

**HONG KONG IDEAS CENTRE**

**DEVELOPMENT OF CHINESE MEDICINE  
IN HONG KONG**

**BACKGROUND REPORT**

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# **DEVELOPMENT OF CHINESE MEDICINE IN HONG KONG**

## **BACKGROUND REPORT**

### **CHAPTER 1 - INTRODUCTION**

#### **I. INTRODUCTION**

- 1.1 The objective of this study is to assess the current state and future potential for developing Chinese medicine (CM) in Hong Kong (HK) and to make constructive and practical recommendations to the authorities and other parties where appropriate on how to further develop the sector.
- 1.2 About ten years ago, the HK Special Administrative Region Government had a vision of developing HK as an international centre for CM. This was mentioned in the Chief Executive's Policy Addresses in 1997 and 1998.
- 1.3 Since then the Government has made substantial efforts in developing the sector, including enactment of the CM Ordinance, introducing degree programs for CM in three local universities, setting up public sector CM clinics, and establishing the Hong Kong Jockey Club Institute of Chinese Medicines (JCICM) to steer the development of the Chinese medicines industry in Hong Kong.
- 1.4 While HK has made considerable progress in regulating and regularizing the CM sector, it is apparent that there is still some way to go before HK can become an international centre for CM.
- 1.5 In 2009, following the financial tsunami the Government is keen to identify economic areas that can help HK to diversify and remain competitive in the long term. Hong Kong Ideas Centre considers that this is an appropriate time to revisit the subject of CM.

## **II. SCOPE OF STUDY**

1.6 This Study covers:

- current state of the CM sector and the Government's role;
- advantages and opportunities facing the sector;
- limiting factors and challenges;
- potential for development; and
- recommendations on how to further develop CM.

1.7 As the CM sector comprises different sub-sectors, this Study will be structured into two parts as follows:

- CM services and education (chapters 3 and 4); and
- CM products, i.e. distribution and development of Chinese medicines (chapters 5 and 6).

## **III. METHODOLOGY OF STUDY**

1.8 In conducting this study, the Consultant has undertaken both desk research and fieldwork. In-depth interviews have been conducted with various stakeholders including Government regulators, service-providers, universities, research institutes, and trade associations. A list of these stakeholders is given in Annex I. A list of the abbreviations used in this report is given in Annex II.

## **CHAPTER 2 - SIGNIFICANT DEVELOPMENTS IN THE LAST DECADE**

### **I. GENERAL**

2.1 While the practice of CM and use of Chinese medicines had a long history in HK, the sector was only given official status and recognition in 1997 upon the return of the territory from Britain to China. In the last decade considerable progress has been made in regulating and regularizing the sector and in laying down a foundation for its further development.

### **II. LAISSEZ FAIRE IN THE 19<sup>TH</sup> AND 20<sup>TH</sup> CENTURIES**

2.2 In the colonial days CM services was regarded as part of Chinese traditions and customs, and the Government left CM services pretty much alone.

2.3 In the 19<sup>th</sup> century the majority of the local population relied heavily on CM for their health and medical needs. In 1872 the Tung Wah Hospital was set up as a CM hospital providing both outpatient and inpatient services. A Western medicine (WM) outpatient clinic was added only in 1896 when WM became popular.

2.4 In the early 1940s CM development suffered a major setback during the Japanese occupation, when Tung Wah Hospital was ordered by the Japanese authorities to close down its CM services. After World War II CM clinics were restored, but by that time WM medicine had taken over as the mainstream medical services.

### **III. REGULATION AND DEVELOPMENT IN THE 1990s**

2.5 Towards the late 1980s the Government took steps to formalize and regularize the CM sector. A Working Party on CM was set up in 1989 to advise the Government on measures that should be taken to promote the proper use and good practice of CM; and a Preparatory Committee was established in 1995 to come up with concrete recommendations on the development and regulation of CM.

- 2.6 CM was first given official status by the Basic Law which came into effect in 1997. Article 138 of the Basic Law provides that:

*“The Government of the HKSAR shall, on its own, formulate **policies to develop Western and traditional Chinese medicine** and to improve medical and health services. Community organizations and individuals may provide various medical and health services in accordance with law.”*

- 2.7 In the late 1990s the CM sector was seen to have received strong policy support from the Government. Mr Tung Chee-wah, former Chief Executive, mentioned CM in two of his Policy Addresses made in 1997 and 1998. These are quoted below.

