Seminar on Research and Development of Chinese Medicines 2015 –

香港的中成藥註冊與規管現況
Registration and regulation of proprietary Chinese medicines in Hong Kong – an update

10 September 2015

香港特別行政區政府
衞生署

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中醫藥規管框架
Regulatory Framework for Chinese Medicine

中成藥在香港
Proprietary Chinese Medicine in Hong Kong

(一) 中成藥悠久使用歷史
Long history of use of Chinese medicines

估計實施中成藥註冊制度前市面銷售中成藥數目： 8,000-10,000
Estimate no. of pCm on market before the implementation of pCm registration : 8,000-10,000

(二) 中成藥企業多為中小型
Most Chinese Medicine Traders are Small and Medium Enterprises (SMEs)

2002年的統計數字 Year 2002 statistics#

中藥批發業的機構單位數目No. of wholesale of Chinese medicines: 371

中藥進出口貿易業數目No. of import/export of Chinese medicines: 722

數據參考自《香港統計月刊-專題文章-二零零三年香港的中醫藥業》
Data take reference from "Hong Kong Monthly Digest of Statistics – Feature Article – The Chinese Medicine Sector in Hong Kong, 2003"

中成藥在香港
Proprietary Chinese Medicine in Hong Kong

(三) 中醫藥理論指導
Traditional Chinese Medicine theory and practice

- 根據經驗 Experience - based
- 多種藥材複方配伍 Comprised multiple Chinese medicines

(四) 缺乏統一標準 Lack of uniform standard

- 作用機制不清 Mechanism unclear
- 物質基礎未明 unknown active composition

中醫藥規管的法律依據
Legal basis for control of Chinese Medicine

- **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衞生服務的政策"

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

中醫藥條例 (第549章)
Chinese Medicine Ordinance (Cap 549)

- 於1999年7月生效

  Enacted in July 1999

目的 Objective

- 對中醫的執業，以及中藥的製造、銷售及使用作出規管，從而保障公眾健康

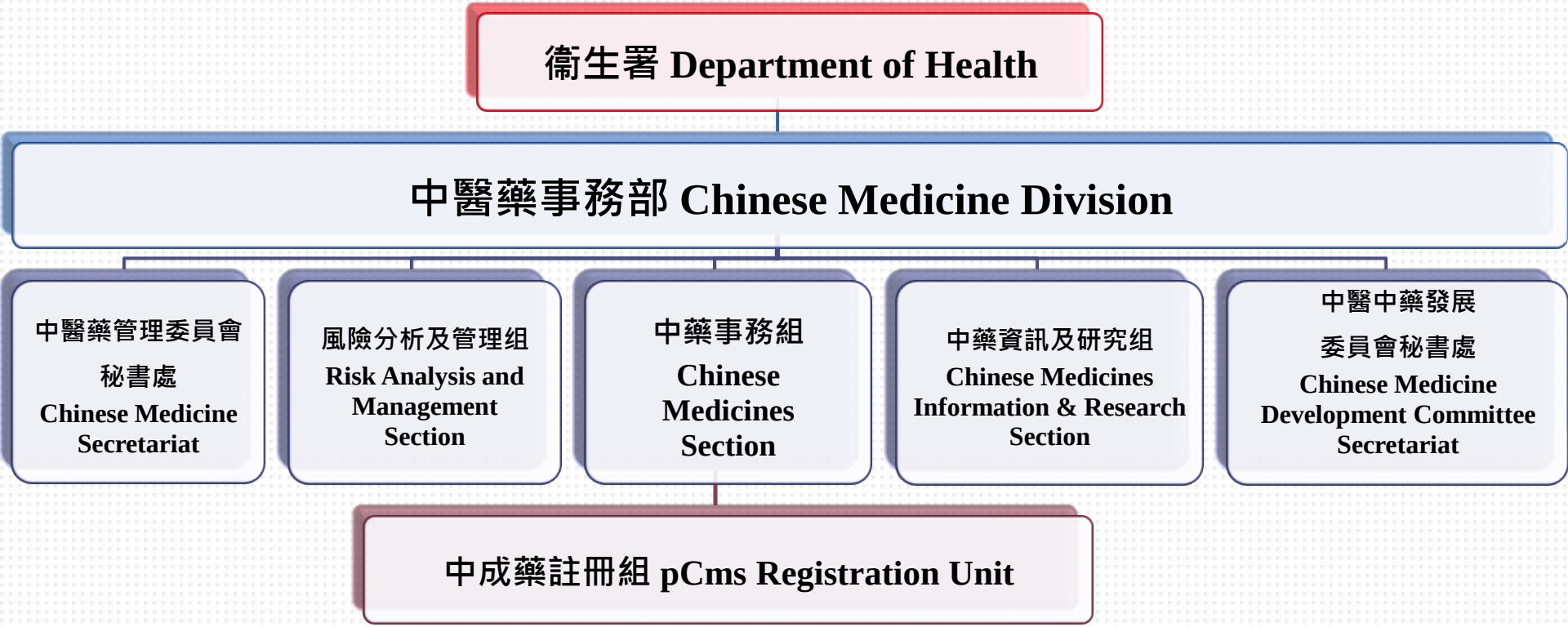
  To regulate the practice of Chinese Medicine Practitioners and the manufacture, sale and use of Chinese medicines, so as to protect public health

