Legislative Council Panel on Health Services

Subcommittee on Issues Relating to the Development of Chinese Medicine

Administration's Reponses on Issues Raised at the Meeting held on 25 November 2014

Purpose

At the meeting of the Subcommittee on Issues Relating to the Development of Chinese Medicine held on 25 November 2014, Members requested for information on the registration and testing of proprietary Chinese medicines ("pCms") and on the introduction of Good Manufacturing Practice ("GMP") requirements to pCms. In response to the requests, this paper briefs Members on the followings -

(1) Registration and testing of pCms

a. Similarities and differences between pCms and pharmaceutical products in terms of registration and testing requirements;

b. Similarities and differences of registration and testing requirements for Chinese medicine products in Hong Kong, the Mainland China and Taiwan;

c. Details of the various tests required for registration of pCms in Hong Kong; and

d. Details of the funding schemes available for application by Chinese medicine sector

(2) Introduction of GMP to pCms

a. Arrangement to address the intellectual property

problems of pCm manufacturers arising from contracting out the manufacturing process to other GMP manufacturer; and

b. Proposal to set up GMP factory premises that could be provided for use by pCm manufacturers under leasing arrangement.

Registration and Testing of pCms

a. Similarities and differences between pCms and pharmaceutical products in terms of registration and testing requirements

2. At present, pCms and pharmaceutical products in Hong Kong are regulated respectively under the *Chinese Medicine Ordinance* (Cap. 549) ("CMO") and the *Pharmacy and Poisons Ordinance* (Cap. 138) ("PPO"). On the whole, pCms and pharmaceutical products are both required to satisfy the criteria of safety, quality and efficacy, and must be registered respectively with the Chinese Medicine Council of Hong Kong (established under the CMO) and the Pharmacy and Poisons Board of Hong Kong (established under the PPO) before they can be sold in Hong Kong.

3. In other words, pharmaceutical products and pCms are regulated respectively by two different and independent statutory bodies. The Chinese Medicines Board of the Chinese Medicine Council of Hong Kong ("CMB") is responsible for formulating registration requirements and processing registration applications of pCms in Hong Kong, while the Pharmacy and Poisons Board of Hong Kong is responsible for the registration of pharmaceutical products in Hong Kong. The Department of Health is responsible for providing professional and administrative support for the two aforesaid statutory bodies.

4. To protect the public in the safe use of medicines, applicants for registration of pCm and pharmaceutical product should submit documents for four types of information, namely the general, safety, efficacy, and quality information.

5. Regarding the general information, applicants respectively for registration of pCm and pharmaceutical product both should provide information about the person-in-charge of the company, manufacturer's license and related information, free sale certificate, master formula, product sample (if applicable) and sales pack, label and package insert (if applicable).

6. Regarding the safety information, applicant for registration of pCm and pharmaceutical both product should provide scientific literature, clinical study report, and/or summary report on safety to substantiate the overall safety of the product. For registration of pCms, the required documents may involve toxicity test reports, microbial limit test report, etc. In addition, as the starting materials for pCms are derived natural materials, the CMB therefore requires the applicant to provide test reports on heavy metals , toxic elements and pesticide residues, so as to ensure the safe use of pCms. If the pharmaceutical product contains new chemical or biological entity, the applicant should also provide expert's evaluation report on safety, risk management requirements by overseas drug regulatory authorities, and risk management plan as applicable to Hong Kong.

7. Regarding efficacy information, applicants for registration of pCm and pharmaceutical product both should provide scientific evidence to substantiate the efficacy of the product, such as scientific literature, clinical study report, and/or pharmacopoeial standards, etc. For pCm and pharmaceutical product considered as new medicines, the applicants should further provide pharmacological and efficacy study reports, and clinical reports to substantiate the efficacy of the product.

8. Besides, having considered that the theory used in Chinese medicines is different from that of pharmaceutical products, especially in terms of compatibility, the applicant for registration of pCm is therefore required to provide the interpretation and principle of formulating a prescription of the product. The contents should include an analysis based on the theory of Chinese medicine, the description on the properties and flavours, channel tropism, functions, indications, compatibility and other related information of each drug in the prescription, and the analysis of the clinical application of this prescription. The applicant for

registration of pCm containing any newly discovered material or Chinese herb should provide documentary proof regarding taxonomy and other evidence (e.g. academic research reports) to prove that the material or Chinese herb is used in accordance with Chinese medicine theories. If the pharmaceutical product contains new chemical or biological entity, the applicant should also provide expert's evaluation report on efficacy.

