

Regulatory Control of Heavy Metals in Chinese Medicines

25 Nov 2015

 Chinese Medicine Division
Department of Health
The Government of the Hong Kong Special Administrative Region

1. Development of Chinese Medicine in Hong Kong
2. Regulatory framework for control of Chinese Medicine in Hong Kong
3. Control of Chinese Medicines
4. Market surveillance





Development of Chinese Medicine in Hong Kong

- Suggestion from the Final report of the Chinese Medicine Working Party:
 - 1) To establish the Preparatory Committee of Chinese Medicine
 - 2) To make recommendations to the government on the promotion, development and regulation of Chinese medicine in Hong Kong
- In April 1995, “**Preparatory Committee of Chinese Medicine of Hong Kong**” was established



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Development of Chinese Medicine in Hong Kong

Policy Address (1997 and 1998)

- **To established a statutory framework** to recognize the professional status of Chinese medicine practitioners, assess their professional qualifications, monitor their standards of practice, and regulate the use, manufacture and sale of Chinese medicines.
- To develop Hong Kong into an **international centre of Chinese medicine**



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Development of Chinese Medicine in Hong Kong

- **Establishment of Regulatory System**

- **1997**
 - ✓ Establishment of Chinese Medicine Division under the Department of Health
- **7/1999 (July 1999)**
 - ✓ Enactment of the Chinese Medicine Ordinance (Cap.549)
- **9/1999 (September 1999)**
 - ✓ Establishment of the **Chinese Medicine Council of Hong Kong**

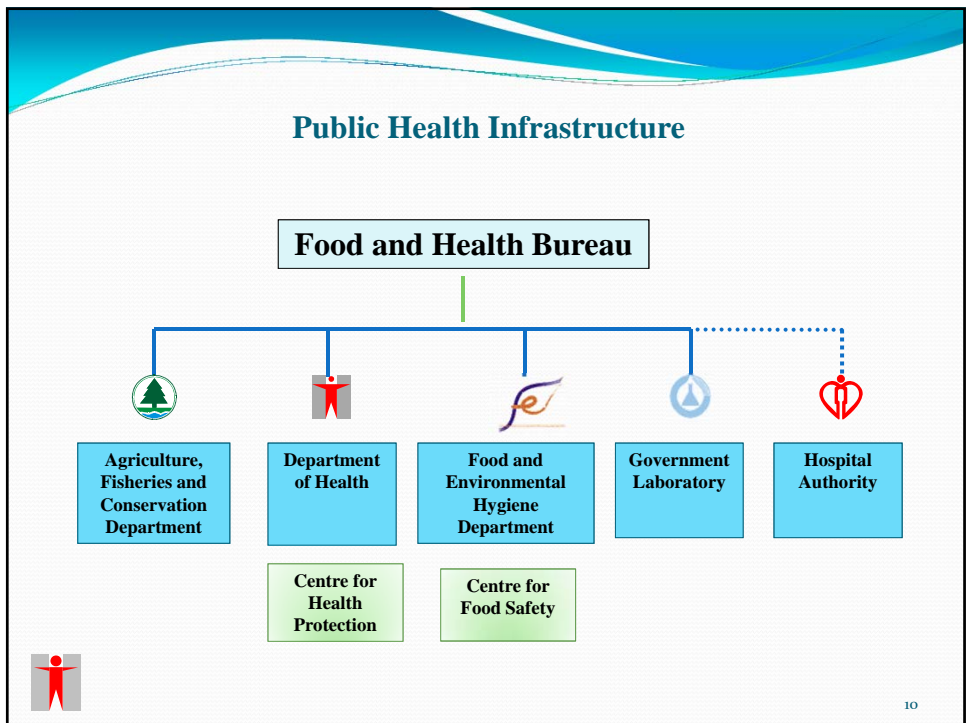
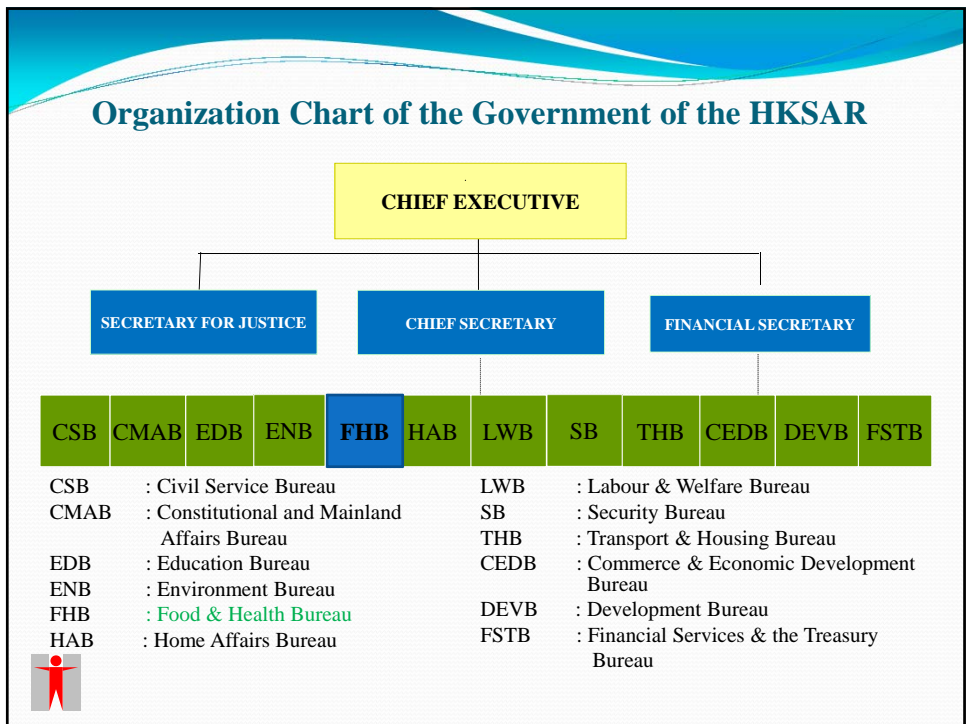