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

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 (Cap 549). Established on 13 September 1999, the Council is responsible for implementing regulatory measures for Chinese medicine practitioners and Chinese medicines.

中醫藥事務部組織圖
Organization Chart of the Chinese Medicine Division



香港中成藥的註冊制度

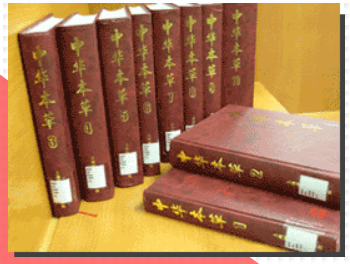
Registration system of proprietary Chinese medicine in Hong Kong

中成藥的釋義

Definition of proprietary Chinese medicine

根據《條例》**第2條**，“**中成藥**”是指任何符合下述說明的專賣產品：

According to **Section 2** of the Ordinance, "**proprietary Chinese medicine**" means any proprietary product -



(a) 純粹由下述項目作為有效成分組成—

composed solely of the following as active ingredients-

(i) 任何**中藥材**；或

any **Chinese herbal medicines**,

(ii) **慣常獲華人使用**的任何源於植物、動物或礦物的物料；或

any materials of herbal, animal or mineral origin **customarily used by the Chinese**; or

(iii) 第(i)及(ii)節分別提述的任何藥材及物料；

any medicines and materials referred to in subparagraphs (i) and (ii) respectively;

(b) 配製成**劑型形式**；及

formulated in a **finished dose form**; and

(c) 已知或聲稱用於診斷、治療、預防或紓緩人的**疾病或症狀**，或用於調節**人體機能狀態**。

known or claimed to be used for the diagnosis, treatment, prevention or alleviation of **any disease or any symptom** of a disease in human beings, or for the regulation of the **functional states** of the human body.

中成藥註冊的規定
Proprietary Chinese medicines to be registered

- 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 (pCm) must first be registered by the Chinese Medicines Board (CMB) under the Council before they can be imported, manufactured and distributed in Hong Kong

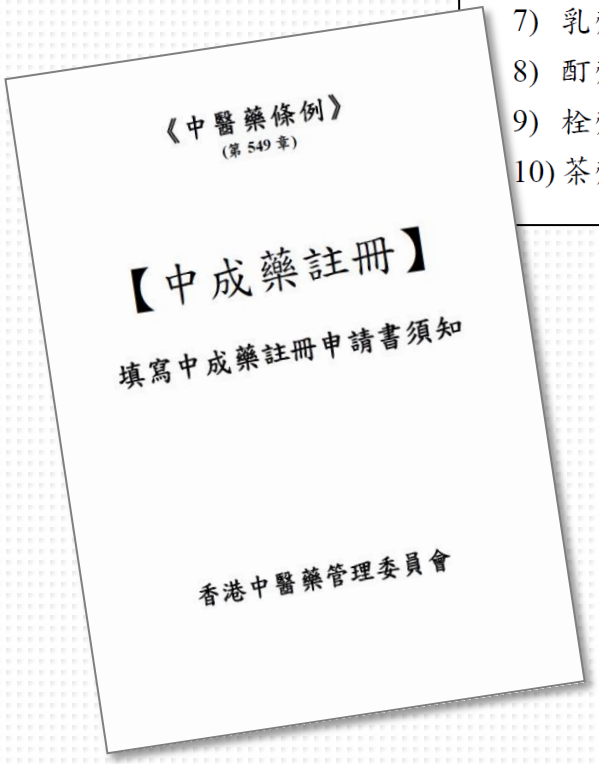
- 符合**安全**、**品質**、**成效**三方面的要求
  Ensure **safety**, **quality** and **efficacy** of products