9. Regarding quality information, applicants for registration of pCm and pharmaceutical product generally should provide product specification, method and certificate of analysis, and stability test data etc., to substantiate the quality of the product. The applicant for registration of pharmaceutical product should provide GMP Certificate of the manufacturer. In addition, if the pharmaceutical product contains new chemical or biological entity, the applicant should also provide expert's evaluation report on quality.

10. In addition to complying with the CMO and PPO respectively, applicants for registration of pCm and pharmaceutical product should also ensure that their products will comply with the requirements of other legislation, such as the *Undesirable Medical Advertisements Ordinance* (Cap. 231), *Public Health and Municipal Services Ordinance* (Cap. 132) and *Trade Descriptions Ordinance* (Cap. 362) and so forth. Moreover, the applicant for registration of pCm should ensure the product complies with requirements of *Trade Marks Ordinance* (Cap. 559). In regard to the comparison of registration and testing requirements for pCms and pharmaceutical products, please refer to **Appendix I** (in Chinese only).

11. Registration certificates will be issued only when the above information submitted by the applicants for registration of pCms and pharmaceutical products have been evaluated and assessed as satisfying the registration requirements by the relevant statutory bodies.

b. Similarities and differences of registration and testing requirements for Chinese medicine products in Hong Kong, the Mainland China and Taiwan

12. As stated above, pCms in Hong Kong are regulated in accordance with the CMO and the CMB is responsible for formulating the registration requirements and processing the registration applications for pCms. In the Mainland China ("the Mainland"), the China Food and Drug Administration ("CFDA") is responsible for the registration and regulation of Chinese medicines and natural medicines pursuant to *Provisions for Drug Registration* (CFDA Order No.28). In Taiwan, Chinese medicines are regulated under *Pharmaceutical Affairs Act* and are registered[1] with the Ministry of Health and Welfare of Taiwan.

13. On the whole, regulatory requirements of Hong Kong, the Mainland and Taiwan on Chinese medicine products are similar. For the sake of medicine safety for consumers, registration applicants in the three places are all required to submit relevant documents in proof of the safety, quality and efficacy of their products. Please refer to **Appendix II** (in Chinese only) for the classification categories and registration groups of pCms in Hong Kong, registration categories of Chinese medicines and natural medicines in the Mainland, and registration categories of Chinese medicines in Taiwan.

<u>Comparison of testing requirements in the three places</u>

14. On the whole, the "established categories" and "non-established categories" in the registration of pCms in Hong Kong correspond to Category 9 (i.e. "generic drugs") in registration of Chinese medicines and natural medicines in the Mainland, and to the Chinese medicines produced in or imported into Taiwan with formulation based on standard formulas or well-established publications. Meanwhile, the "new medicines category" in Hong Kong corresponds to Categories 1 to 8 of new medicines in registration of Chinese medicines and natural medicines in the Mainland, and to the "new Chinese medicines" in Taiwan.

[1] Known as "review and registration" in Taiwan.

15. Testing requirements for registration of "new medicines category" in Hong Kong, the Mainland and Taiwan respectively are compared at below:

Product safety documents

(i) Toxicity tests are required in Hong Kong, the Mainland and Taiwan, for example, acute, long-term and local toxicity tests;

(ii) In Hong Kong and the Mainland, mutagenicity / genotoxicity test, carcinogenicity test and reproductive and development toxicity test are required depending on the properties of the medicines (e.g. whether the medicines have cytotoxic effects, are used in population of reproductive age and have a possible effect on the reproductive system); in Taiwan, however, all medicines are subject to mutagenicity / genotoxicity test, carcinogenicity test and reproductive and development toxicity test;

(iii) In the Mainland, hemolysis and dependence tests are required depending on the route of administration and properties of preparations; in Taiwan, medicinal products are subject to antigenicity and dependence tests depending on the properties thereof;

(iv) On the other hand, Hong Kong and Taiwan request heavy metals and toxic element test and pesticide residues test;

Product efficacy documents

Documents of pharmacological and pharmacodynamic studies and clinical trial are required in Hong Kong, the Mainland and Taiwan;

Product quality documents

Applicants are required to submit product specification, certificate of analysis and stability test documents in proof of the

quality of their products in Hong Kong, the Mainland and Taiwan.

