

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
衛生署中醫藥事務部

14 September, 2012

目錄 CONTENT

香港中藥規管的最新情況

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

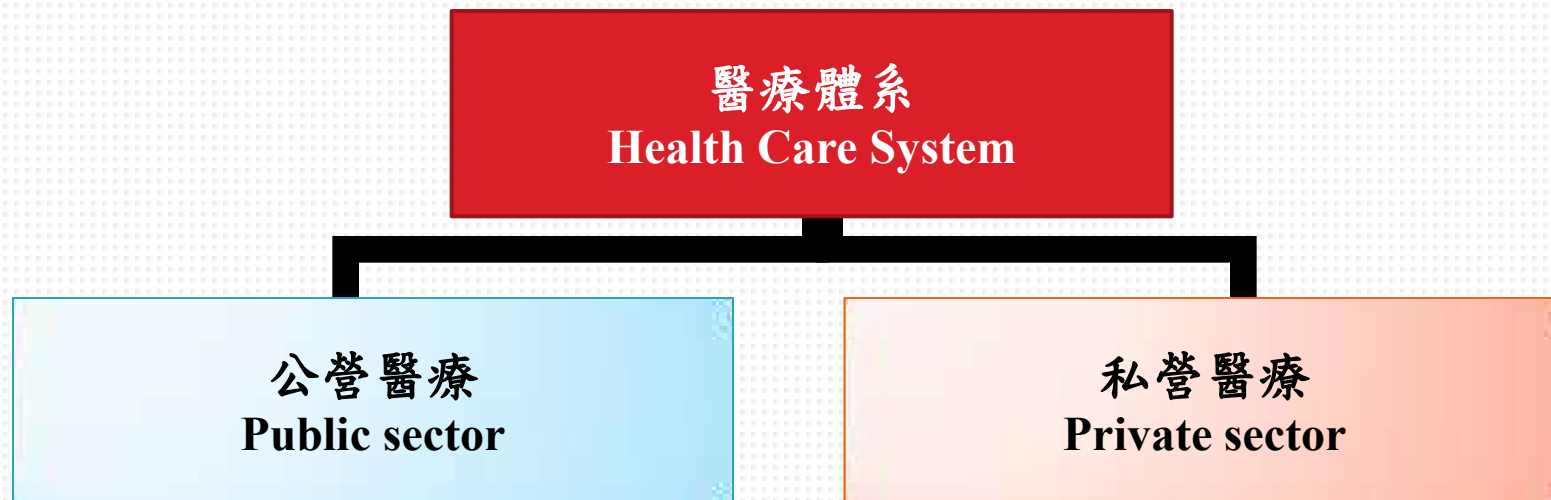
背景
Background

規管
Regulation

發展
Development

中醫藥在本港的使用情況

The Usage of Chinese Medicine in Hong Kong



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

公營 Public (28.3%)

- 衛生署 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**

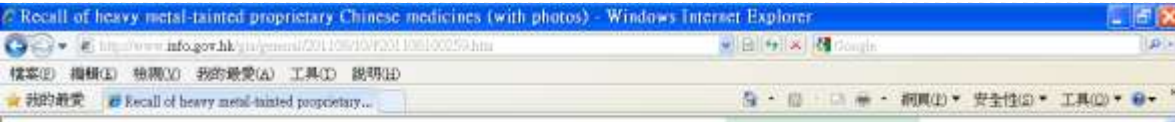
(%) 診症醫生類別, 主題性住戶統計調查第四十五號報告書(2010), 政府統計處

*figures(%) based on type of medical practitioners consulted

(Thematic Household Survey No.45, 2010), Census and Statistics Department, HKSAR

涉及中醫藥事故

Adverse Incidents related to CM



Press Releases

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

The Department of Health (DH) today (August 10) urged members of the public not to buy or use three proprietary Chinese medicines named [LuZhenFai] Specific Hou Ton Qing (registration no.: HRF-01694; batch no.:130401), [Gong Lien] Ni Yan Pian (registration no.: HRF-00241; batch no.:14911009), and [AA] Fe Min Yan Wan (registrations no.: HRF-10067; batch no.: 1405). 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 Ni Yan Pian and Fe Min Yan Wan samples respectively.