- 自2003年12月19日中成藥註冊制度開始，中藥組共收到接近18,000 份中成藥註冊申請
  Since the implementation of pCm registration system on 19 Dec 2003, the CMB has received nearly 18,000 applications for pCm registration

- 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。有關條文已於2010年12月3日開始生效
  no person shall sell, import or possess any pCm unless the pCm is registered under section 121. The relevant provision has become effective on 3rd Dec 2010

劑型 Dose form

1) 丸劑	11) 酒劑	21) 膠劑	31) 混懸劑	41) 糖衣片
2) 丹劑	12) 釘劑	22) 糕劑	32) 眼膏劑	42) 糖漿劑
3) 片劑	13) 條劑	23) 錠劑	33) 軟膏劑	43) 顆粒劑(沖劑)
4) 合劑	14) 散劑	24) 露劑	34) 微囊劑	44) 巴布膏劑
5) 釉劑	15) 棒劑	25) 綫劑	35) 煎膏劑(膏滋)	45) 流浸膏劑
6) 灸劑	16) 搽劑	26) 口含片	36) 滴丸劑	46) 橡膠膏劑
7) 乳劑	17) 膏劑(膏藥)	27) 口服液	37) 滴眼劑	47) 其他(請註明)
8) 酊劑	18) 熨劑	28) 注射劑	38) 滴鼻劑	
9) 栓劑	19) 糊劑	29) 氣霧劑	39) 噴霧劑	
10) 茶劑	20) 膜劑	30) 浸膏劑	40) 膠囊劑	



1) Pill	11) Medicinal wine	21) Glue	31) Suspension	41) Sugar-coated tablet
2) Dan	12) Cone-shaped drug	22) Medicinal pastry	32) Eye ointment	42) Syrup
3) Tablet	13) Medicated roll	23) Troch	33) Ointment	43) Granule
4) Mixture	14) Powder	24) Medicinal distillate	34) Microcapsules	44) Cataplasm (Babu Plaster)
5) Fermented preparation	15) Medicinal stick	25) Medicinal thread	35) Concentrated decoction	45) Liquid extract
6) Moxa-preparation	16) Liniment	26) Lozenge	36) Dripping pill	46) Adhesive plaster
7) Emulsion	17) Plaster	27) Oral liquid	37) Eye drops	47) Other (Please specify)
8) Tincture	18) Hot medicated compress	28) Injection	38) Nasal drops	
9) Suppository	19) Paste	29) Aerosol	39) Spray	
10) Medicinal tea	20) Medicinal membrane	30) Extract	40) Capsule	

食品處理
Food

受《公眾衞生及市政條例》(第132章)的規管governed by the Public Health and Municipal Services Ordinance (Cap. 132):

同時符合以下的要求
meet all the following ：

a) 以一般食物形式或方式使用的產品;
Used in form or manner of normal foods;

b) 不宣稱有任何治療或保健用途;及
The product does not contain any claim on curative or health care function; and

c) 有關藥材為一般認同可用作食品。
All the Chinese herbs used in the product are generally being considered as food.

註冊豁免 EXEMPTIONS

個人護理用品或化粧品處理
Personal hygiene products or cosmetics

受《消費品安全條例》(第456章)的規管governed by the Consumer Goods Safety Ordinance (Cap. 456):

同時符合以下的要求
meet all the following ：

a) 以塗擦、噴灑或其他類似方法散佈於人體表面;
To be spread, sprayed or applied on the surface of the human body;

b) 不宣稱有任何治療或保健用途;及
The product does not contain any claim on curative or health care function; and

c) 以清潔、消除不良氣味、護膚、美容等作為使用目的。
Can only be used for cleansing, beautifying, maintaining the skin in good condition or altering the odours of the body.

中成藥的註冊申請人
Applicant for registration of pCms

根據《條例》第120及128條，中成藥的註冊申請：

According to **Section 120** & **128** of the Ordinance, an application for the registration and transitional registration of a pCm shall be made -

- **本地製造的中成藥**
  for pCm being manufactured in Hong Kong
  - 由其本地製造商向中藥組提出
    by the local manufacturer
- **外地製造的中成藥**
  for pCm being manufactured outside Hong Kong
  - 由製造商的本地代表/代理或
    by the local representative or agent of the manufacturer
  - 由有關的進口商向中藥組提出
    by the importer

中成藥的註冊安排
Registration Arrangement of Proprietary Chinese Medicines

中成藥的註冊申請安排可分為：

Registration Arrangement of Proprietary Chinese Medicines can be classified into:

