p>(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. <i>[February 2007]</i></p> <p>The traders are very concerned about and have different views on the requirements on assay as set out in the existing pCm registration guidelines and the restrictions under the UMAO. <i>[March 2007]</i></p>	<ul style="list-style-type: none"> • To review the existing Ordinance with participation from the trade. <i>[February 2007]</i> • To arrange for an in-depth discussion between the trade and the DH. <i>[March 2007]</i> 	<ul style="list-style-type: none"> • 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. <i>[February 2007]</i>

Trade's concern	Improvement proposal	Response by Department of Health
		<ul style="list-style-type: none">• 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. <i>[February 2007]</i>• 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. <i>[February and May 2007]</i>• 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. <i>[February 2007]</i>• There is no plan to review the UMAO for the time being. Traders are encouraged to express their views regarding the implementation of the UMAO to DH. <i>[May 2007]</i>

Trade's concern	Improvement proposal	Response by Department of Health
(I) Limited sales channels		
<p>(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. <i>[February 2007]</i></p>	<ul style="list-style-type: none"> • To include pCms for use in the public medical sector and to speed up the setting up of Chinese medicine out-patient clinics. <i>[February 2007]</i> 	<ul style="list-style-type: none"> • 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. <i>[February 2007]</i>
(J) Inadequate support for the pCm industry		
<p>(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. <i>[February 2007]</i></p>	<ul style="list-style-type: none"> (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. <i>[February 2007]</i> (b) To expand the coverage of subsidy funds, simplify their application procedures and relax the approval criteria. <i>[February 2007]</i> 	<ul style="list-style-type: none"> • The DH will continue to explore possible ways to facilitate the trade and resolve technical problems without compromising the public interest. <i>[February 2007]</i>

Trade's concern	Improvement proposal	Response by Department of Health
<p>(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. <i>[February 2007]</i></p>	<ul style="list-style-type: none">• 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. <i>[February 2007]</i>	<ul style="list-style-type: none">• 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. <i>[February 2007]</i>• 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. <i>[February 2007]</i>

Department of Health
May 2007