Extract from 1997 Policy Address:

*“For the protection of public health, we aim to introduce a bill in the next legislative session **to establish a statutory framework** to recognize the professional status of traditional Chinese medicine practitioners; to assess their professional qualifications; to monitor their standards of practice; and, to regulate the use, manufacture and sale of Chinese medicine. The establishment of a sound regulatory system will **lay a solid foundation for the future development of traditional Chinese medicine** within our overall medical care system. I strongly believe that Hong Kong has the potential to develop over time into **an international centre for the manufacture and trading of Chinese medicine, for research, information and training in the use of Chinese medicine, and for the promotion of this approach to medical care.**”*

Extract from 1998 Policy Address

*“In last year’s Policy Address I affirmed my belief in Hong Kong’s potential to become an international centre for Chinese medicine and medical practitioners. This is another industry which, through the **application of innovation and technology**, can enhance our economic growth and give us a competitive edge on a global scale.”*

- 2.8 In the ensuing years the Government took a number of measures to pursue this policy objective, as set out below:

- In 1999 the **CM Ordinance** was passed to regulate the practice of CM

and the use, manufacture and sale of Chinese medicines;

- In 1999 the **CM Council** was set up to serve as regulator. The CM Council is a statutory body governed by a board appointed by the Chief Executive. Council members comprise the Director of Health and other public officers, CM practitioners, persons from the Chinese medicines trade and CM educational or research institutions, and lay persons. Administratively it is supported by **Department of Health as its executive arm.**
- In 1999 the Industry Department drew up a **10-year Development Plan for Chinese medicines.** Although details of this plan cannot be traced, it is noted from media reports that the plan provides the following milestones:
  - Strengthen technological infrastructure by 2000: introduce regulatory regime, quality control/quality assurance capability, research and development (R&D) activities, and cultivate business interest.
  - Modernize traditional Chinese medicines by 2002: develop health food and dietary supplements based on traditional CM formulations.
  - Develop modernized Chinese medicines by 2004: develop health food and dietary supplements based on new CM formulations.
  - Develop new Chinese medicines by 2009: first Chinese medicines to obtain registration as drugs.

2.9 Largely due to the Government's initiatives in regularizing and promoting the sector, considerable interest in this subject was generated in the community around 2000 or so. A number of studies were undertaken by various parties which came up with various proposals on how to pursue the matter. These studies include the following:

- Studies by the One Country Two Systems Economic Research Institute (1999 (Part 1) and 2001 (Part 2)), which advocated, amongst other things, that the Government should set up a high-level inter-bureau organization to steer the development of the practice of CM and the CM products industry and to establish a CM-based hospital.
- Studies by the State Planning Commission Economic Research Institute (reports in March and December 2001), which advocated greater

collaboration between HK and the Mainland on developing the CM products industry, and proposed HK to set up a world-class CM-based hospital, and a CM products testing and certification (T&C)/R&D/incubation centre in the Lok Ma Chau Loop.

2.10 Around this time there was much talk of Hong Kong developing a Chinese medicines port, similar to the Cyberport development in Pokfulam. It was reported that a number of local business groups put forward various proposals to the Government for the setting up of Chinese medicines distribution/T&C/R&D centres in Hong Kong. None of these proposals, however, got off the ground.

2.11 In the meantime, other business groups embarked on various joint ventures with Mainland partners to explore the production of Chinese herbs and development of CM-based drugs on the Mainland. Most of these were reported to be not successful, due to difficulties in ensuring consistent quantity and quality of the products.

#### **IV. CONTINUING REGULATION AND DEVELOPMENT IN THE 2000s**

2.12 In the years that followed the excitement about CM quieted down. CM no longer featured in the Chief Executive's Policy Addresses except in terms of how many new public sector CM clinics would be provided, etc. On the other hand, the Government continued with its regulatory and other efforts. These included the following:

a) CM services and education

- In 2000 all **CM practitioners** (CMP) were required to be registered, with transitional arrangements for those practising before 2000.
- In 2000 the Hospital Authority Chinese Medicine Limited (HACML) was established with the objective of setting up **18 CM outpatient clinics** in the public sector by phases.
- Since the early 2000s **CM degree courses** have been provided at the University of HK (HKU), the Chinese University of Hong Kong (CU) and the Baptist University (BU).