16. Generally speaking, the registration and testing requirements for the "established medicines category" and "non-established medicines category" of pCms in Hong Kong, for "Category 9 - generic drugs" of Chinese medicines and natural medicines in the Mainland, and for Chinese medicines produced in or imported into Taiwan with formulation based on standard formulas or well-established publications, are more simplified than those for their corresponding new medicines, as specified below:

Product safety documents

(i) In Hong Kong, pCms of both "established medicines category" and "non-established medicines category" are subject to acute toxicity test while health-preserving medicines of "non-established medicines category" need to supplement an additional long-term toxicity test given possible long-term use of such medicines; regarding the application for registration of generic drugs in the Mainland, since the drug entity of the existing National Drug Standards has already undergone acute toxicity and long term toxicity tests during application for registration as new medicines, the safety of the generic drugs are ensured; whereas in Taiwan, basic safety documents are required for registration of these applications to ensure safe medicine use;

(ii) Since the starting materials of pCms are derived from natural materials, medicinal products in Hong Kong and Taiwan are also subject to heavy metals and toxic element test and pesticide residues test;

(iii) In addition, sensitivity/anaphylaxis and irritation tests are also required in both Hong Kong and the Mainland, in the case of specific route of administration (e.g. percutaneous drug absorption);

(iv) Still, in the Mainland, hemolysis and dependence tests are required depending on the route of administration and properties of preparations;

Product efficacy documents

All the three places require applicants for registration to submit formulation basis of relevant medicines as reference materials on product efficacy; and Hong Kong requires applicant to submit "Interpretation and Principle of Formulating A Prescription"[2] in accordance with Chinese medicine theory in support of product efficacy. In all the three places, registrations of such drugs do not require submission of research documents on pharmacological and pharmacodynamic studies or conducting clinical trials.

Product quality documents

Hong Kong, the Mainland and Taiwan all require applicants for registrations to submit manufacturing method, specification of crude drugs and the products, certificate of analysis and stability test documents of the drugs in proof of their product quality.

c. Details of various tests required for registration of *pCms in Hong Kong*

17. The various tests for registration of pCms must meet the requirements as set out in the "Application Handbook for Registration of Proprietary Chinese Medicines" and the "Technical Guidelines for Registration of Proprietary Chinese Medicines" formulated by the CMB. Please refer to **Appendix III** (in Chinese only) for the details of the price and time required for pCms testing by local laboratories.

[2] The contents of the interpretation and principle of formulating a prescription should include an analysis based on the theory of Chinese medicine, the description on the properties and flavours, channel tropism, functions, indications, compatibility and other related information of each drug in the prescription, and the clinical application of this prescription shall be analyzed.

d. Details of the funding schemes available for application by Chinese medicine sector

18. There are several funding schemes available for application by Chinese medicine manufacturers, related research and development companies, universities and other institutions. These funding schemes are industry-neutral and enterprises/organisations meeting the said requirements, including those from Chinese medicine sector, are eligible to apply. Details of these funding schemes are set out in **Appendix IV**.

Introduction of GMP to pCms

a. Arrangement to address the intellectual property problems of pCm manufacturers arising from contracting out the manufacturing process to other GMP manufacturer

19. According to section 120 of the CMO, an application for registration of a pCm shall be made by the manufacturer if it is manufactured in Hong Kong, or by the importer or the local representative or agent of the manufacturer if it is manufactured outside Hong Kong.

20. In view of the above regulations, some local pCm manufacturers are concerned that if the manufacturing process of their pCms is contracted out to another GMP manufacturer (original equipment manufacturer, OEM), such arrangement may result in losing their status as the holders of "Notice of confirmation of Transitional Registration of pCm" ("HKP-notice") or "Certificate of Registration of pCm" ("HKC certificate").

21. The CMB had discussed the above concern of the trade and adopted the following arrangements:

<u>Certain part of the manufacturing process is contracted out to GMP manufacturer</u>

If a HKP-notice/HKC certificate holder contracts out certain

part of the manufacturing process to a GMP manufacturer and retains part of the manufacturing process, he is still a manufacturer of the pCm and can keep the registration under his name.

<u>The whole manufacturing process is contracted out to GMP manufacturer</u>

(i) If a HKP-notice holder contracts out the whole manufacturing process to a GMP manufacturer, he will lose the registration under his name as he ceases to be a manufacturer of the pCm.

