香港中藥規管的最新情況
Development of regulatory regime for Chinese Medicines in Hong Kong - the latest update

香港特別行政區政府
衞生署中醫藥事務部

14 September, 2012

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Development of regulatory regime for Chinese Medicines in Hong Kong - the latest update

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中醫藥在本港的使用情況
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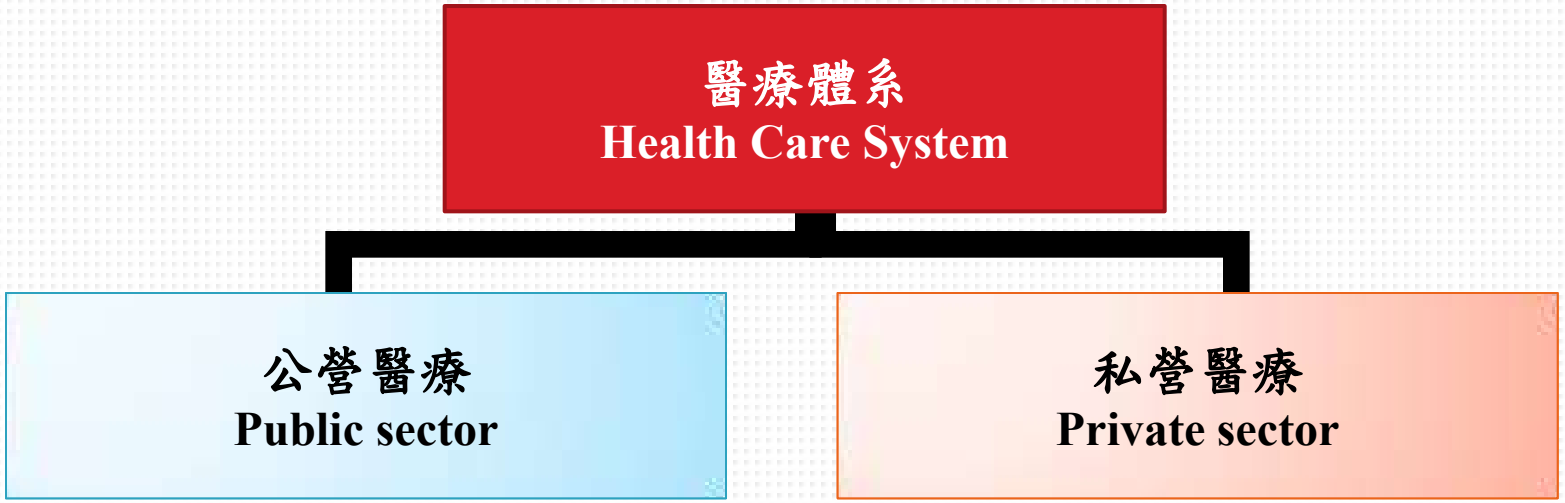

- 基層醫療措施***Primary health care service**:**

公營 Public (28.3%)

- **衞生署**Department of Health (3.7%)
- **醫管局**Hospital Authority (24%)
- **醫管局轄下的中醫診所 (0.6%)**

Chinese medicine clinics under HA

私營 Private (71.7%)

- 私家西醫 Private practitioner (56.1%)
- 其它地區 other regions (1%)
- **私家中醫 (14.6%)**

Private Chinese medicine practitioner

(%)診症醫生類別, 主題性住戶統計調查第四十五號報告書(2010), 政府統計處
**figures(%) based on type of medical practitoners consulted*
(Thematic Household Survey No.45, 2010), Census and Statistics Department, HKSAR

涉及中醫藥事故
Adverse Incidents related to CM

Recall of heavy metal-tainted proprietary Chinese medicines (with photos) - Windows Internet Explorer

Press Releases

Recall of heavy metal-tainted proprietary Chinese medicines (with photos)

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The Department of Health (DH) today (August 10) urged members of the public not to buy or use three proprietary Chinese medicines named [LuShenPai] Specific Hou Ton Qing (registration no.: HKP-01494; batch no.:100401), [Chung Lien] Bi Yan Pian (registration no.: HKP-00241; batch no.:48911004), and [AA] Fe Min Kan Wan (registration no.: HKP-10005; batch no.: 1495). The DH's drug surveillance programme found them to contain excessive amounts of heavy metals (see table). To protect public health, the drugs need to be recalled from consumers.