b) CM products

- In 2001 the **HK Jockey Club Institute of Chinese Medicine (JCICM)** was set up with a donation of \$500M from the HK Jockey Club to “serve as the focal point for action and coordination to steer the development of the Chinese medicines industry”.
- In 2003 all **proprietary Chinese medicines (PCM)** were required to be registered, with transitional arrangements for those manufactured or sold in HK before March 1999.

c) Trade promotion

Since the early 2000s the HK Trade Development Council has been co-organizing with a local trade association called Modernized Chinese Medicine International Association an annual conference called “International Conference & Exhibition of the Modernization of Chinese Medicine & Health Products” **to promote CM** trade and research.

d) Other developments

In 2003 the Consortium for Globalization of Chinese Medicine was set up as “a global, non-profit and non-political organization, with a mission of advancing the field of Chinese herbal medicine to benefit human kind through joint efforts of the academic institutions, industries and regulatory agencies around the world.” Headquartered in Hong Kong, the Consortium is chaired by Prof. Yung-chi Cheng, Professor of Pharmacology, Yale University School of Medicine, and comprises members from institutes in Hong Kong, Mainland, Taiwan, Macau, Singapore, US, UK, Germany, Denmark, Italy, Canada and Australia. The 8<sup>th</sup> meeting of the Consortium was held in UK in August 2009.

## V. LATEST DEVELOPMENTS

2.13 In 2008 the Government’s **Central Policy Unit sponsored CU to undertake a study** into the development of CM in HK. The study recommended a basket of measures, including a special task force to steer CM development.

2.14 After the financial tsunami in August 2008, it became apparent it was not

sufficient for HK to rely solely on its traditional industries such as financial services and tourism to sustain its economy. In early 2009, the Government set up a **Task Force on Economic Challenges** with the objective of formulating measures to stabilize the economy in the short term and to help it grow in the long term. In June the Task Force identified the following six economic areas with good potential for growth: medical services, T&C, innovation and technology, education services, environmental industry and cultural and creative industries. CM was not specifically mentioned as a potential growth area, but it is generally considered that CM development is related to at least two of the economic areas, viz medical service and T&C.

2.15 In the Chief Executive's **Policy Address** delivered in October 2009, the Government showed a renewed interest in the development of CM. The specific initiatives proposed by the Government are quoted below.

a) On CM services and education

*“We will further consider allowing more **renowned Chinese medicine practitioners from the Mainland** to join clinical teaching and research programmes in Hong Kong so as to **make Hong Kong a stage for promoting Chinese medicine to the world.**”*

*“To develop our medical services, we will, by the end of this year, invite expressions of interest from the market to develop **private hospitals, which may provide traditional Chinese medicine services**, on four sites at Wong Chuk Hang, Tseung Kwan O, Tai Po and Lantau.”*

b) On distribution and development of CM products

*“In September this year, the Government established the Hong Kong Council for Testing and Certification, which comprises members from the testing and certification industry, business sector, professional bodies and relevant public organisations. The first and foremost task of the Council is to draw up a three-year development plan for the industry. One of the major objectives of the plan is to **promote the development of Chinese medicine and help establish Hong Kong as a testing and certification centre in the region by introducing new certification services.**”*

*“To facilitate the development of Chinese medicine, the Government will expedite the **setting of standards for Chinese herbal medicines** commonly used in Hong Kong. We aim to extend our coverage from the current 60 herbal medicines to about 200 by 2012. To enhance our capability to test Chinese medicines, we will assist and **promote the establishment of testing laboratories** in the local market.”*

## **CHAPTER 3 - CM SERVICES AND EDUCATION: CURRENT SITUATION**

### **I. GENERAL**

- 3.1 CM services and education can be considered both as a service for the community and as an economic sector meeting domestic demand and contributing to employment and Gross Domestic Product (GDP).

#### **Contribution to the community**

- 3.2 As a service, CM is making a significant contribution to primary healthcare in HK and playing a supplementary role in treating patients in hospitals. Figures derived from the General Household Surveys conducted by the Government show increasing acceptance and demand from the community for CM services: the number of CM consultations increased by 33% between 2002 and 2006. According to the CM Council, CM consultations accounted for about 22% of all medical consultations in HK in 2007.