過渡性註冊

Transitional registration of pCms

根據《條例》第128條，任何於1999年3月1日時在香港製造或銷售的中成藥

According to s.128 of the CMO, an applicant may apply to the CMB for transitional registration of a pCm that was, on 1 March 1999, manufactured, sold or supplied for sale in Hong Kong

正式註冊

Registration of pCms

根據《條例》第121條申請註冊

Apply for registration of pCm in accordance with section 121 of the CMO

過渡性註冊的有效期
Validity of transitional registration of pCm

根據《條例》第128條，中成藥的過渡性註冊繼續有效，直至 -

According to section 128 of the CMO, the transitional registration of pCm shall continue in effect until -

1. 該中成藥獲得正式註冊；
   the pCm is formally registered；
2. 該中成藥的正式註冊申請遭拒絕;或
   the refusal of its application for registration；or
3. 食物及衞生局局長於憲報公布的日期；
   a date to be promulgated by the Secretary for Food and Health;

以最早出現者為準

whichever is the earliest

中成藥的註冊詳情
Registration particulars of the pCm

- **產品的註冊詳情如需要更改的話，註冊持有人可根據《中醫藥條例》第124條以書面向中藥組申請**

  According to section 124 of the CMO, the holder of a certificate of registration may apply in writing to the CMB for approval to vary the registration particulars of the pCm to which the certificate relates

1. **產品的中英文名稱***
2. **劑型形式***
3. **每種有效成分的名稱及份量***
4. 每種賦形劑(如有)的名稱及份量
5. 產品的規格說明
6. 主治用途(如有)
7. 用量及使用方法
8. 標籤
9. 在香港銷售而供應的說明書
10. 在香港境外銷售(如有)而供應的說明書
11. 產品每一位製造商的名稱及地址
12. 產品的功能或藥理作用

1. **its Chinese and English name;***
2. **its dose form;***
3. **the name and quantity of each of its active ingredient;***
4. the name and quantity of each of its excipient (if any);
5. its specification;
6. its indication (if any);
7. its dosage and method of usage;
8. each of its labels to be attached or printed on its package;
9. the package insert to be supplied for its sales inside Hong Kong;
10. each of the package inserts to be supplied for its sales outside Hong Kong (if any);
11. the name and address of each of its manufacturer; and
12. its function or pharmacological action.

* 任何以上三項的更改，須以新的中成藥的註冊申請辦理

Any variation in any of these three particulars will require a new application for registration of the pCm

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
    For the purposes of providing samples and seeking registration
  - 教學或科研用途
    For the purposes of education or scientific research
  - 中成藥批發商轉出口
    For the purpose of re-exporting by the same wholesale dealer
  - 進行臨床證驗或藥物測試
    For the purposes of clinical trial or medicinal test
  - 按照中醫開出的處方而合成的
    Prepared or compounded according to a prescription given by a Chinese medicine practitioner