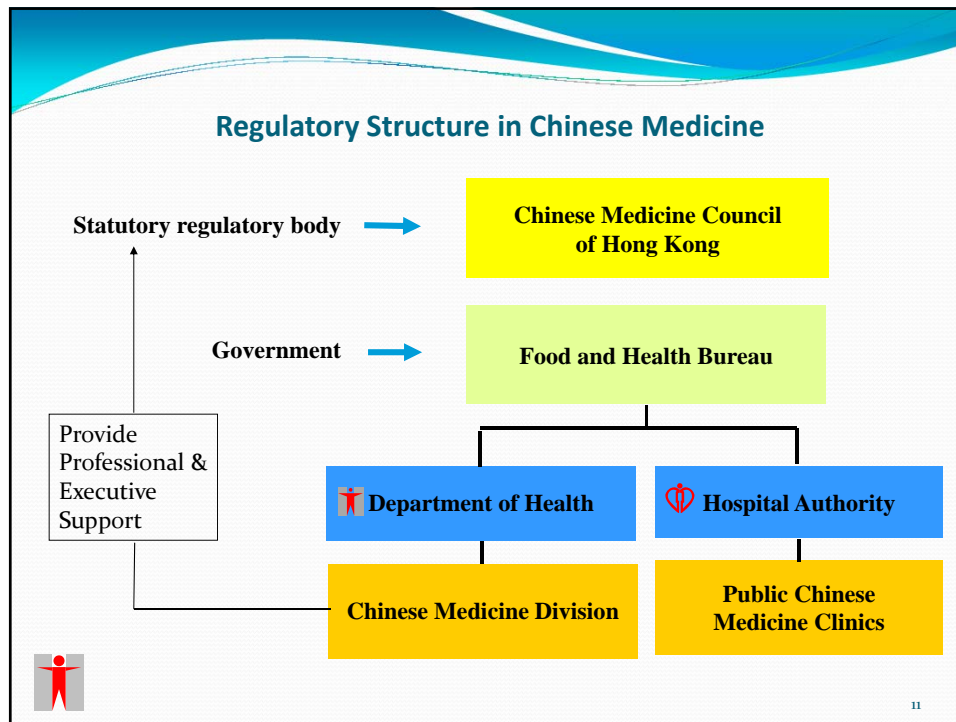
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Regulatory framework for control of Chinese Medicines in Hong Kong