All three proprietary Chinese medicines were manufactured on the Mainland, and Ni Yan Pian and Fe Min Yan 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 Hwa Trading Co., Fung Wah (SH) Company, and M & A Natural Healthcare Products Company Limited. M & A Natural Healthcare Products Company Limited is also a licensed manufacturer of proprietary Chinese medicines.

"Hou Ton Qing is used to relieve throat discomfort. Ni Yan Pian and Fe Min Yan 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 Hwa Trading Co. performed secondary packaging of Hou Ton Qing, while M & A Natural Healthcare Products Company Limited performed both primary and secondary packaging of Fe Min Yan Wan in Hong Kong; the other drug, Ni Yan Pian was sold intact," the spokesman said.

ATTACHMENTS

Table

女子服含西藥草藥 致腎衰竭

由美容院中醫處方 衛署促停用

【本報訊】一名三十歲女子因服用含西藥成分的草藥，導致腎衰竭，目前正接受治療。衛生署呼籲市民，切勿自行採集或購買未經衛生署註冊的草藥，以免誤食含有西藥成分的草藥，造成健康問題。

據悉，該名女子在美容院中醫處方下，服用了一種名為「補腎丸」的草藥。該藥含有西藥成分，導致其腎功能受損，最終發展為腎衰竭。衛生署表示，目前正與相關部門合作，調查該藥的來源及成分，並呼籲市民停止服用該藥。

東方日報

毒洋金花當凌霄花食壞人

【本報訊】廣東第一間發行所具有毒性的中藥材「洋金花」，近日在多處市場出現。衛生署呼籲市民，切勿購買或食用該藥材，以免中毒。該藥材含有強烈的毒性，誤食後會導致嚴重中毒，甚至危及生命。

男界中招 昌記藥行受查

衛生署呼籲市民，切勿購買或食用含有西藥成分的草藥。衛生署表示，目前正與相關部門合作，調查該藥的來源及成分，並呼籲市民停止服用該藥。

烏頭類生物鹼中毒

【本報訊】衛生署昨日調查一宗烏頭類生物鹼中毒個案。一名男子因服用含有烏頭類生物鹼的草藥，導致中毒。衛生署呼籲市民，切勿購買或食用含有烏頭類生物鹼的草藥，以免中毒。



商人疑亂服中藥 心臟衰竭亡

中藥店東介紹「噬酥」 代替「干蟾皮炭」

【本報訊】一名商人因亂服中藥，導致心臟衰竭死亡。據悉，該名商人曾服用一種名為「噬酥」的中藥，該藥含有強烈的毒性，導致其心臟功能受損，最終發展為心臟衰竭。衛生署呼籲市民，切勿亂服中藥，以免誤食含有強毒性成分的中藥，造成健康問題。

亂執藥補身 恐傷身行命

烏頭鹼中毒三年58宗 九成需入院

【本報訊】不正當服用中藥，恐致傷身行命。衛生署呼籲市民，切勿亂服中藥，以免誤食含有強毒性成分的中藥，造成健康問題。據悉，目前已有58宗烏頭鹼中毒個案，其中九成需要入院治療。衛生署表示，烏頭鹼是一種強毒性物質，誤食後會導致嚴重中毒，甚至危及生命。