#### **Economic contribution**

- 3.3 As an economic sector, the practice of CM services is providing employment to at least 8,638 CMPs representing 0.24% of total employment in HK, and contributing \$375M in terms of value added or 0.02% of our GDP. It should be cautioned that these figures tend to understate the contribution of the sector as they have not taken into account other people engaged in providing CM services such as CM pharmacists, nor those engaged in providing CM education.

### **II. CHINESE MEDICAL PRACTITIONERS (CMP)**

- 3.4 At present CM services are provided by there are a total of 8,638 CMPs in HK, **plus** about 70 CMPs from the Mainland brought in under the Limited Registration scheme. The composition of CMPs is given below

Type of CMP		
1. Registered and Listed CMPs		8,638
1.1 Registered CMPs	5,835	
(CMPs by Direct Registration)	(2,367)	
(originally Listed CMPs who passed Registration Assessment or Licensing Examination)	(2,434)	
(graduates of recognized degree courses who passed Licensing Examination)	(1,034)	
1.2 Listed CMPs	2,803	
2. CMPs with Limited Registration		70

3.5 To understand these figures we need to explain the registration system for CMPs under the CM Ordinance.

3.6 **“Grandfather” CMPs:** When the registration system for CMPs was introduced in 2000, the CM Council provided transitional arrangements in order that “grandfathers” who had been practising in HK would not be put out of practice immediately. Under these transitional arrangements,

- CMPs who had been practising In HK for a continuous period of at least 15 years before 3 January 2000 could apply directly to become registered CMPs. There are **2,367** Direct Registration CMPs now.
- CMPs with more than 10 years’ but less than 15 years’ experience might continue to practise by the title of Listed CMPs; in order to become Registered CMPs they would have to pass the Registration Assessment or Licensing Examination provided by the CM Council. There are now **2,434** Registered CMPs who were originally Listed CMPs, and **2,803** who continue to practice as Listed CMPs.

3.7 **CMPs with recognized degrees:** There are **1034** Registered CMPs with recognized degrees which may be provided by the three local universities or 28 universities in the Mainland recognized by the CM Council for this purpose. The split between local graduates and Mainland graduates is about 70 to 30. All of these graduates are required to pass the Licensing Examination provided by the CM Council.

3.8 **CMPs with Limited Registration:** The CM Ordinance also provides a

system of Limited Registration for CMPs, whereby six designated institutions in HK may apply for CMPs with the appropriate qualifications and experience to be brought in to HK to be engaged in clinical teaching and/or research for the institutions. The six institutions are the HKU, CU, BU, the HK Polytechnic University (PolyU), the City University of HK (CityU) and the Hospital Authority. CMPs with Limited Registration are not permitted to be engaged in private practice with patients.

- 3.9 In practice, the six institutions would rigorously assess CMPs before offering them employment as professors/lecturers. Besides teaching and research, most of them also practice as CMPs in the teaching/research clinics of the universities and HACML. Some of them have in the years built up a reputation in HK of being experienced and proficient doctors and are in great demand.
- 3.10 It can be seen that the registration system of CMPs under the CM Ordinance has brought quality assurance to the hitherto unregulated trade and consumer protection for the general public. For example, it is now easy for the discerning patient to differentiate between Registered and Listed CMPs. The bringing in of experienced and proficient CMPs under the Limited Registration scheme has further enhanced the quality and reputation of CMPs in HK.

### **III. CM CLINICS**

- 3.11 Traditionally CMPs in HK carried out their practice in CM herbal shops, most of them quite small and the surroundings quite unwelcoming.
- 3.12 The situation is changing today. There are now over 50 modernized CM clinics employing Registered CMPs in various districts in the territory. Many of these are public sector clinics provided by HACML (14 clinics), the local universities and the Tung Wah Hospital Group (11 clinics). An increasing number are being provided by private medical groups such as Tong Ren Tang (10 clinics) and Quality Health Care (10 clinics).
- 3.13 The clinics are **modernized in both outlook and management**. For example, the clinics provided by HACML are served by:

- computerized CM information systems to support clinic administration, consultation records and pharmacy management;
- modernized CM pharmacy systems which are comparable to WM pharmacy standards; and
- centralized purchase and testing of herbs to ensure safety and quality.

Many of these HACML clinics are staffed not only by Registered CMPs but also CMPs with Limited Registration.