中成藥註冊的審核

Assessment of pCm

中成藥註冊分類
Classification Category of pCms

- **中成藥註冊類別**

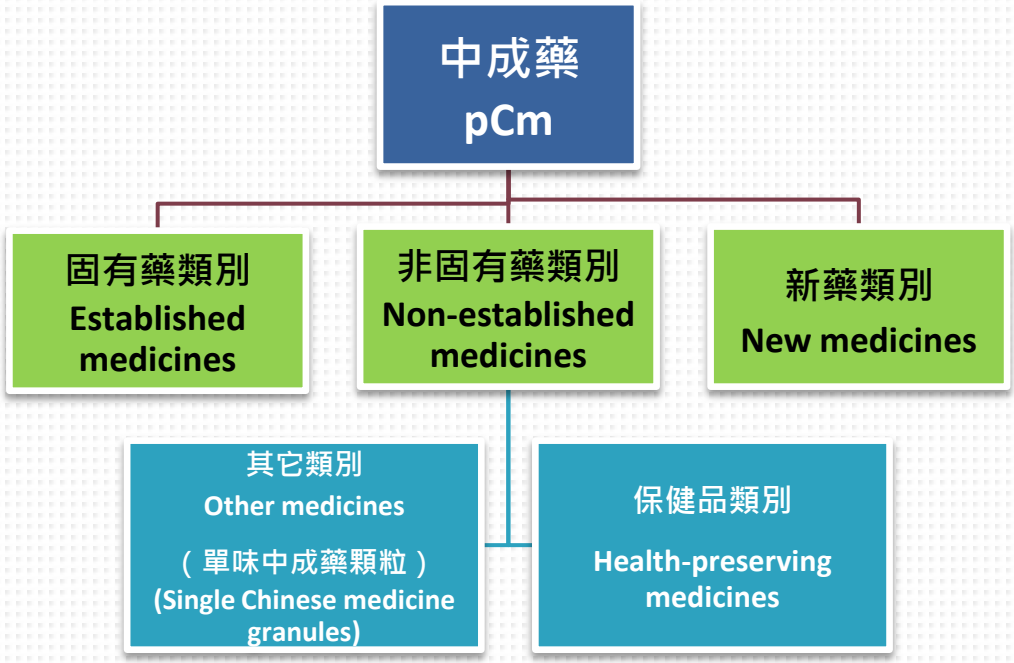
  Classification category

  - 固有藥類別

    Established medicines
  - 非固有藥類別

    Non-established medicines
  - 新藥類別

    New medicines



固有藥類別
Established medicines category

- 符合以下任何一項描述的中成藥(中藥注射劑除外)，其處方為：

  Except for Chinese medicine injections, pCm that is formulated according to any of the following prescription shall be regarded as "Established medicines":

古方 **an ancient prescription**	• 源於清代或以前中醫藥文獻所記載的處方 • **prescription has been documented in Chinese medicines bibliography in, or before, the Qing dynasty**
古方加減 **a modified ancient prescription**	• 於古方基礎上作適當的藥味加減的處方，並獲中藥組認同是合理的 • **the prescription of which is based on an ancient prescription with reasonable and rational modifications**
藥典方 **a pharmacopoeia prescription**	• 中華人民共和國藥典內所記載的處方 • **prescription has been documented in the Pharmacopoeia of the People's Republic of China)**
國家藥品標準 **other prescriptions originated from the National Drug Standards of the People's Republic of China**	• 並獲中藥組接納的處方 • **prescription also being accepted by the Chinese Medicines Board**

- 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)，否則當新藥類別處理

  The original dose form of the prescription should not be changed, otherwise the pCm will be regarded as "New medicines category"

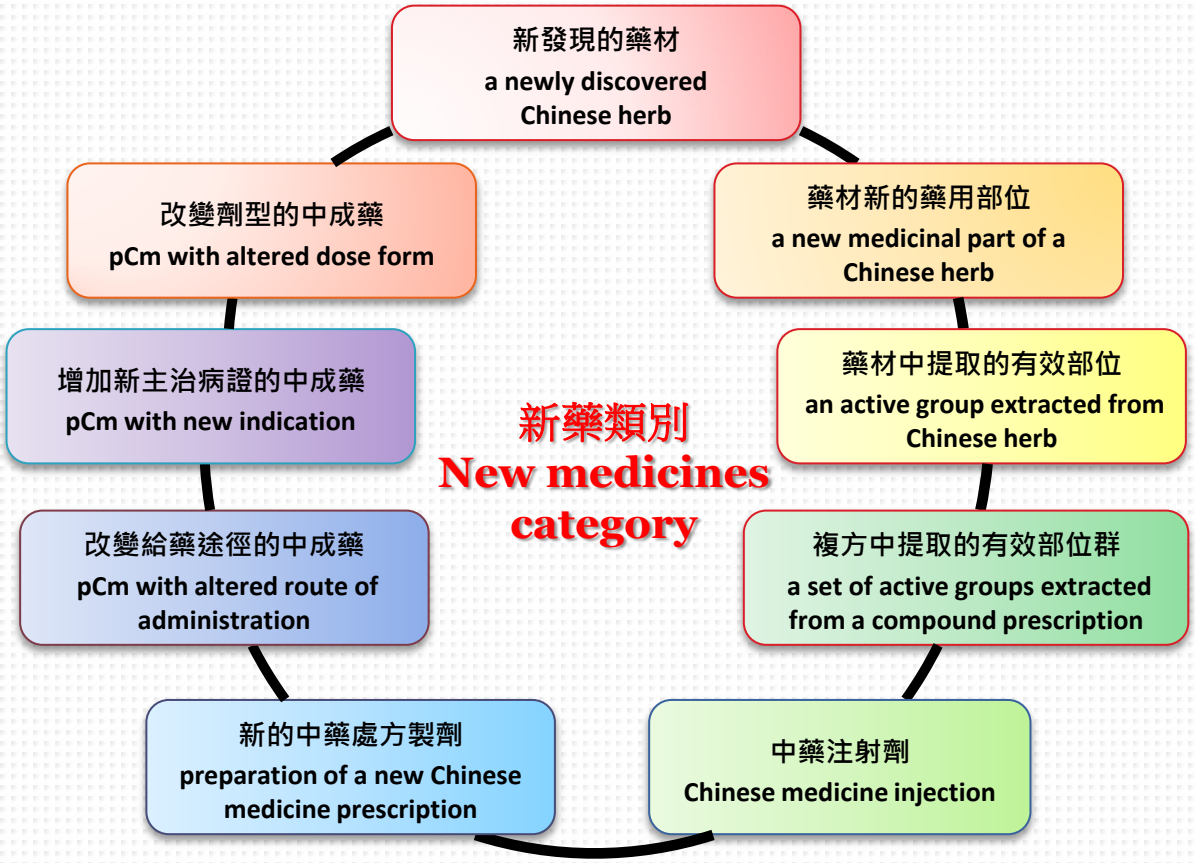
非固有藥類別
Non-established medicines category