衛生署呼籲市民，切勿亂服中藥，以免誤食含有強毒性成分的中藥，造成健康問題。衛生署表示，目前正與相關部門合作，調查該藥的來源及成分，並呼籲市民停止服用該藥。

衛生署呼籲市民，切勿亂服中藥，以免誤食含有強毒性成分的中藥，造成健康問題。衛生署表示，目前正與相關部門合作，調查該藥的來源及成分，並呼籲市民停止服用該藥。

中醫處方類固醇予380人

【本報訊】衛生署昨日調查一宗中醫處方類固醇中毒個案。一名男子因服用含有固醇類成分的中藥，導致中毒。衛生署呼籲市民，切勿購買或食用含有固醇類成分的中藥，以免中毒。

衛生署呼籲市民，切勿購買或食用含有固醇類成分的中藥，以免中毒。衛生署表示，目前正與相關部門合作，調查該藥的來源及成分，並呼籲市民停止服用該藥。

衛生署呼籲市民，切勿購買或食用含有固醇類成分的中藥，以免中毒。衛生署表示，目前正與相關部門合作，調查該藥的來源及成分，並呼籲市民停止服用該藥。

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

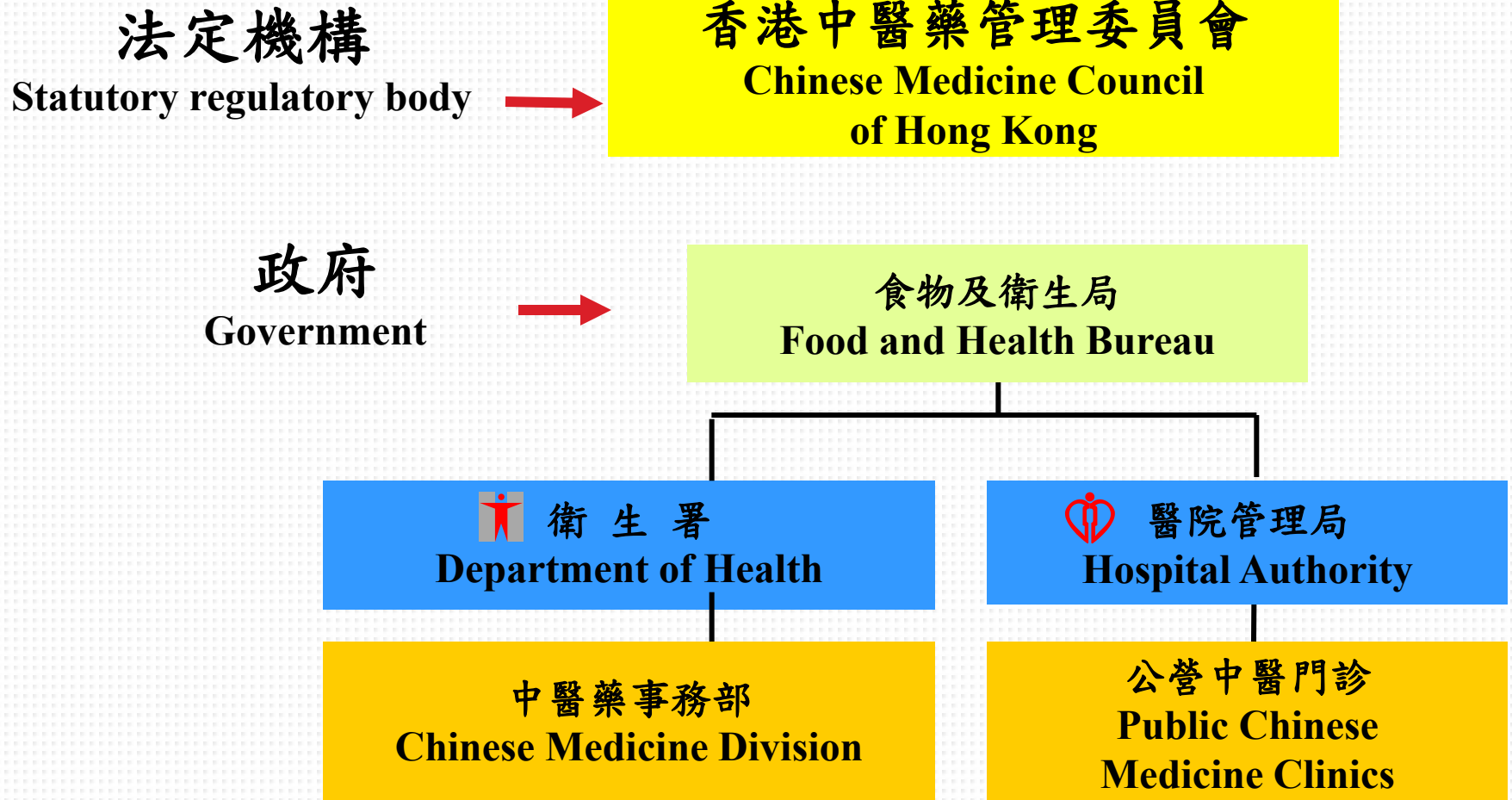
Policy Address (1997 and 1998)