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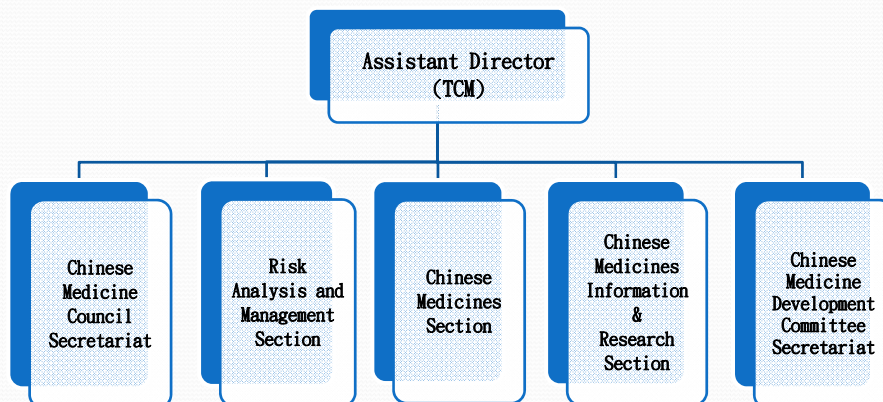
Functions of the Chinese Medicine Council of Hong Kong

- To ensure adequate standards of **practice** and conduct in the Chinese medicine practitioners and Chinese medicine traders
- To promote professional **education** of Chinese medicine practitioners
- To promote and ensure (i) the proper use of **Chinese herbal medicines**; (ii) the safety, quality and efficacy of **proprietary Chinese medicines**
- To co-ordinate and supervise the **activities** of the Chinese Medicine Practitioners Board and the Chinese Medicines Board
- To carry out any **other functions** assigned to it under the Chinese Medicine Ordinance



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Organization Chart of the Chinese Medicine Division



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Functions of the Chinese Medicine Division

- Responsible for the enforcement of the **Chinese Medicine Ordinance**
- Providing **professional** and **administrative support** to the **Chinese Medicine Council of Hong Kong**
- Conducting Chinese medicine related **public health** and **health promotion activities**
- Liaising with local and overseas institutions and government departments for **information exchange** about Chinese medicine



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Control of Chinese Medicines



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Definition of proprietary Chinese medicine

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

- (a) composed solely of the following as active ingredients-
 - (i) any **Chinese herbal medicines**,
 - (ii) any materials of herbal, animal or mineral origin **customarily used by the Chinese**; or
 - (iii) any medicines and materials referred to in subparagraphs (i) and (ii) respectively;
- (b) formulated in a **finished dose form**; and
- (c) 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



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Registration of proprietary Chinese medicine

According to **section 119** of the Ordinance, all "**proprietary Chinese medicine**" (pCm) sold, imported, or possessed in Hong Kong must apply for registration with the Chinese Medicines Board under the Chinese Medicine Council of Hong Kong

A pCm must comply with the requirements in the aspects of **safety, quality and efficacy** set out by the CMCHK in order to obtain the registration



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Definition of Chinese herbal medicine

According to **Section 2** of the Ordinance, “**Chinese herbal medicine**” (Chm) means any of the substances specified in Schedule 1 or 2

Schedule 1	Schedule 2
31 types of toxic Chm	574 types of Chm which are commonly used in Hong Kong
Prescription only	OTC



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The licensing of Chinese Medicine traders

Four types of Chinese medicines traders must apply for a licence and comply with the practicing guidelines:

Retail of Chinese
herbal medicines
(~4, 700)

Wholesale of Chinese
herbal medicines
(~900)

Wholesale of proprietary
Chinese medicines
(~1, 050)

Manufacture of proprietary
Chinese medicines
(~280)



(As of 31.10.2015)

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Market Surveillance



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Market surveillance of Chinese medicines

Background

- Monitoring **safety** and **quality** of Chm and pCm for sale in the market
- Obtaining samples of Chm and pCm from the market according to risk assessment for analysis
- ~9400 registered pCm in Hong Kong
- 31 Schedule 1 Chm and 574 Schedule 2 Chm
- List of pCm in Hong Kong (http://www.cmchk.org.hk/pcm/eng/#main_dis.htm)



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Testing items

Testing is mainly conducted by the Government Laboratory

pCm samples

- Testing items include **heavy metals, pesticide residues, microbial content and western medicine**

Chm samples

- Testing items include **heavy metals, pesticide residues and morphological identification**