A spokesman for the DH said the action was initiated after the Department learnt from the Government Laboratory earlier today that about 17.5 times the permitted level of arsenic was detected in a Hou Ton Qing sample, and 3.4 times and 2.7 times the permitted level of mercury were found in the Bi Yan Pian and Fe Min Kan Wan samples respectively.

All three proprietary Chinese medicines were manufactured on the Mainland, and Bi Yan Pian and Fe Min Kan Wan were made by the same manufacturer. Three proprietary Chinese medicines were imported by three local licensed wholesalers of such medicines (see table), namely Sing Kwan Trading Co., Fung Wah (HK) Company, and H & A Natural Healthcare Products Company Limited. H & A Natural Healthcare Products Company Limited is also a licensed manufacturer of proprietary Chinese medicines.

"Hou Ton Qing is used to relieve throat discomfort. Bi Yan Pian and Fe Min Kan Wan are used to manage symptoms of rhinitis," the spokesman said.

"Arsenic and mercury are both toxic heavy metals. Acute arsenic poisoning may cause severe vomiting, diarrhoea, confusion and coma. Prolonged exposure can adversely affect the liver, kidney and heart. Acute mercury poisoning can cause inflammation of the mouth, while prolonged exposure can damage the neurological system and kidney.?Young children are particularly vulnerable to both heavy metals," the spokesman said. No adverse event related to consumption of the three drugs has been reported to DH.

"Initial investigation by DH revealed that Sing Kwan Trading Co. performed secondary packaging of Hou Ton Qing, while H & A Natural Healthcare Products Company Limited performed both primary and secondary packaging of Fe Min Kan Wan in Hong Kong; the other drug, Bi Yan Pian was sold intact," the spokesman said.

香港的中醫藥發展
Development of Chinese Medicine in Hong Kong

中醫藥條例生效前
Before the enactment of Chinese Medicine Ordinance

- 中醫師絕大部分是以自雇或受雇於藥材鋪的形式，為市民服務。一些慈善機構也有提供中醫服務

  Chinese medicine practitioners provided services in an outpatient basis, including self-employment or practice in herbal store. Some non-government organisations also provided Chinese medicine services
- 中醫師並無認可的資格

  No recognised qualification for Chinese medicine practitioner
- 中藥材及中成藥並無法例規管

  No regulations on Chinese medicines
- 中醫藥業以家庭模式營運

  Chinese medicine practice and trade operated as family business

香港對藥品規管相關法規
Legal Basis for Drug Control

- **基本法第138條**
  Article 138 of Basic Law

香港特別行政區政府自行制定發展中西醫藥和促進醫療衛生服務的政策

The HKSAR Government shall, on its own, formulate policies to develop western and Chinese medicine and to improve medical and health services