- 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



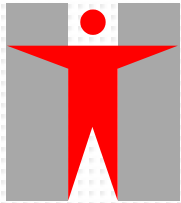
香港中醫藥管理委員會

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)
- 不良事件匯報 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)
- 不良事件匯報 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

已填妥的中藥材出口許可證填表格式樣本

附錄五

The form is a detailed application for an export license. It includes sections for the applicant's details (1), the medicinal material's name and quantity (2, 3, 4), the date of issue (5), and the license number (6). There are also sections for the applicant's signature and stamp (7, 8), and the issuing authority's details (9, 10, 11, 12, 13, 14, 15, 16, 17). The form is filled out with sample information.

凡進/出口必須事先向衛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

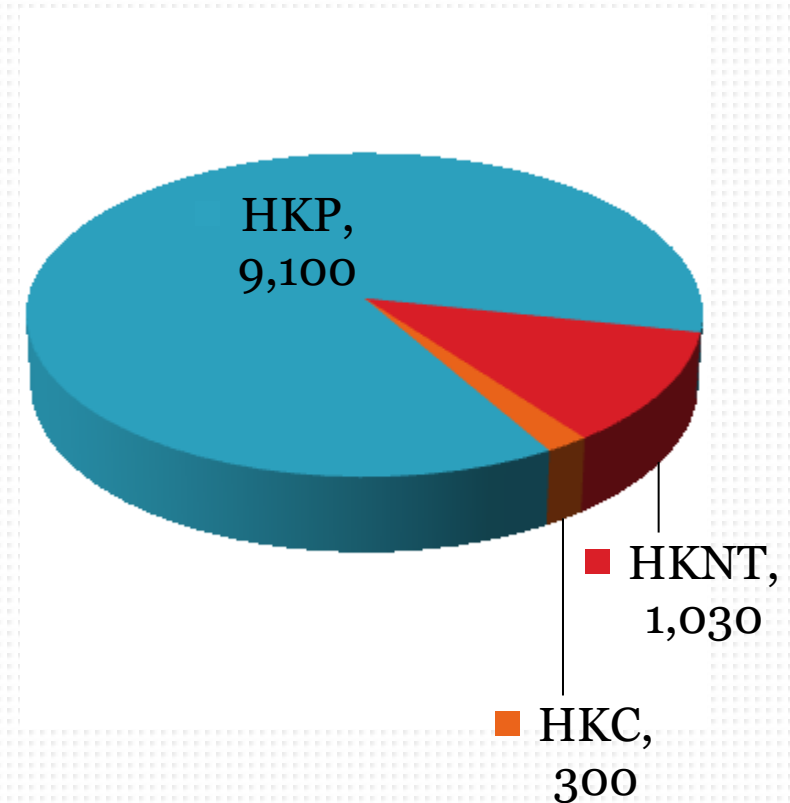
- 中成藥的註冊申請(~17,000 份)
pCm registration application (~17,000)