(ii) If a HKC certificate holder contracts out the whole manufacturing process to a GMP manufacturer, he can still keep the registration under his name if he remains to be a wholesaler of the pCm (i.e. a holder of wholesaler licence in pCm). He is liable to ensure the quality, safety and efficacy of the pCm, and subject to relevant practising guidelines.

b. Proposal to set up GMP factory premises that could be provided for use by pCm manufacturers under leasing arrangement

22. The Government is aware of the concerns of the industry for hardware and technical support for GMP implementation. The Innovation and Technology Fund and The Hong Kong Jockey Club Charities Trust will jointly support the Hong Kong Institute of Biotechnology Limited ("HKIB") to conduct a three-year project to set up a GMP product development and technical support platform for traditional oral solid pCm products. It is expected to provide an option of GMP technical support services to the local manufacturers after the project is successfully completed. At present, the project concerned is still at its planning stage. Upon completion of the project, HKIB's existing pCm GMP production area will be expanded from 2,880ft^2 to 8,500ft^2; and production lines for two new types of pCm solid formulations (i.e. pills and granules; the existing two are capsules and powder) will be established, which will enable HKIB to provide GMP

contract manufacturing services for the four most common types of pCm solid formulations in Hong Kong. The Government will continue to gauge the views of stakeholders, and explore other initiatives which can facilitate further development of the local Chinese medicines industry.

Food and Health Bureau
15 December 2014

(In Chinese only)

Appendix I

中成藥及藥劑製品註冊及檢測要求的比對

	中成藥	藥劑製品
註冊條例	《中醫藥條例》(第 549 章)	《藥劑業及毒藥條例》(第 138 章)
註冊條件	必須符合中藥組在安全、品質及成效方面訂定的註冊要求	必須符合有關的安全、素質和效能方面的標準
註冊類別	可分為： (i) 固有藥類別 (ii) 非固有藥類別(包括保健品) (iii) 新藥類別(如含有新發現的藥材、新的藥用部位的中成藥、新的中藥處方製劑、改變給藥途徑的中成藥等)	可分為： (i) 仿製藥 (ii) 新藥(例如:未在香港註冊的新藥劑製品或新物質、新用藥途徑、及主要成分的新組合等)
製造商的要求	必須持有有效的製造商牌照	除持有有效的製造商牌照外，必須符合 GMP 的要求
檢測機構的要求	檢測報告須由符合中藥組要求的化驗場所發出，如符合國際標準化組織所訂定的規範，即 ISO17025、《藥品非臨床研究質量管理規範》("GLP")、《中成藥藥品臨床試驗質量管理規範》("GCP")或內地國家食品藥品監督管理總局及中藥組認同的內地藥檢所／內地臨床試驗基地	檢測報告可由產品的 GMP 製造商，或由獲香港實驗所認可計劃 ("HOKLAS")或同等水平認可的檢測機構提供
審批程序	由中藥組負責審批中成藥註冊申請	由藥劑業及毒藥管理局負責審批藥劑製品的註冊申請

	中成藥	藥劑製品
註冊文件要求：一般資料		
申請人資料	• 申請公司負責人的資料	• 申請人的聯絡資料 • 申請人的商業登記証副本
製造商資料	• 生產地發出的生產許可證明文件的核證本(如適用)	• 製造商牌照的鑑證本 • 製造商藥品 GMP 證明書的鑑證本 • 在本港以外地方製造的藥劑製品，須提交由海外製造商發出的授權信
銷售證明文件	• 生產地發出的銷售許可證明文件的核證本(如適用) • 該中成藥在香港的製造或銷售歷史證明文件副本(如適用)	• 仿製藥：本港製造的藥劑製品除外，由原產地當局所發出的自由銷售證明書的正本或鑑證本 • 新藥：由兩個或以上的指定國家的當局所發出的註冊證明(如自由出售證明書的正本或鑑證本)
產品資料	• 標籤 • 說明書 • 銷售包裝的樣板 • 產品樣本 • 由製造商發出的完整處方	• 標籤 • 建議說明書 • 銷售包裝的樣本 • 藥劑製品的樣本或圖像掃描 • 由製造商提供的完整成分及份量資料
註冊文件要求：安全性資料		
	• 重金屬及有毒元素含量的測試報告 • 農藥殘留量的測試報告 • 微生物限度的測試報告 • 急性毒性試驗報告 • 長期毒性試驗報告# • 局部毒性試驗報告(如屬外用製劑)	• 科學文獻或文件以證明產品的建議用途、劑量、用法及說明書上其他有關安全資料 (i) 文獻副本 (ii) 由指定國家的當局所發出的文件，證明說明書已被批准 • 若為新藥，需要提交以