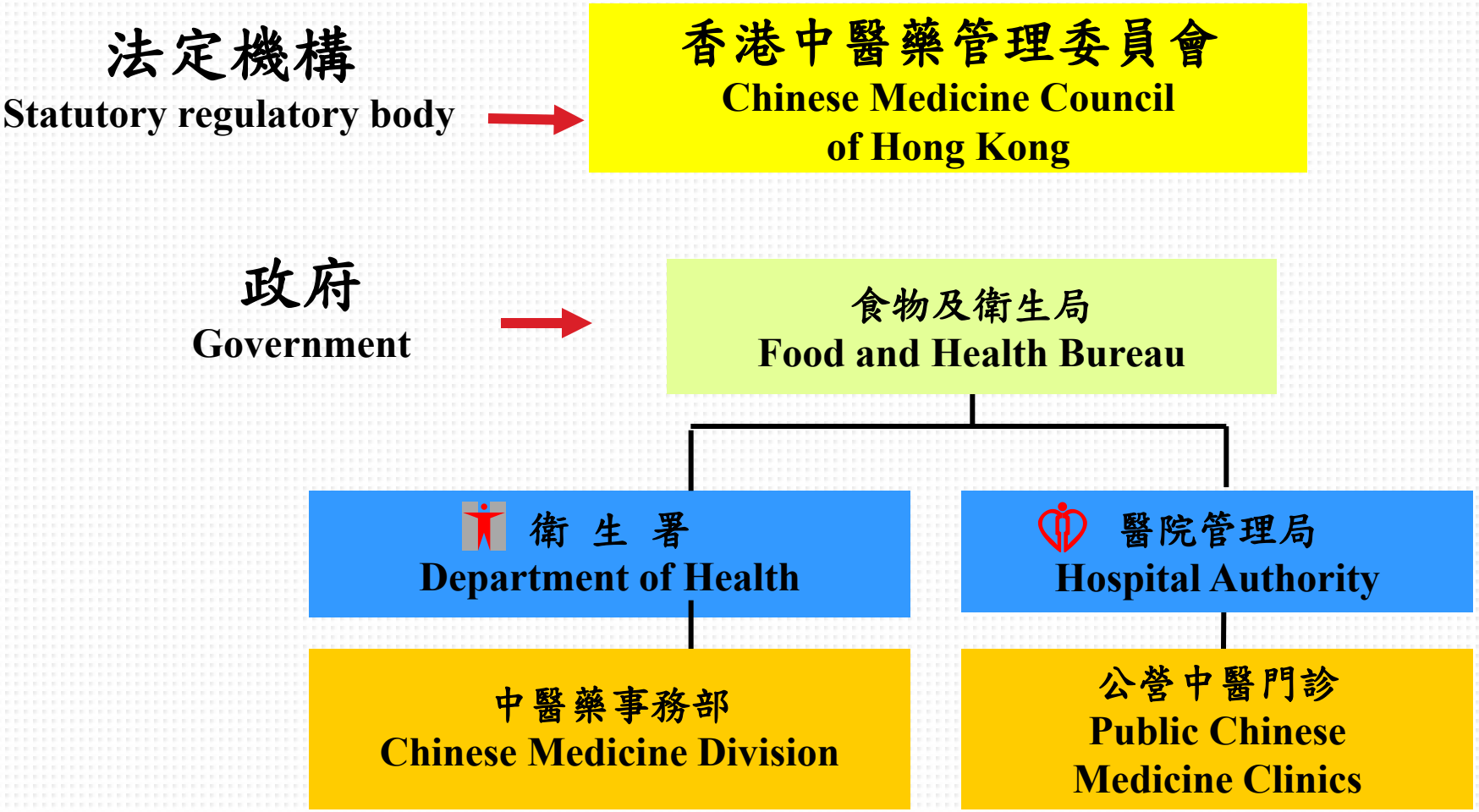
香港的中醫藥發展
Development of Chinese Medicine in Hong Kong

1997-1998年度施政報告
Policy Address (1997 and 1998)

- 香港特別行政區行政長官在施政報告中，提出發展香港成為**國際中醫藥中心**的理念，並要**建立中醫藥管理架構**，以規管中醫藥業

  The Chief Executive of Hong Kong had articulated his vision to develop Hong Kong into an **international centre of Chinese medicine** and to established **a statutory framework** to regulate the use of Chinese medicine

中醫藥規管架構
Regulatory Structure in Chinese Medicine



香港中醫藥管理委員會
Chinese Medicine Council of Hong Kong

- 是根據《中醫藥條例》(第549章)成立的獨立法定組織，於1999年 9月13日成立，負責制訂及實施各項中醫中藥的規管措施。

The Chinese Medicine Council of Hong Kong (the Council) is a statutory body established under the Chinese Medicine Ordinance. Established on 13 September 1999, the Council is responsible for implementing regulatory measures for Chinese medicine practitioners and Chinese medicines.

中藥業的規管

Regulation of Chinese Medicines

中藥業的規管
Regulation of Chinese Medicines

中藥材 Chinese herbal medicines

- 中藥發牌制度（零售/批發）
  Wholesale & Retail Licensing
- 出入口管制
  Import and Export Control
- 香港中藥材標準
  Development of Hong Kong Chinese Materia Medica Standards (HKCMMS)
- 市場監察 Post market surveillance
  - 藥材化驗Testing of drug samples (CM)
  - 不良事件滙報Reporting of adverse drug reaction

中成藥 Proprietary Chinese medicines

- 中藥發牌制度（製造/批發）
  Wholesale & Manufacturing Licensing
- 出入口管制
  Import and Export Control
- 中成藥註冊制度
  Registration of proprietary Chinese medicines
- 香港中成藥生產品質管制規範 GMP
- 市場監察 Post market surveillance
  - 中成藥化驗Testing of drug samples (pCm)
  - 不良事件滙報Reporting of adverse drug reaction

中藥材及中成藥的進出口管制
Import/ Export Control on Chinese Medicines

香港法例第60章附屬法例A《進出口（一般）規例》
the First Schedule to the Import and Export (General) Regulations (Chapter 60, sub Leg.A)