保健品類別 Health-preserving medicines	其他類別 Other medicines
• 具有調節人體機能狀態功能的產品 • used for the purpose of regulating the functional states of the human body	• 單味中成藥顆粒 • Single Chinese medicine granules

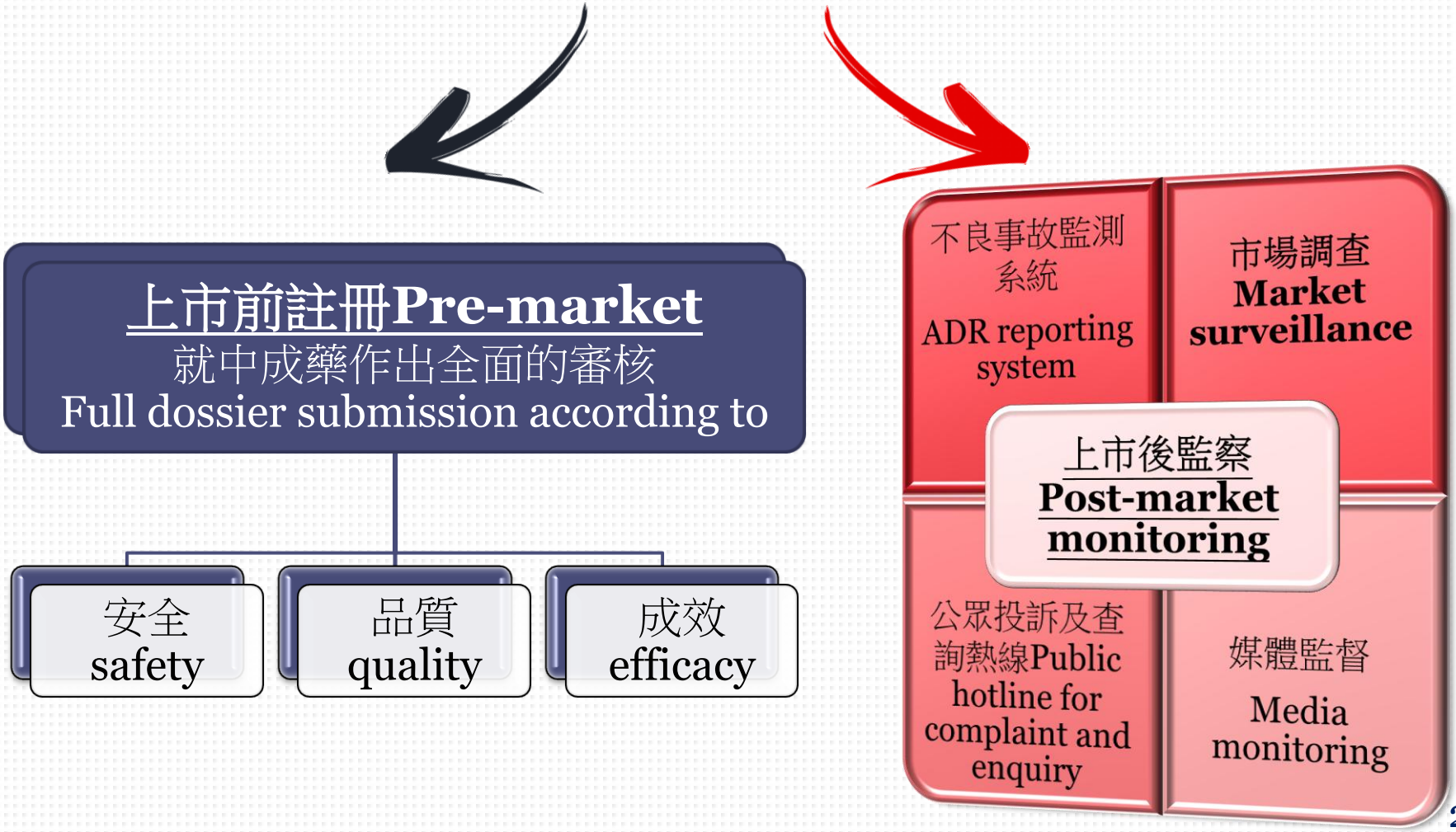
新藥類別
New medicines category

- 符合以下任何一項描述的中成藥：

  pCms that meet any of the following descriptions shall be regarded as “New medicines”:



中成藥註冊的規管框架
Regulatory Framework for pCm registration



中成藥註冊基本要求
Basic requirements for pCm registration

- ☑ 重金屬或有毒元素不能超標
  Not exceeding limits of heavy metals and toxic elements
- ☑ 農藥殘留含量不能超標
  Not exceeding limits of pesticide residues
- ☑ 微生物限度不能超標
  Not exceeding limits of microbes
- ☑ 不能摻雜西藥
  No adulteration with western medicines
- ☑ 符合其他法例要求
  Compliance with other legal requirements

註冊資料的要求
Documents required for registration of pCm

一般資料 General documents

- 完整處方
  Master formula
- 製造或銷售歷史證明文件
  proof of manufacturing or sales history
- 標籤、說明書
  label & package insert
- 樣本及銷售包裝的樣板
  product sample & prototypes of sales pack

安全性資料 Product Safety documents

- 重金屬及有毒元素含量測試報告
  heavy metals & toxic elements test report
- 農藥殘留量測試報告
  pesticide residues test report
- 微生物限度測試報告
  microbial limit test report
- 急性/長期/局部毒性試驗報告
  acute / long term /local toxicity test report
- 致突變試驗報告、致癌試驗報告、生殖毒性試驗報告
  Test reports on mutagenicity , carcinogenicity & reproductive toxicity

成效性資料 Product Efficacy documents

- 組方原則及方解
  Interpretation & principle of formulating a prescription
- 成效性參考資料
  reference materials on product efficacy
- 藥效學藥理學臨床研究報告
  reports on product efficacy evaluation & clinical trials

品質性資料 Product Quality documents

- 製造方法
  Manufacturing method
- 原料理化性質資料
  physicochemical properties of crude drug
- 品質標準、化驗方法及化驗報告
  product specification, certificate of analysis
