

Regulatory Perspectives on Chinese Proprietary Medicines

Victor Wong
Deputy Head (Chinese Proprietary Medicines)
Centre for Drug Administration
Health Sciences Authority
Singapore

22 November 2006

Role of Traditional Chinese Medicine (TCM) in Singapore

- **Population of Singapore consists of**
 - Chinese (77%)**
 - Malays (14%)**
 - Indians (8%)**
 - Other ethnic groups (1%)**
- **Western medicine is the main form of local healthcare system.**
- **TCM serves as a key complementary form of primary healthcare to the local population.**

Development of TCM in Singapore

Recognising the importance of TCM in Singapore, the Ministry of Health, Singapore appointed a National TCM Committee in July 1994 to:

- **Review the practice of TCM and control of TCM products in Singapore.**
- **Recommend future measures to safeguard public health by enhancing the standards of TCM practice and products.**

Outcomes of the TCM White Paper 1995 by the National TCM Committee:

Outcomes

Registration of acupuncturists*	1 Jan 2002
Registration of TCM practitioners*	1 Jan 2004
Upgrading of TCM herbal dispensers*	On-going
Regulation of Chinese Proprietary Medicines (CPM)#	1 Sep 1999

* Traditional & Complementary Medicines Branch, Ministry of Health

Centre for Drug Administration, Health Sciences Authority

Regulation of CPM in Singapore

Definition of CPM

A CPM is a preparation in finished dosage form containing herbs, animal parts and/or minerals that are used in the practice of TCM.



Objectives of CPM Control

Ensure that CPM sold in Singapore are:

- **safe and of good quality.**
- **labelled according to requirements.**
- **efficiently recalled from the market when deemed necessary.**

Principles Adopted in CPM Control

- Recognise the differences between TCM and Western medicine.

TCM

Holistic approach addressing the person's entire constitution.

Based on concepts anchored on a long history of use and practice. Cannot be totally expounded scientifically.

Uses TCM prescriptions which consist of herbs, animal parts and/or minerals. Usually tailored to individual patient.

Western Medicine

Specific to disease and symptoms.

Based on clinical / scientific evidence. Relatively shorter history of use.

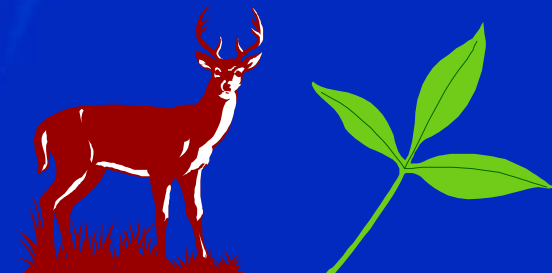
Uses drugs which are chemical entities with distinct pharmacological activities.

Principles Adopted in CPM Control

- Practical and balanced:
Meeting the objective of safeguarding public health,
but not impeding CPM development.

HSA regulates the wide spectrum of health products for human use through a risk-based approach.

Compared to Western medicines, natural health products such as CPM are regarded as having lower inherent risk and are less likely to cause serious harm unless adulterated or contaminated with potent/toxic chemical substances.



Principles Adopted in CPM Control

- Assess product safety and quality, but not efficacy.

Focus is on product safety and quality parameters which are well established and have direct impact on the health of consumers (e.g. toxic heavy metals and microbial contamination).

Efficacy of CPM products are generally based on documented history of use according to TCM practice. As modern medical research has yet to reach a stage to clearly elucidate CPM efficacy in a scientific manner, efficacy is currently not assessed.

Principles Adopted in CPM Control

- Prohibit exaggerated claims for treatment of serious medical conditions (e.g. cancer, diabetes).

Serious medical conditions warrant prompt and professional medical attention rather than relying on self-medication of over-the-counter CPM products which efficacy is not assessed.



Principles Adopted in CPM Control

- Proper labelling displaying important information e.g. product formula, batch number and expiry date.

Important for consumers to make an informed choice when purchasing CPM products.

It is also to facilitate efficient market withdrawal of sub-quality and/or harmful products when deemed necessary.



CPM Control: Pre and Post-marketing – A Three-Pronged Approach

(1) Pre-marketing

- Licensing of local CPM dealers (importers, wholesalers, manufacturers and re-packers).
- Listing of CPM products.