	中成藥	藥劑製品
	• 致突變試驗報告* • 致癌試驗報告* • 生殖毒性試驗報告* • 安全性資料總結報告	下額外文件：- • 有關藥劑製品的臨床及科學研究文獻以證明其安全 • 有關藥劑製品的安全性的專家報告 • 就該藥劑製品的海外藥監局對風險管理的要求，及適用於本港的風險管理計劃書
註冊文件要求：成效性資料		
	• 組方原則及方解 • 成效性參考資料 • 主要藥效學研究報告* • 一般藥理學研究報告* • 臨床試驗研究方案及總結報告* • 成效性資料總結報告	• 科學文獻或文件以證明產品的建議用途、劑量、用法及說明書上其他有關成效資料 (i) 文獻副本 (ii) 由指定國家的當局所發出的文件，證明說明書已被批准 若為新藥，需要提交以下額外文件：- • 有關藥劑製品的臨床及科學研究文獻以證明其成效 • 有關藥劑製品的成效性的專家報告
註冊文件要求：品質性資料		
	• 由製造商發出的製造方法 • 由製造商或化驗所為產品制定的品質標準 • 品質標準的化驗方法 • 品質標準的化驗報告 • 穩定性測試報告 • 原料理化性質資料	• 海外製藥商的製藥設施及製藥工序 • 製造商提供的品質標準說明 • 品質標準的化驗分析方法 • 化驗分析報告 • 穩定性測試資料

	中成藥	藥劑製品
		若為新藥，需要提交以下額外文件：- • 有關藥劑製品的品質性的專家報告

(In Chinese only)

Appendix II

香港中成藥註冊

分類

香港的中成藥註冊申請，分為三類註冊類別，分別為(i)「固有藥類別」、(ii)「非固有藥類別」及(iii)「新藥類別」。各註冊類別的定義如下：

(i) 固有藥類別

除中藥注射劑外，符合以下任何一項描述的中成藥，均屬固有藥類別：

(a) 其處方為—
  (i) 古方(即指源於清代或以前中醫藥文獻所記載的處方)；或
  (ii) 古方加減(其處方是在古方的基礎上，並獲中藥組認同是合理及作適當的藥味加減的處方)；或
  (iii) 藥典方(即指《中華人民共和國藥典》內所記載的處方)；或
  (iv) 其他中華人民共和國國家藥品標準，並獲中藥組接納的處方。

處方不能改變其原有的劑型(沒有改變主要製造工藝的古方除外)，否則作新藥類別處理。

(b) 其處方由單味藥材製備而成，而產品的主治及功能均與原藥材相同(單味中成藥顆粒除外)。

(ii) 非固有藥類別

除中藥注射劑外，任何具有調節人體機能狀態功能的中成藥，屬於非固有藥類別的保健品。但保健品的處方中不能含有新發現的藥材、藥材新的藥用部位、藥材中提取的有效部位及複方中提取的有效部位群，否則屬於新藥類別的中成藥。

「單味中成藥顆粒」是指符合中成藥定義，並由單味藥材製備而成的顆粒劑，而其聲稱的主治與功能應與原藥材相同。

(iii) 新藥類別

符合以下任何一項描述的中成藥，屬新藥類別:

(a) 處方由下列任何一項或多項組成：
    (i) 新發現的藥材；
    (ii) 藥材新的藥用部位；
    (iii) 藥材中提取的有效部位；
    (iv) 複方中提取的有效部位群；
(b) 中藥注射劑；
(c) 新的中藥處方製劑；
(d) 改變給藥途徑的中成藥；
(e) 增加新主治病證的中成藥；及
(f) 改變劑型的中成藥。