- 《中醫藥條例》訂明的31種附表1中藥材
  31 Chinese herbal medicines specified in Schedule of the CMO

- 5種附表2的中藥材
  5 Chinese herbal medicines specified in Schedule 2
  - 凌霄花（Flos Campsis）；
  - 製川烏（processed Radix Aconiti）；
  - 製草烏（processed Radix Aconiti Kusnezoffii）；
  - 威靈仙（Radix Clematidis）；
  - 龍膽（Radix Gentianae)

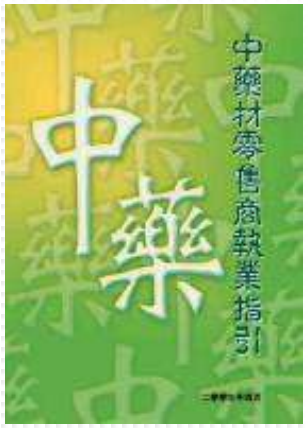
- 《中醫藥條例》第2條所界定的中成藥
  All pCms as defined in section 2 of the CMO

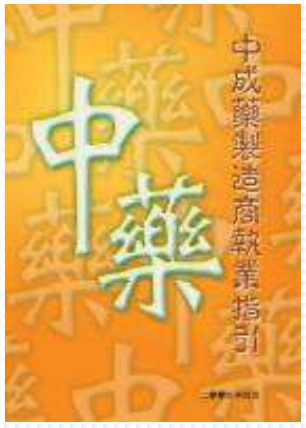
凡進/出口必須事先向衞生署申領相關的**進口許可證/出口許可證**。
Importation /Exportation of these articles must be covered by an **import/ export licence** issued by the Department of Health.

中藥商發牌制度
The licensing of Chinese Medicine traders

- **中藥商領牌制度已於2008年1月11日全面實施，違例者有可能被判罰款和監禁**
- 下列業務必須領有牌照及遵守相關執業指引：
  Four types of Chinese medicines traders must apply for a licence and comply with the practicing guidance:

中藥材零售 Retail of Chinese herbal medicines (~4,300)	中藥材批發 Wholesale of Chinese herbal medicines (~800)	中成藥批發 Wholesale of proprietary Chinese medicines (~1,100)	中成藥製造 Manufacture of proprietary Chinese medicines (~300)





香港中成藥生產質量管理規範

Hong Kong Good Manufacturing Practice for proprietary Chinese medicines

2010-11年度施政報告

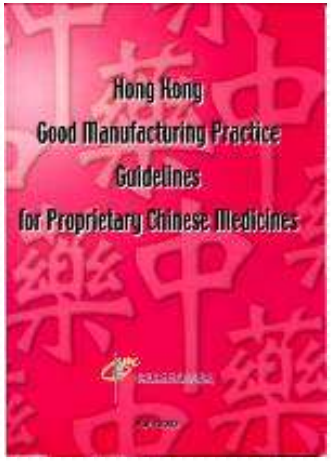
2010-11 Policy Address

- 為推行製造中成藥必須依循「生產質量管理規範」訂定時間表

  To work out a timetable for mandatory compliance with the Good Manufacturing Practice for the manufacture of proprietary Chinese medicines