CPM Control: Pre and Post-marketing – A Three-Pronged Approach

(2) Post-marketing

- **Mandatory submission of test reports for every consignment at point of import.**
- **Surveillance programme to sample and test CPM products from the local market using a risk-based approach.**
- **Adverse reaction monitoring programme.**
- **Feedback from consumers and trade.**
- **Advertisement permits for sale and promotional activities.**

CPM Control: Pre and Post-marketing – A Three-Pronged Approach

(3) Monitoring & Information Exchange

- Pro-actively monitoring internet and other media for overseas reports and developments e.g. adulterated products.
- Information exchange with overseas regulatory counterparts.



CPM Product Listing

Assessment criteria

- **Must not contain Western drugs and naturally occurring, potentially toxic substances.**
- **Must not contain excessive toxic heavy metals and microbial counts.**
- **Must label product in English and other suitable language(s).**
- **Must not make reference for usage on serious medical conditions and diseases e.g. cancer, diabetes, impotency.**

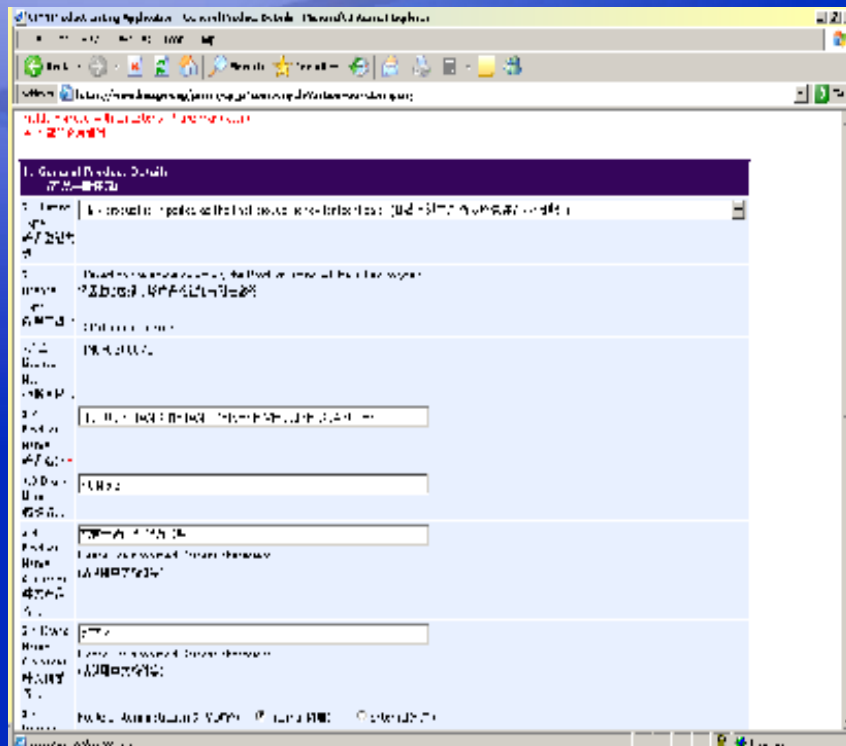
CPM Product Listing

Assessment criteria

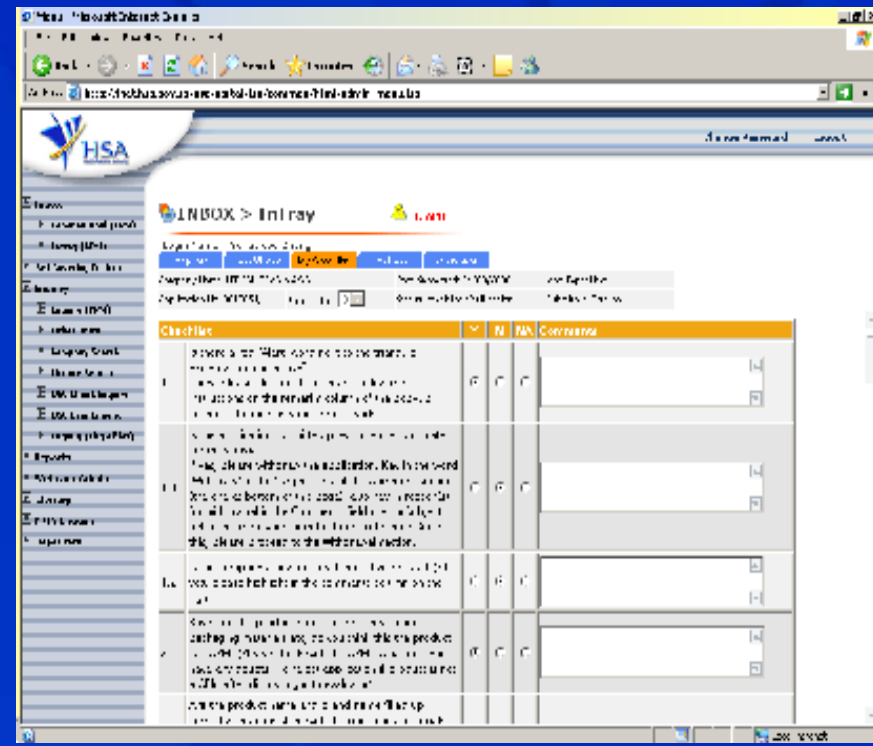
- **Manufacturer must be licensed.**
- **Product must be freely sold in country of manufacture.**
- **With effect from 1 Jan 2004, certain categories of CPM that have been assessed to have higher risks of adulteration must be tested by recognised laboratories.**

CPM Product Listing

Entire process from application to approval is done via an electronic internet-based system.



Application by dealer



Assessment by HSA

Statistics

	<u>Number</u>
CPM products	9585
Importers	178
Wholesalers	276
Local manufacturers	21
Local re-packers	27

(Figures till 31 October 2006)

Areas of Challenge

Adulteration

Adulteration with Western drugs / active synthetic substances, especially “lifestyle-enhancing” products (e.g. indicated for slimming, sexual health).

e.g. NSAIDs, anti-histamines, sedatives, sildenafil (active ingredient of Viagra), slimming drugs (e.g. fenfluramine, thyroid components), modified analogues of Western drugs is an emerging trend.