3.14 HACML is the biggest provider of modernized clinics. Set up in 2000 and tasked to provide a total of 18 public sector CM clinics in HK, HACML has up to now set up 14 CM such clinics under what is known as a tripartite model.<sup>1</sup> Under this model, HACML collaborates with non-government organizations (NGO) and local universities in establishing and operating the clinics. The Government provides partial subsidy to the clinics via HACML while the NGOs are responsible for operating them on a self-financing basis.

3.15 In these clinics HACML is also taking up the role of providing **in-training to junior CMPs**. Previously a one-year program was provided for about 70 junior CMPs per year. In 2009 HACML has extended this training to a 3-year program for 70 junior CMPs.

#### **IV. CM EDUCATION**

3.16 Degree courses for CMP are provided by three local universities:

- HKU;
- CU; and
- BU.

3.17 The three universities together produce roughly 80 graduate CMPs each year. The courses are five-year programs, with a 30-week internship in hospitals in the Mainland. At the end of the five years the student is entitled to sit for the unified CMP Licensing Examination provided by the CM Council, and to practice as a CMP upon passing the Examination. This system is different

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<sup>1</sup> The 14 HACML clinics are located in Central and Western, Wan Chai, Eastern, Kwun Tong, Wong Tai Sin, Sham Shui Po, Tsuen Wan, Kwai Tsing, Tuen Mun, Yuen Long, North, Tai Po, Sha Tin and Tseung Kwan O. Four more clinics will be provided by HACML in Southern, Yau Tsim Mong, Kowloon City and Islands Districts.

from that for Western medical practitioners (WMP) in HK, which consists of a five-year program followed by one-year internship in a local public hospital. Also unlike WMPs, there is at present no post-graduate specialist training for CMPs in HK.

3.18 Since 2005, CMPs are required under the CM Ordinance to undertake **continuing education** to maintain their professional standard and to update and enhance their knowledge. CMP licences are issued on three-year cycles, and CMPs are required to acquire not less than 60 credits in continuing education within each three-year period before they can renew their practising licences.

3.19 The main teaching medium of CM courses in HK is Chinese. Textbooks used are mainly in Chinese and examinations are conducted in Chinese. Acupuncture is the only area where textbooks are available in English and teaching can be conducted in the English language.

## V. RECENT DEVELOPMENTS

3.20 In recent years there have been a number of developments in CM services which are worthy of note:

- Leave applications endorsed by CMPs;
- Insurance for CMPs and CM patients;
- Specialization in CM services;
- CM/WM collaboration;
- Other innovations in service delivery; and
- Developments in other areas.

### Sick leave certificates

3.21 Before 2006, sick leave certificates issued by CMPs were not given legal recognition. This had hindered CM services in assuming a mainstream role in the medical system. Since December 2006 the Employment Ordinance has been amended, and sick leave certificates issued by registered CMPs and CMPs with Limited Registration are now recognized under the law. To facilitate implementation of the new scheme and to prevent abuse, the CM Council has given guidelines to Registered CMPs on the issue of sick leave certificates.



### **Medical insurance**

- 3.22 Traditionally, most insurance schemes do not cover CM treatment, and CMPs do not take out any professional indemnity insurance. Our enquiries with The Hong Kong Federation of Insurers indicate that most insurance schemes for patients now cover consultations with registered CMPs as an outpatient benefit, usually with a sub-limit on the number of visits per year. On the other hand, professional indemnity insurance is less common among CMPs, although a few insurance companies do provide such schemes.

### **Specialization in CM services**

- 3.23 Traditionally the majority of CMPs in HK operate as general practitioners or family doctors. The nature of CM is that it is holistic in concept and the human body is considered as a whole.
- 3.24 On the other hand, it is well-known that CM is particularly effective in treating certain diseases such as chronic diseases 慢性病 and elderly ailments 老人病 and in prevention of disease and management of health 治未病. Patients tend to consult CMPs for certain conditions or diseases rather than others. The current development is that some medical groups begin to provide specialist clinics. For example, the Tung Wah Hospital Group is providing five specialist clinics in collaboration with the local universities. The specialist areas include internal medicine, pediatrics, women health, bone injury, acupuncture, tui-na, dermatology, allergy and oncology. In addition, Kwong Wah Hospital is providing a Health Management Centre 治未病上醫館 targeted at people who are not suffering from any major disease but nevertheless would like to improve their health conditions. In the private sector some medical groups are also offering specialist CM services particularly in bone injury, acupuncture and tui-na.