- 穩定性試驗報告
  stability reports

技術指引
Technical Guidelines

- 各項安全性、品質性、成效性試驗的技術要求，可參閱有關的技術指引
  Refer to the Technical Guidelines for Registration of pCm for the requirements on the tests of product Safety, Quality and Efficacy

【中成藥註冊】
安全性資料
技術指引
Product Safety
Documents
Technical Guidelines

【中成藥註冊】
品質性資料
技術指引
Product Quality
Documents
Technical Guidelines

【中成藥註冊】
成效性數據
技術指引
Product Efficacy
Documents
Technical Guidelines

進行試驗場所的水平要求
Requirements for test laboratories

- **進行各項安全性、成效性及品質性試驗的場所都應達到一定的水平，例如：**

  Laboratories conducting the product safety, quality and efficacy tests for pCms must have met the requirements, such as :

  - 《藥品非臨床品質管制規範》

    Good Laboratory Practice (GLP)

  - 《藥品臨床品質管制規範》

    Good Clinical Practice (GCP)

  - ISO/IEC 17025

  - 內地國家食品藥品監督管理總局及中藥組認可的藥品檢驗所

    Other municipal Institutes for Drug Control in China that are recognized both by the China Food & Drug Administration (CFDA) and the CMB

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 CMO,

- 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**

在香港銷售的中成藥的標籤
Labelling of proprietary Chinese medicines to be sold in Hong Kong

- 根據《中藥規例》，在本地銷售的中成藥的標籤，須最少以中文標示以下內容-

a) 產品名稱；
b) 主要有效成分的名稱；
c) 生產地；
d) 註冊編號；
e) 註冊證明書持有人的名稱；
f) 包裝規格說明；
g) 用量及使用方法；
h) 失效日期；及
i) 批次編號。

- **According to Chinese Medicines Regulation, person who sells in Hong Kong a pCm shall ensure that a label on a package of the medicine includes,at least in Chinese, the following particulars-**

a) the name of the medicine;
b) the active ingredient(s);
c) the name of the country the medicine is produced;
d) the registration no.;
e) the name of the certificate holder;
f) its packing specification;
g) its dosage and method of usage;
h) its expiry date; and
i) its batch number.