- **《香港中成藥生產質量管理規範指引》**

  Guideline has been published to traders for reference



- 目前有9間中成藥製造商領有製造商證明書

  （香港中成藥生產品質管制規範）

  Number of GMP certificate holders:9

中成藥註冊制度
Registration of proprietary Chinese medicines

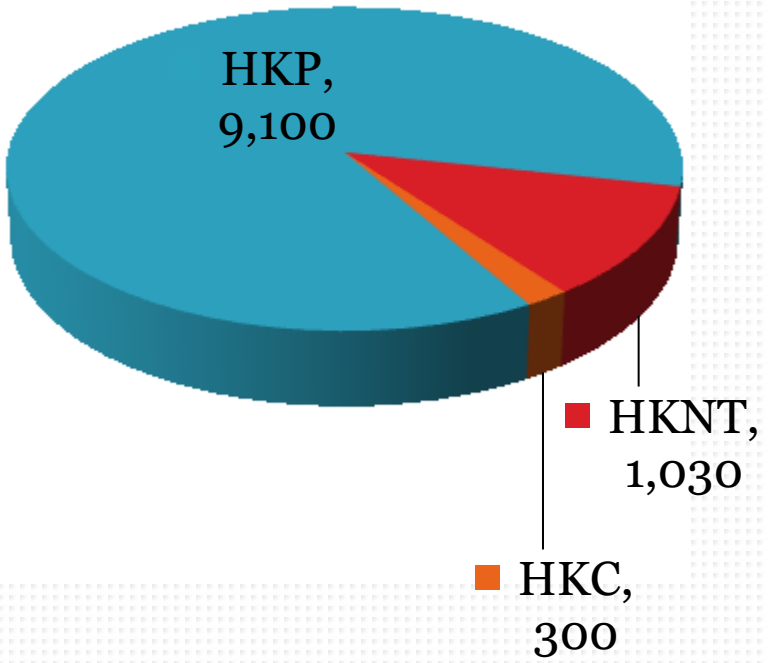
- 所有中成藥均須註冊，方可進口、在本港製造和銷售
  All kinds of proprietary Chinese medicines must first be registered by the Chinese Medicines Board before they can be imported, manufactured and distributed in Hong Kong

- 符合安全、品質、成效三方面的要求
  Ensure safety, quality and efficacy of products

- 中成藥的註冊申請(～17, 000 份)
  pCm registration application (~17,000)

中成藥產品數目
Number of pCm registration applications

- ~9,100 (HKP-XXXXX)
  「確認中成藥過渡性註冊通知書」
  "Notice of confirmation of transitional registration of proprietary Chinese medicine"
- ~1,030 (HKNT-XXXXX)
  「確認中成藥註冊(非過渡性)申請通知書」
  "Notice of confirmation of (non-transitional) registration application of proprietary Chinese medicine"
- ~300 (HKC-XXXXX)
  「中成藥註冊證明書」
  "Certificate of registration of a pCm"



中成藥須註冊規定
Proprietary Chinese medicines to be registered

根據《條例》**第119條**規定
According to the **Section 119** of the Ordinance,

- 任何人不得銷售、進口或管有任何未經註冊的中成藥，否則即屬違法。
  no person shall sell, import or possess any proprietary Chinese medicine unless the proprietary Chinese medicine is registered under section 121.

- 已於2010年12月3日開始生效
  has become effective on 3rd Dec 2010

中成藥註冊的豁免
Proprietary Chinese medicines exempted from registration

- **以下情況的中成藥可豁免註冊**
  the following pCms may be exempted from registration

  - 提供樣本作註冊用途
    The purposes of providing samples and seeking registration
  - 科研或教學用途
    The purposes of education or scientific research
  - 中成藥商轉出口
    The purpose of re-exporting by the same wholesale dealer
  - 進行臨床證驗或藥物測試
    The purposes of the clinical trial or medicinal test
  - 按照中醫開出的處方而合成的
    Prepared or compounded with a prescription given by a registered Chinese medicine practitioner

中成藥標籤及說明書要求
Package inserts for proprietary Chinese medicines

根據《條例》第143及144條規定
According to the **Section 143**&**144** of the Ordinance,

- 任何人不得銷售或為銷售而管有，沒有附上符合訂明規定的標籤或說明書的中成藥。
  No person sell or have in his possession for the purpose of selling any proprietary Chinese medicine without label and package insert.

- 已於2011年12月1日開始生效
  has become effective on **1st Dec 2011**

市場售後監察
Post market surveillance

- 監察市面上銷售中藥材及中成藥的安全與品質

  Monitoring safety and quality of medicines and related products (including pCm) for sale in the market