### **CM/WM collaboration**

- 3.25 Traditionally there is a lack of trust and little collaboration between CMPs and WMPs in HK. This is reflected in the rules and regulations governing the practice of CM in HK. For example, in the Mainland CMPs are allowed to use WM diagnostic techniques and equipment such as X-ray, scans, etc. and even to prescribe western medicines such as anti-biotics. In HK traditionally

CM practitioners (CMP) were not trained in using WM diagnostic facilities, and they have not been included in the list of professionals in the relevant codes of practice as being permitted to use WM diagnostic facilities. Prescription of western medicines is also not allowed. Where education is concerned, while CMP courses in HK have some WM element, this is considerably less than what is taught in the Mainland; and WMPs in HK generally do not receive CM education. These conditions are not favorable to the development of WM/CM collaboration.

3.26 On the other hand, patient behavior in recent years suggests that there is both **demand and need** for CM/WM collaboration. A survey conducted by Kwong Wah Hospital in 2004 showed that about 30% of their patients were also receiving CM treatment at the same time. In August 2009, Mr Anthony Wu, Chairman of HA was reported as saying that 90% of HA's cancer patients were also consulting CMPs. Because of the lack of proper channels or arrangements for CM/WM collaboration, most of these WM patients are consulting CMPs without the knowledge of their WMPs; some do not even let their CMPs know that they are also receiving WM treatment. Demand aside, this has raised a safety concern that there may be adverse interactions between the two types of treatment, and points to a need for a more formalized and open form of collaboration between CMPs and WMPs.

3.27 **The Government's views on CM/WM collaboration are positive and supportive.** In a reply to LegCo dated 11 November 2009, the Secretary for Food and Health said that "our long-term goal is to develop through an evidence-based approach, a model of collaboration between CMPs and WMPs that can meet the actual circumstances and needs of HK." The Government has also taken the initiative, mainly via HACML, to introduce different forms of CM/WM collaboration. To promote CM/WM collaboration, HACML has commissioned the local universities to conduct a Certificate Program for WMPs on an annual basis in order to heighten the awareness and knowledge of WMPs in CM. HACML is also undertaking research into the subject of interactions between Chinese and Western medicines/treatment.

3.28 CM/WM collaboration is now taking the following forms:

- CM treatment for WM hospital inpatients;
- CM/WM rehab centre; and
- WM/CM collaboration clinics.

### **CM treatment for WM hospital inpatients**

- 3.29 At present, 13 public hospitals are making arrangements for inpatients of selected departments to visit and receive treatment at HACML clinics if the patient so chooses. For example:
- Acupuncture is used for pain relief for terminal cancer patients in a number of hospitals, including the Tung Wah Hospitals;
  - combined CM/WM programs using acupuncture/acupressure for chronic pain are piloted at the United Christian Hospital; and
  - CM/WM shared care services are provided in the geriatric wards of Tung Wah Fung King-yiu Hospital and Princess Margaret Hospital.

### **CM/WM rehab center**

- 3.30 WM/CM collaboration also takes the form of a CM/WM cancer rehab centre with 110 hospital beds set up in 2009 by the HK Anti-cancer Society. The service provided is for rehabilitation and not treatment. Most of the patients are receiving cancer treatment elsewhere. At the rehab centre they may choose to receive CM or WM services for rehabilitation, pain relief and maintenance of health.
- 3.31 The HK Jockey Club has provided initial setting up costs and expects the rehab centre to be self-financing on a recurrent basis. Given the narrow scope of its services this has proved to be difficult. The centre has been approached by a US investor who is interested in expanding it into a CM/WM centre for cancer treatment as well as rehab; but the limited space at the site may be a constraint.

### **CM/WM collaboration clinics**

- 3.32 While quite a number of clinics claim to provide CM/WM services, the degree of collaboration varies. Some are simply in the form of a CM clinic and a WM clinic being located next to each other. The patient chooses which clinic he wants to attend upon entry of the premises. The **degree of collaboration is relatively low** but the operation at least provides an opportunity for the CMPs and WMPs concerned to get to know more about each other's profession, and to make cross-referrals once the knowledge and trust is built up.