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**

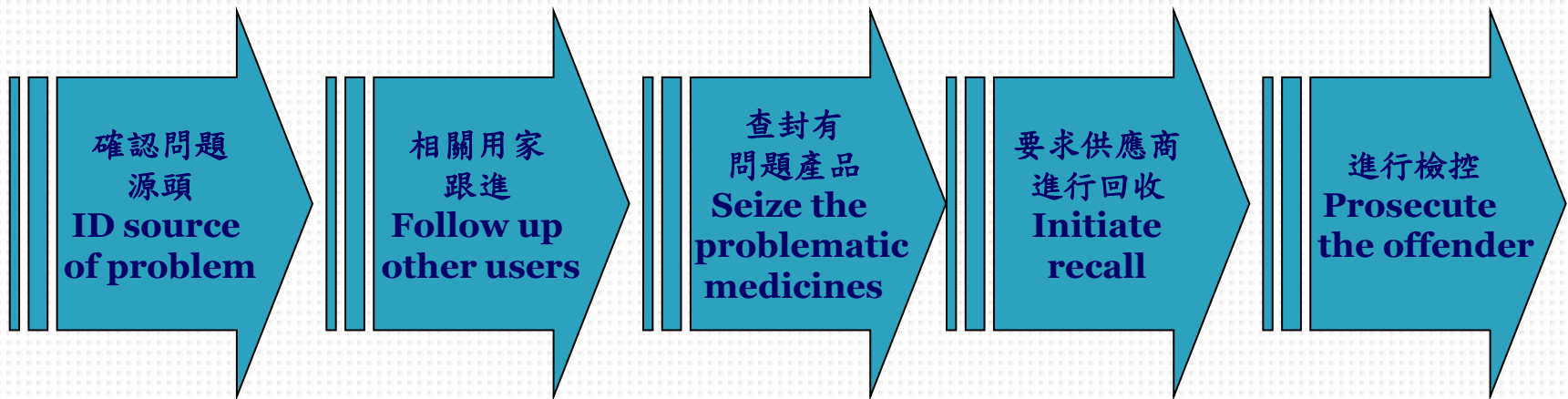
- 從中成藥註冊證明書持有人抽取樣本測試產品是否含有**重金屬及農藥殘留**

- 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衛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

Report can be returned by fax to 2147 8487
For Follow up report (see Question 10),
Please provide ADRM/ Ref No. _____

Department of Health
Adverse Drug Reaction (ADR) Report Form

Please read the following instructions:
1. Please read the Questions/Notes for ADR Reporting before completing the ADR report form.
2. This report form is used for voluntary report of all suspected ADR. There is no need to put down the full name of the patient.
3. ADR can be broadly described as a possible and unwanted response to a drug or vaccine when the normal dose is used.
4. Please provide information to every section. Information of individual reports will be treated as strict confidence.
5. As limited space is provided, please use another page for additional information if necessary.
6. For further enquiries, please contact the ADR Monitoring Unit of Drug Office of the DH at 2147 2078.

Section (A): Patient Information
Patient initials or ref. no. _____ Sex: M F Pregnant? No Yes Unknown
Weight (if known) _____ kg Date of birth: (dd/mm/yyyy) / / or age (at last birthday) _____
Ethnic group: Chinese Asian African Caucasian European Unknown Others _____

Section (B): About the Adverse Drug Reaction
Date of onset of ADR: (dd/mm/yyyy) / /
Description of event: _____

ADR category (for vaccine related ADR only):
 Allergic reaction Local reaction Systemic reaction Neurological disorders
Severity (can tick more than 1 box if appropriate):
 Life-threatening Prolonged Hospitalization Hospitalized on: (dd/mm/yyyy) / /
 Hospitalization NOT required
Laboratory result (if applicable): _____

AE Drug Therapies/Vaccines Prior to ADR (Please use trade names and, for certain injectable bulk samples, Provide serial for requested drug.)	Daily Dosage (Show number for vaccines, e.g. 1* DTP)	Route	Date Began	Date Stopped	Reason for Use

Section (C): Treatment & Outcome
Treatment of ADR: No Yes: Details (including dosage, frequency, route, duration) _____
Laboratory result (if applicable): _____
Outcome: Recovered on: (dd/mm/yyyy) / / Not yet recovered Unknown
 Died on: (dd/mm/yyyy) / /
Sequelae: No Yes: Persistent disability Birth defect Medically significant event
Details: _____
Allergies or other relevant history (including medical history, liver/kidney problems, smoking, alcohol use etc) _____

Section (D): Reporter Details
Name: _____ Sector of service: Private Public
Occupation: Doctor Chinese medicine practitioner Dentist Pharmacist Nurse Other _____
Correspondence Address: _____
Tel. no. _____ Fax. no. _____ Email: _____
Also report to: Manufacturer Distributor/Importer Other _____ Date of this report: _____

