Regulatory Control of Heavy Metals in Chinese Medicines

1. Development of Chinese Medicine in Hong Kong
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Development of Chinese Medicine in Hong Kong

- The Chinese Medicine Working Party was established in August 1989 to review the use and practice of traditional Chinese medicine.

- The working party invited the Chinese Medicines Research Centre of CUHK to investigate the usage of traditional Chinese medicine, the framework and operation of Chinese medicine industry, together with the training and practice of Chinese medicine practitioners in Hong Kong.
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, the "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
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

Regulatory framework for control of Chinese Medicines in Hong Kong
Organization Chart of the Government of the HKSAR

CHIEF EXECUTIVE

SECRETARY FOR JUSTICE  CHIEF SECRETARY  FINANCIAL SECRETARY

CSB  CMAB  EDB  ENB  FHB  HAB  LWB  SB  THB  CEDB  DEVB  FSTB

CSB: Civil Service Bureau
CMAB: Constitutional and Mainland Affairs Bureau
EDB: Education Bureau
ENB: Environment Bureau
FHB: Food & Health Bureau
HAB: Home Affairs Bureau
LWB: Labour & Welfare Bureau
SB: Security Bureau
THB: Transport & Housing Bureau
CEDB: Commerce & Economic Development Bureau
DEVB: Development Bureau
FSTB: Financial Services & the Treasury Bureau

Public Health Infrastructure

Food and Health Bureau

Agriculture, Fisheries and Conservation Department
Department of Health
Food and Environmental Hygiene Department
Government Laboratory
Hospital Authority
Centre for Health Protection
Centre for Food Safety
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.
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

Organization Chart of the Chinese Medicine Division

- Assistant Director (TCM)
  - Chinese Medicine Council Secretariat
  - Risk Analysis and Management Section
  - Chinese Medicines Section
  - Chinese Medicines Information & Research Section
  - Chinese Medicine Development Committee Secretariat
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

Control of Chinese Medicines
**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.
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

<table>
<thead>
<tr>
<th>Schedule 1</th>
<th>Schedule 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>31 types of toxic Chm</td>
<td>574 types of Chm which are commonly used in Hong Kong</td>
</tr>
<tr>
<td>Prescription only</td>
<td>OTC</td>
</tr>
</tbody>
</table>

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)
Market Surveillance

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)
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

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

<table>
<thead>
<tr>
<th>Heavy metals or toxic element</th>
<th>Maximum Permitted Level*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arsenic</td>
<td>1500 mcg/day</td>
</tr>
<tr>
<td>Cadmium</td>
<td>3500 mcg/dose</td>
</tr>
<tr>
<td>Lead</td>
<td>179 mcg/day</td>
</tr>
<tr>
<td>Mercury</td>
<td>36 mcg/day</td>
</tr>
</tbody>
</table>

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

- ADR report
- Market Surveillance
- Media monitoring
- Notification from overseas
- Complaints

Department of Health

- Investigation
  - Product recall
  - Prosecution
  - Disciplinary action
  - Notification to overseas health authorities
  - Press statement

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

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
**Statistics of market surveillance – Heavy Metals in pCm**

<table>
<thead>
<tr>
<th>Year</th>
<th>No. of failed pCm samples</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>As</td>
</tr>
<tr>
<td>2013</td>
<td>0</td>
</tr>
<tr>
<td>2014</td>
<td>1</td>
</tr>
<tr>
<td>2015 (up to August)</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>1</td>
</tr>
</tbody>
</table>

**Control measures - Assessment**

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

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

Control measures - Communication

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

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
Thank you