- 測試中成藥樣本

  Testing of pCm samples

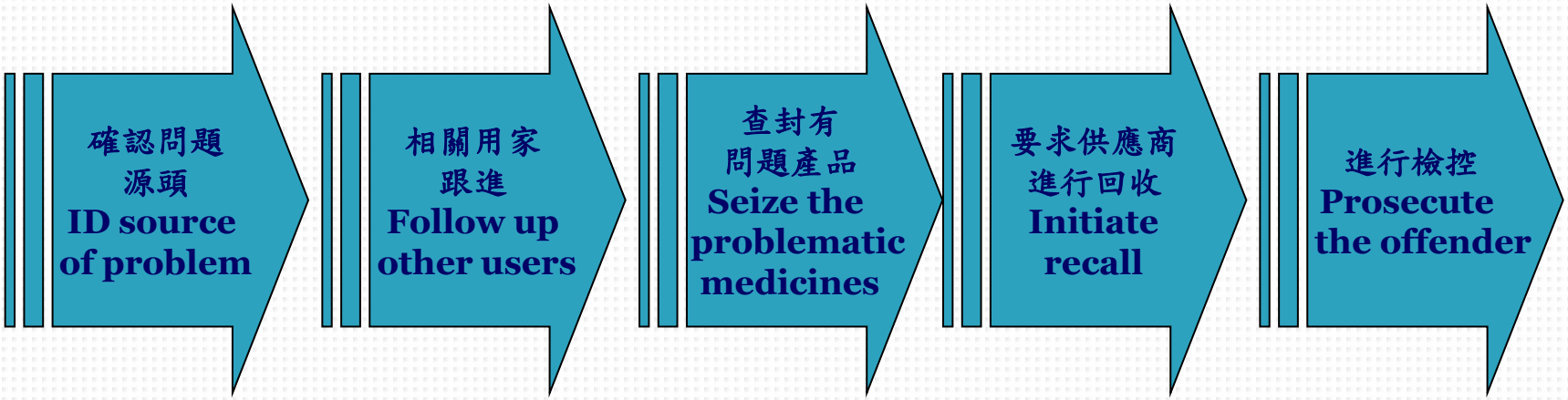
  - 由市場抽取樣本測試產品是否含有重金屬及攙雜西藥

    Draw pCm samples from the market for testing of heavy metals, western medicine adulteration

  - 從中成藥註冊證明書持有人抽取樣本測試產品是否含有重金屬及農藥殘留
  - Draw samples from pCm registration holder (Heavy metals and pesticides residues)

市場售後監察
Post market surveillance

跟進行動Follow up action



- 與其他相關部門進行聯合行動(如警察、海關)

  Cooperate with other Enforcing departments (e.g. Police, Custom and Excise)

市場售後監察
Post market surveillance

藥品不良反應呈報系統
Adverse Drug Reaction reporting system

- 醫生、中醫師、牙醫及藥劑師可以自願性向衞生署藥品不良反應監察組呈報於本地發生的病人疑涉藥品的不良反應
  Encourage Doctors, Dentists, Chinese Medicine Practitioners and Pharmacists to report voluntarily

- 呈報範圍包括西藥(包括疫苗)及中藥(中藥材及中成藥)
  Submitted for all western and Chinese medicines (including Chinese herbs and proprietary Chinese medicines and vaccines)

- 所有報告均會交由監察組的專業人員評估
  Analysis the report by health professionals

- 藥品安全性如有新的風險監察組將會發出相應的安全性警示
  Safety alerts will be issued when new hazards are found

http://www.drugoffice.gov.hk/eps/root/tc/healthcare_providers/adr_reporting/reporting_guideline.html

Department of Health
Adverse Drug Reaction (ADR) Report Form

藥物不良反應申報表
ADR Report Form

香港中藥材標準

Development of Hong Kong Chinese Materia Medica Standards

- 四冊《香港中藥材標準》已於2005，2008，2010，2012年出版，涵蓋了96種中藥材的研究結果和標準
  The Hong Kong Chinese Materia Medica Standards (HKCMMS) Volume 1, Volume 2, Volume 3 and Volume 4 were published in 2005, 2008, 2010 and 2012 respectively

- 在2012年或之前，中藥材的涵蓋範圍由目前的**60種中藥材增至大約200種**
  Aims to extend the Chinese herbs coverage from **the current 60 Chinese herbs to about 200** by 2012

- Download of HKCMMS volume 1,2,3 and 4
  www.dh.gov.hk/english/main/main_cm/main_cm_hkcmms.html