DH 2181 (Revised 9/2011)

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

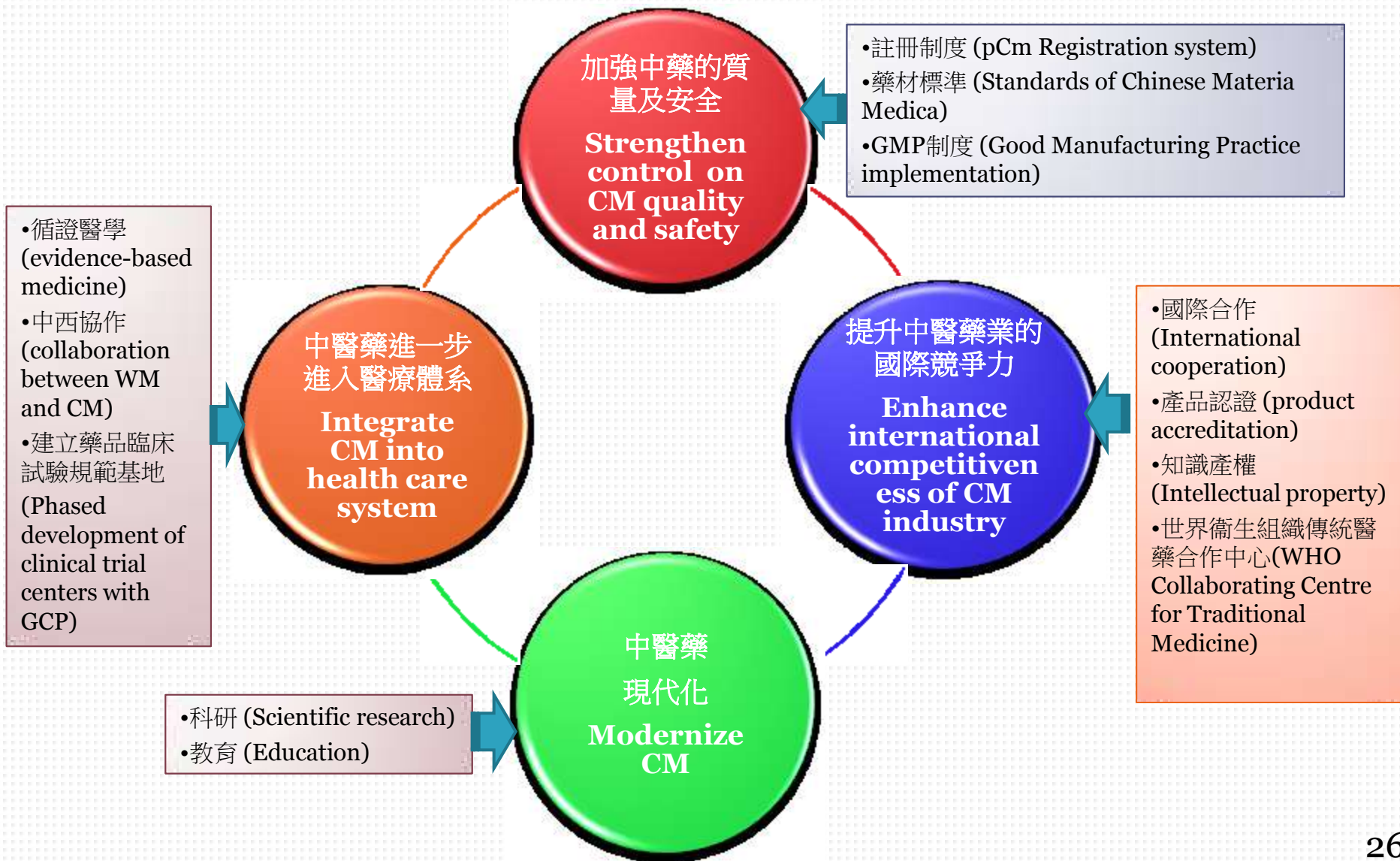
香港中醫藥的特色

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



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