Product Quality and Contamination

Sub-standard products, lack of standardisation and batch variation.

Products exceeding legal limits for toxic heavy metals (mercury, arsenic, copper, lead).

CPM products exceeding legal limits for total aerobic microbial count, yeast and mould counts.

Too much mercury in four medicines

FOUR Chinese medicines have been tested and found to contain more than the permitted level of mercury, the Ministry of Health said yesterday.

It warned that taking excessive amounts of mercury over a long period can cause abdominal pain, vomiting, bloody diarrhoea and, in serious cases, death.

The four products are:

- ◆ Chun Zhen Zhen Zhu Fen.
- ◆ Ding Fa Hair Nutritional Capsule.

- ◆ San Pian Zhuang Long Tonic Pill.

- ◆ Lingzhi Pearl Woman Tonic.

The ministry advised those who have these products to either destroy them or send them to its inspectorate section at 2, Jalan Bukit Merah for disposal.

Under the Medicines Act, anyone caught selling Chinese medicine containing toxic substances above the legal limit may be fined \$5,000 and jailed for two years.

Properties & Identification

Misidentification

e.g. Aristolochia fangchi and Stephania tetrandra (Both herbs are commonly known as “Fang Ji” in Chinese. The former contains aristolochic acid which is known to be nephrotoxic).

Non-traditional / Inappropriate usage resulting in adverse reactions

e.g. Misuse of ephedra for slimming in the US resulting in adverse reactions and deaths.

Product Classification

Important factors which determine the classification of a grey area product are:

- **Presentation (Is product presented and perceived as a food or health product?)**
- **Purpose (Is product for general consumption as a food or for a medicinal purpose?)**
- **Dosing (Is there a specific dosage regime?)**
- **Ingredients (Are the active ingredients of the product commonly used in food?)**

Constant liaison between HSA and AVA on classification of grey area products in the health product-food interface.

Information on CPM Control

Information on CPM Control

**Details of CPM control are available on the
HSA website at this URL:**

http://www.hsa.gov.sg/html/business/cda_cpm_guide_product.html

Thank you