3.33 Other collaboration clinics are in fact **CM clinics which employ WMPs to assist in diagnosis** using WM techniques. The fact that CMPs are not allowed to use WM techniques has given rise to this mode of operation which is one step closer to CM/WM collaboration. One example is the BU clinic at Queen Elizabeth Hospital.

3.34 Still another model is that practiced at the Kwong Wah Hospital which represents a **relatively higher degree of collaboration**. Under this model

- consultations are attended by a CM practitioner and a WM practitioner at the same time in a consultation room provided with two computer terminals for use by the two practitioners;
- for diagnosis, WM techniques are used in addition to CM techniques, to enhance the efficiency and accuracy of diagnosis;
- for treatment, either WM or CM or a combination of treatments is prescribed depending on the disease and the conditions of the patient, and then
- for monitoring of results of treatment, WM techniques (e.g. blood test for liver function and kidney function) are used in addition to CM techniques, to enhance the efficiency and accuracy of monitoring.

3.35 This mode of operation is relatively high-cost but nevertheless interesting in that it has the following advantages:

- the use of WM techniques for diagnosis and monitoring reduces the risk of traditional CM diagnosis and treatment; and
- the choice of the most appropriate form of treatment among WM, CM and WM-cum-CM is clearly in the interest of the patient.

3.36 Kwong Wah Hospital will undergo a major redevelopment during 2011 to 2019. As part of this redevelopment, a CM building will be provided. With the new infrastructure, it is expected CM/WM collaboration will be taken even further.

#### **Other innovations in CM services**

3.37 One of strengths of CM is in treatment of elderly ailment. In HK the elderly tend to prefer the CM approach to medical and health care. However, many

of them lack mobility and have difficulty in travelling to clinics or in waiting in long queues for consultations. To cater for the needs of these elderly people, innovative forms of service delivery have been developed in recent years. For example, the Neighbourhood Advice-Action Council, an NGO, is providing 23 **mobile CM clinics converted from vehicles** to reach out to elderly patients who are unable to attend clinics. Such a mobile CM clinic is now available to serve even the remote villages of Lantau Island. Other medical groups are providing **CMP out-reach** services to elderly homes.

- 3.38 In 2009 BU was awarded the right to revitalise the historic Lui Seng Chun building 雷生春 under the Government's "Revitalising Historic Buildings Through Partnership Scheme". Built in 1931, Lui Seng Chun is a four-storey building located at 119 Lai Chi Kok Road. "Lui Seng Chun" was the name of a Chinese bone-setting medicine shop on its ground floor, which came to be regarded as representative of the development of local Chinese medicine. The University plans to turn the building into a Chinese medicine and healthcare centre which will double as a cultural landmark and tourist attraction. The new Centre will offer a range of Chinese medicine services, including free medical consultations to the needy, training for Chinese medicine students and practitioners, and exhibitions, talks and guided tours for the public.

#### **Developments in other areas**

- 3.39 With increasing recognition of the effectiveness of CM and growing awareness of the limitations of Western medicine, CM is attracting more interest in the West. Many countries including US, Australia, Singapore, South Korea and Japan are investing an increasing amount of resources into developing complementary and alternative medicines, many of which are CM-based products. CM services are attracting Western clients. Two examples of such developments are given below.
- 3.40 In 1991 a Traditional Chinese Medicine hospital was set up as part of the health and rehabilitation resort in Kotzting in Germany with the assistance of Beijing University of Traditional Chinese Medicine. The hospital provides 84 beds, has a staff of 9 CMPs and 6 WMPs, and specialties include orthopedics, rheumatology, neurology and other chronic conditions. Reportedly the waiting time for a hospital bed is three months. 95% of the

patients are covered under the national insurance scheme in Germany.

- 3.41 It is also reported that 30% of the inpatients of the First Affiliated Hospital of Tianjin University of Chinese Medicine on the Mainland are patients from overseas. The hospital has 900 beds, but regularly handles 1,000 inpatients using make-shift beds due to high demand. Specialties include chronic diseases and other diseases found to be difficult to cure with Western medicine.

## CHAPTER 4 - CM SERVICES AND EDUCATION: OPPORTUNITIES AND CHALLENGES

### I. GENERAL

- 4.1 In this chapter we are going to consider:
- HK's opportunities and challenges; and
  - development potential.