內地的中藥、天然藥物註冊分類

內地中藥及天然藥物的註冊，分為兩大類別，分別為(i)新藥及(ii)仿製藥。各分類的內容如下：

(i) 新藥

新藥包括以下 8 類藥物：

1. 未在內地上市銷售的從植物、動物、礦物等物質中提取的有效成分及其製劑；
2. 新發現的藥材及其製劑；
3. 新的中藥材代用品；
4. 藥材新的藥用部位及其製劑；
5. 未在內地上市銷售的從植物、動物、礦物等物質中提取的有效部位及其製劑；
6. 未在內地上市銷售的中藥、天然藥物複方製劑；
7. 改變內地已上市銷售中藥、天然藥物給藥途徑的製劑；及
8. 改變內地已上市銷售中藥、天然藥物劑型的製劑

上述第 1 至 6 類為新藥，第 7 及 8 類則按新藥申請程序申報。

(ii) 仿製藥

仿製藥申請，是指生產國家食品藥品監督管理總局已批准上市的已有國家標準的藥品的註冊申請。

台灣的中藥註冊分類

在台灣，中藥註冊可分為三個類別：

(i) 台灣產中藥藥品；
(ii) 輸入中藥產品；及
(iii) 中藥新藥 (根據台灣《藥事法》，中藥新藥包括新療效、新使用途徑、新藥材、藥材新藥用部位及新複方中藥方劑。)

(In Chinese only)

Appendix III

本地化驗所中成藥測試服務收費及測試所需時間參考

測試項目	市場測試費用*	測試所需時間
安全性資料		
重金屬及有毒元素含量	共$3,000 - $5,000	約 1 個月
農藥殘留量		
微生物限度		
急性毒性試驗（適用於口服中成藥）	$8,500-$20,000	6-9 個月
急性毒性及局部毒性試驗（適用於外用中成藥）	$30,000-$100,000	9-12 個月
局部毒性試驗（適用於黏膜用藥）	$10,000-$30,000	6-9 個月
長期毒性試驗（適用於「非固有藥類別-保健品」及「新藥類別」）	$200,000 或以上	18-24 個月
品質性資料		
甲：品質標準、化驗方法及化驗報告		
制定中成藥品質標準（如需要）	開發含量測定及鑒別項目收費： $50,000-&70,000	3-6 個月
製成品品質化驗：	$4000 - $10,000 收費按測試項目的數量調整	約 3 個月
乙：穩定性試驗		
一般穩定性試驗 [1] (3 批樣品)	按品質標準化驗的收費 x 化驗次數 以有效期為 3 年（於 0 年	按產品有效期調整 以有效期為 3 年計算： 需約 39 個月

[1] 任何於中成藥註冊法例生效前(即於 2003 年 12 月 19 日前)，已在香港銷售或製造的中成藥，該中成藥的一般穩定性資料，其申請人可於該中成藥註冊續期時提交最少一批產品的檢驗報告及已開展其他批號測試的證明予中藥組;其餘批次產品的檢驗報告，則必須於該中成藥註冊再續期時提交。至於三批產品的加速穩定性試驗報告或常温穩定性試驗報告，其申請人須於該中成藥註冊續期時提交。

於過渡性註冊申請截止日前(即於 2004 年 6 月 30 日或之前)，已在香港銷售或製造的中成藥，若銷售年期已多於 2 年，該中成藥只須提交一般穩定性資料；若銷售年期不足 2 年，則須額外提交加速穩定性試驗報告。

測試項目	市場測試費用*	測試所需時間
	及 3 年進行試驗）計算： $25,000-$60,000	
加速穩定性試驗 [2] (3 批樣品)	$48,000-$120,000	約 6 個月
常溫穩定性試驗 [3] (3 批樣品)	以有效期為 3 年計算： $150,000-$330,000	按產品有效期調整 以有效期為 3 年計算： 需約 39 個月

備註：

* 資料來源自本地化驗所經由電話查詢提供。

[2] 於在中成藥註冊法例生效後（即於 2003 年 12 月 19 日及以後）至過渡性註冊申請截止日前（即 2004 年 6 月 30 日或以前），才在香港銷售或製造的中成藥，申請人須於申請註冊時立即提交三批產品的加速穩定性試驗結果、留樣觀察的方案、最少一批產品出廠時（0 年）的原始檢驗結果及已開展其他批號測試的證明予中藥組。

[3] 如已提交常溫穩定性試驗報告,可毋須提交加速穩定性試驗報告及一般穩定性資料。

Appendix IV

Details of the Funding Schemes Available for Application by Chinese Medicine Sector