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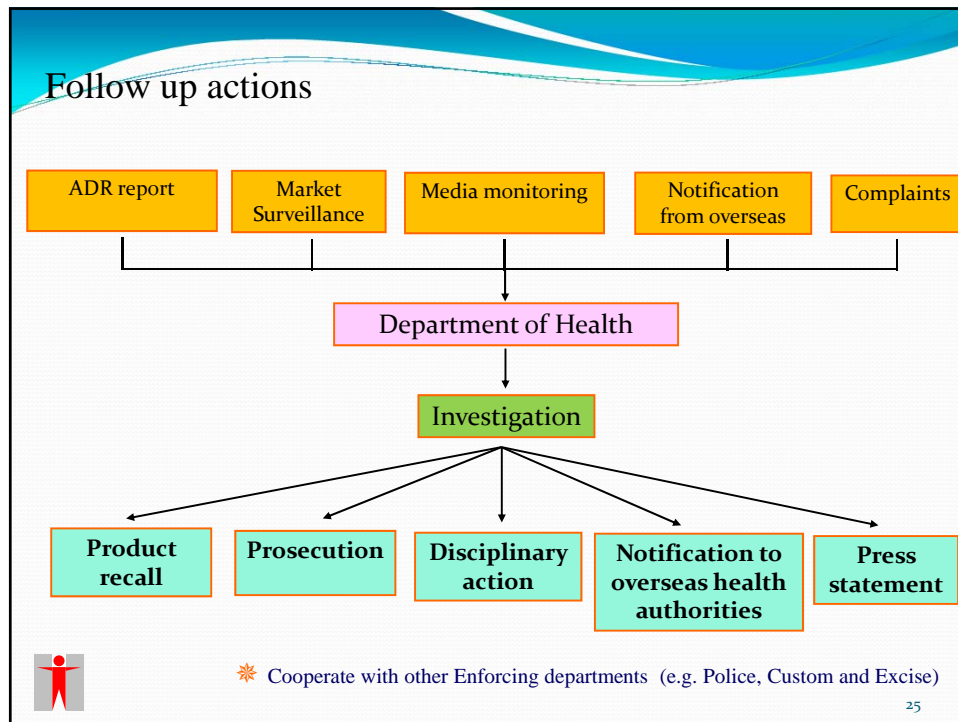
Limits of heavy metals and toxic elements in pCm and Chm set out by the Chinese Medicine Council of Hong Kong

Heavy metals or toxic element	Maximum Permitted Level*
Arsenic	1500 mcg/day
Cadmium	3500 mcg/dose
Lead	179 mcg/day
Mercury	36 mcg/day



*Applicable to pCm and Chm which does not originate from mineral substances containing heavy metals or toxic elements as ingredients

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Results of market surveillance – Heavy Metals


(From 2013 to August 2015)

pCm

- about 4900 pCm samples were tested for heavy metals
- 8 samples exceeded the limit

Chm

- about 1000 Chm samples were tested for heavy metals
- none of them was tested to have abnormal results after decoction


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Statistics of market surveillance – Heavy Metals in pCm

Year	No. of failed pCm samples				
	As	Cd	Pb	Hg	Total
2013	0	0	1	3	4
2014	1	0	3	0	4
2015 (up to August)	0	0	0	0	0
Total	1	0	4	3	8



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Control measures - Assessment

- Identify the source and scope of distribution
- Investigate the cause of contamination
- Health effect



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Control measures - Management

- **Product recall**
- **Preventive measures**
- **Import control**
- **Review of product registration**
- **Disciplinary action**
- **Prosecution action**
- **Referral to relevant department**



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Control measures - Communication

- **Press statement**
- **Web message**
- **Notifications**
 - **Chinese medicines traders**
 - **Chinese medicine practitioners**
 - **Relevant health authorities and organizations**



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Summary of Regulatory Control of Heavy Metals in Chinese Medicines

- Market surveillance system for Chinese medicines put in place.
<0.2% failure rate for heavy metals in pCm samples in the past three years
- Investigation and control measures for failed samples
- Keep vigilance and collaboration with medical and Chinese medicine sectors to ensure safe use of Chinese medicines



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Related Websites

- Chinese Medicine Council of Hong Kong
www.cmchk.org.hk
- Chinese Medicine Division Website
www.cmd.gov.hk
- Department of Justice
www.legislation.gov.hk



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