關於說明書的規定
Requirements for package inserts

- **根據《中藥規例》，在本地銷售的中成藥的說明書須最少以中文列明有以下內容-**

a) 產品名稱；
b) 主要有效成分的名稱；
c) 註冊證明書的持有人名稱或生產商的名稱；
d) 用量及使用方法；
e) 功能或藥理作用；
f) 主治用途(如有的話)；
g) 禁忌(如有的話)；
h) 副作用(如有的話)；
i) 毒性作用(如有的話)；
j) 使用時須採取的預防措施(如有的話)；
k) 貯存指示；及
l) 包裝規格說明。

- **According to Chinese Medicines Regulation, person who sells in Hong Kong a pCm shall ensure that a package insert shall include,at least in Chinese, the following particulars in respect of the medicine-**

a) the name of the medicine;
b) the active ingredient(s) and its quantity
c) the name of the certificate;
d) its dosage and method of usage;
e) its functions or pharmacological action;
f) its indications (if any);
g) its contra-indications (if any);
h) its side-effects (if any);
i) its toxic effects (if any);
j) the precautions to be taken regarding its use (if any);
k) its storage instructions; and
l) its packing specification.

出口的中成藥的標籤
Labelling of proprietary Chinese medicines to be exported

- 根據《中藥規例》，只供出口的中成藥的最外層包裝，須標示以下內容：

a) 產品名稱；
b) 註冊證明書持有人的名稱；及
c) 註冊編號。

- **According to Chinese Medicines Regulation, proprietary Chinese medicine manufactured in Hong Kong for exports only shall ensure that a label on the outermost package of the medicine includes the following particulars-**

a) the name of the medicine;
b) the name of the certificate holder;
c) the registration number.

中成藥產品數目
Number of pCm registration applications

~8480 (HKP-XXXXX)

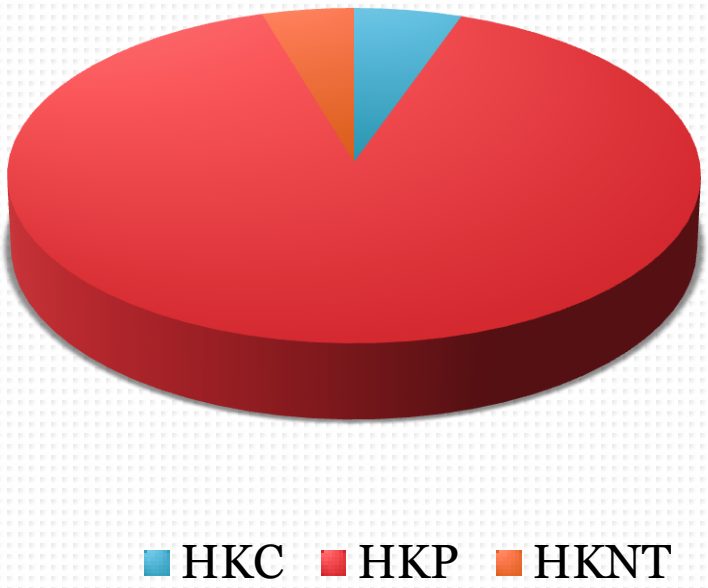
- 「確認中成藥過渡性註冊通知書」(HKP)
  "Notice of confirmation of transitional registration of pCm"

~530 (HKC-XXXXX)

- 「中成藥註冊證明書」(HKC)
  "Certificate of registration of a pCm"

~430 (HKNT-XXXXX)

- 「確認中成藥註冊(非過渡性)申請通知書」(HKNT)
  "Notice of confirmation of (non-transitional) registration application of pCm"



至2015年8月31日
Up to 31Aug 2015

中成藥註冊的未來挑戰

Future challenges in pCm registration

未來挑戰
Future challenges

加強中成藥的品質及安全的控制
Strengthening the quality & safety control of pCm

新發現及技術創新
New discoveries and advance in technology

審批註冊
Registration assessment

相關網址
Related Websites

- 中醫藥管理委員會

  Chinese Medicine Council of Hong Kong

  www.cmchk.org.hk

- 衞生署中醫藥事務部

  Chinese Medicine Division Website

  www.cmd.gov.hk

- 香港法規

  Department of Justice

  www.legislation.gov.hk

多謝

Thank you