	Government department	Funding schemes	Objectives of the funding schemes
1	Innovation and Technology Commission ("ITC")	Innovation and Technology Fund ("ITF"): 1. Innovation and Technology Support Programme 2. University-Industry Collaboration Programme 3. Small Entrepreneur Research Assistance Programme	Provides funding support to the local universities, research institutions, and companies to conduct applied research projects (including Chinese medicines Research and Development ("R&D")), as well as projects relating to Chinese medicines testing and analysis method development. Among various funding programmes under the ITF, the Innovation and Technology Support Programme and the University-Industry Collaboration Programme aim to encourage companies to jointly carry out R&D projects with the universities by leveraging their expertise. The Small Entrepreneur Research Assistance Programme provides funding support for small and medium-sized enterprises to conduct R&D of Chinese Medicines so as to facilitate their business development.
2	ITC	General Support Programme ("GSP") under the ITF	Catering for non-R&D projects that contribute to the upgrading and development of our industries (including Chinese medicines industry) as well as fostering an innovation and technology culture in Hong Kong. Projects to be supported under GSP may include conferences, exhibitions, seminars,

			workshops, promotional events, studies and surveys, youth activities, events or projects to support platform building / upgrading of industry, etc. In general, the GSP will not support projects for promotion of products/services of a specific commercial entity. Examples of GSP supported projects which are related to Chinese medicines industry are: (1) "Developing Hong Kong into an International Testing, Certification, and Trading Center for Chinese Medicines by Establishing a Product Certification Scheme for Chinese Materia Medica in Compliance with the ISO Guide 67"; and (2) "Chinese Medicines Manufacturing:- Basic GMP Training and Post-Training Information Acquisition"
3	ITC	Research and Development Cash Rebate Scheme	To reinforce the research culture among private companies and encourage them to establish stronger partnership with designated local public research institutions. Under the Scheme, a company will receive a cash rebate equivalent to 30% of its expenditure in two types of applied R&D projects: (1) projects under ITF; and (2) projects funded entirely by the

			companies and conducted by the designated local public research institutions.
4	Trade and Industry Department ("TID")	Dedicated Fund on Branding, Upgrading and Domestic Sales: 1. Organisation Support Programme 2. Enterprise Support Programme	To encourage Hong Kong enterprises to enhance their competitiveness and further their business development in the Mainland market through developing brands, upgrading and restructuring their business operations, and promoting domestic sales in the Mainland. Provides financial support to non-profit distributing organisations operating as support organisations, trade and industrial organisations, professional bodies or research institutes as well as all non-listed enterprises registered in Hong Kong under the Business Registration Ordinance (Cap 310).
5	TID	SME Export Marketing Fund ("EMF")	To help small and medium enterprises ("SMEs")[1] that are registered in Hong Kong under the Business Registration Ordinance with substantive business operations in Hong Kong[2] expand their business through providing financial assistance for their participation in export promotion activities including local and overseas trade fairs and exhibitions, overseas trade promotion missions,

[1] The definition of an SME is a manufacturing business which employs fewer than 100 persons in Hong Kong; or a non-manufacturing business which employs fewer than 50 persons in Hong Kong.

[2] In applying for EMF, SMEs must have substantive business operation in Hong Kong. An SME holding a shell business registration or having its main business operation outside Hong Kong will not be regarded as having substantive local business operation.

			placing advertisements on printed trade publications and eligible trade websites.
6	TID	SME Loan Guarantee Scheme ("SGS")	To facilitate SMEs that are registered in Hong Kong under the Business Registration Ordinance with substantive business operations in Hong Kong[3] in securing loans from the participating lending institutions for acquiring business installations and equipment, or meeting working capital needs of general business uses. The overall objective is to assist SMEs in enhancing their productivity and competitiveness.
7	TID	SME Development Fund	To provide financial support to non-profit distributing organisations operating as support organisations, trade and industrial organisations, professional bodies or research institutes to implement projects which aim to enhance the competitiveness of Hong Kong's SMEs in general or in specific sectors.

[3] To be eligible for applying for loan guarantee under the SGS, an enterprise should have substantive business operation in Hong Kong. In this connection, an enterprise holding a shell business registration or having most of its main business operation outside Hong Kong will not be regarded as having substantive local business operation. "Business" refers to any form of trade, commerce, craftsmanship, professional, calling or other activity carried on for the purpose of gain.