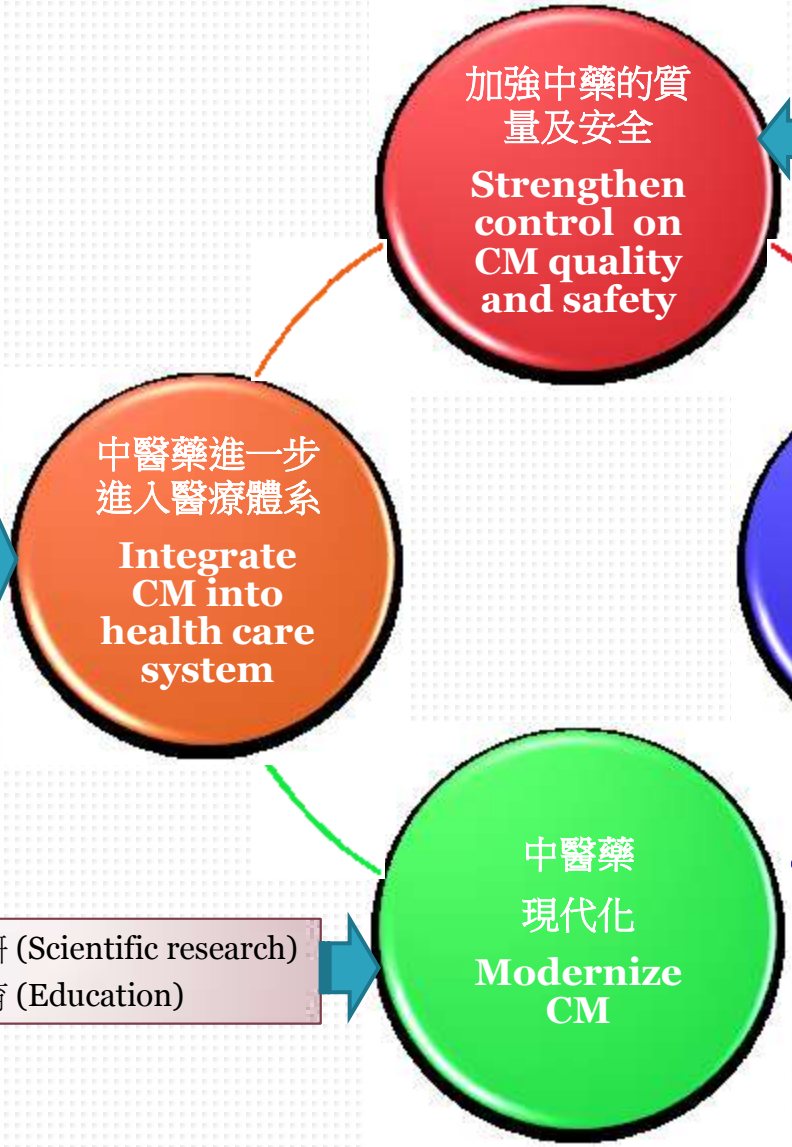
國際專家委員會
International Advisory Board

- **工作範圍Scope of Work:**
  - 為「港標」之方向、研究及分析方法內容提供建議
    Give advice on principles, methodologies, test parameters and analytical methods
  - 覆核研究結果
    Examine and endorse research results
- **科研機構包括Research institution including:**
  - 6所本地大學 6 Local Universities
    - 香港中文大學The Chinese University of Hong Kong
    - 香港浸會大學Hong Kong Baptist University
    - 香港大學The University of Hong Kong
    - 香港科技大學The Hong Kong University of Science & Technology
    - 香港理工大學The Hong Kong Polytechnic University
    - 香港城市大學City University of Hong Kong
  - 中國食品藥品檢定研究院National Institutes for Food and Drug Control
  - 台灣的中國醫藥大學China Medical University, Taiwan

香港中醫藥的特色
Distinctive Features of Chinese Medicine in Hong Kong

- 純中醫
  Pure Chinese Medicine practicing Model
- 社區模式：公營/ 私營中醫診所
  Community based: Public / Private Chinese Medicine Clinics
- 讓中醫藥界積極參與醫療規劃
  Active engagement of Chinese medicine sector in healthcare planning

促進中醫藥的發展 Promotion of CM development



- 註冊制度 (pCm Registration system)
- 藥材標準 (Standards of Chinese Materia Medica)
- GMP制度 (Good Manufacturing Practice implementation)

- 國際合作 (International cooperation)
- 產品認證 (product accreditation)
- 知識產權 (Intellectual property)
- 世界衛生組織傳統醫藥合作中心(WHO Collaborating Centre for Traditional Medicine)

- 科研 (Scientific research)
- 教育 (Education)

- 循證醫學 (evidence-based medicine)
- 中西協作 (collaboration between WM and CM)
- 建立藥品臨床試驗規範基地 (Phased development of clinical trial centers with GCP)

相關網址
Related Websites

- **香港中醫藥管理委員會**
  Chinese Medicine Council of Hong Kong
  www.cmchk.org.hk

- **衛生署中醫藥事務部**
  Chinese Medicine Division Website
  www.cmd.gov.hk

- **香港法規**
  Department of Justice
  www.legislation.gov.hk

多謝

Thank you