### II. OPPORTUNITIES AND CHALLENGES

#### Advantages and opportunities

- 4.2 These include advantages of CM in general and advantages specific to HK. Advantages of CM in general are set out below:
- CM has taken care of the health of Chinese people for centuries and there is an abundance of wisdom in its theories and doctrines. It is long recognized that CM is **particularly effective in treating certain diseases** such as chronic diseases and elderly ailments, and in prevention of diseases and maintenance of health.
  - In the meantime, there is a growing awareness of the **limitations of Western medicine** (WM) in treating some diseases such as allergy and chronic pain. As a result, more people are turning to the use of alternative medicine, and CM is one of the main types of alternative medicine being used.
  - CM in general and **acupuncture** in particular, is gaining increasing acceptance worldwide. There have been a substantial amount of studies and clinical trials on acupuncture. These studies have confirmed the safety of its use and provided considerable support that it is effective for relief of pain and treatment of insomnia and depressive disorders. Many medical insurance schemes in the US and Canada provide coverage for treatment by acupuncture.
- 4.3 Advantages specific to Hong Kong comprise the following:

- In the past ten years HK has built up a **sound foundation** to facilitate CM development. We have now a regulatory system in the form of the CM Ordinance and the CM Council, three universities providing degree courses and a network of modernized CM clinics.
- HK has well-established and indeed **world-class WM services and excellent medical management**. This has provided HK with the environment and opportunity to develop WM/CM collaboration. As discussed in Chapter 3, in response to demand from patients, the hospitals and clinics have developed various forms of WM/CM collaboration, such as allowing inpatients of WM hospitals to receive CM treatment, WM diagnosis combined with CM treatment, and joint CM/WM consultations, etc.

### **Limiting factors and challenges**

- 4.4 Limitations of CM services in general include relatively slow results, the poor presentation of the traditional sector, and the fact that CM treatment mechanism has yet been reconciled with the language of modern science or the principles of WM.<sup>2</sup>
- 4.5 Limitations specific to HK include the following:
- There are a number of traditional restrictions in the HK medical system that are not favorable to CM development. For example, traditionally most CM practitioners (CMP) were not trained in using WM diagnostic facilities, and they have not been included in the list of professionals in the relevant codes of practice as being permitted to use WM diagnostic facilities.
  - Our CM services are in a relatively “young” stage of development, and there appears to be a “mismatch” of supply and demand. Although HK does have experienced and proficient CMPs, including “professor-grade” CMPs with Limited Registration, they are insufficient to meet demand as witnessed by the long waiting times and high fees of the more renowned CMPs. On the other hand, most of our junior CMPs have yet to gain the experience to be able to inspire confidence in patients or to meet market

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<sup>2</sup> The thinking processes of CM and WM are totally different and it is difficult to explain CM theory in modern science terms. WM uses deduction analysis while CM uses induction synthesis.



demand. The fault lies not in the practitioners but in the fact that CM is a discipline where experience and judgment of the individual are particularly important.<sup>3</sup>

- We have no CM hospital and this is hampering not only service development but also training and clinical research.
- Except for acupuncture, our teaching medium is Chinese. It will be difficult for us to attract international students.

### **III. DEVELOPMENT POTENTIAL**

4.6 Against these opportunities and challenges, development potential can be identified in the areas below:

- platform for promoting CM to the world;
- WM/CM collaboration; and
- specialization in CM services.

4.7 With HK's solid foundation in developing CM and strength in modernized medical management, there is potential for HK to develop into a **platform for promoting CM to the world**, as recently announced by the Government. The Government has said recently that it will consider allowing more renowned CMPs from the Mainland to join teaching and research programs in HK. We understand that the State Administration of Traditional Chinese Medicine is also interested in "exporting" Mainland CMPs to practice in HK on a rotation basis in order that they may gain outside exposure and acquire knowledge in modern medical management; it is envisaged that these CMPs are also expected to act as a referral point for difficult cases requiring intensive care to Mainland hospitals.

4.8 Another area with potential is **WM/CM collaboration**. As mentioned in Chapter 3, patient demand is such that there is now both demand and need for

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<sup>3</sup> The practice of CM requires more experience and judgment than, for example, WM.

- While WMP can make use of diagnostic techniques such as X-ray and scan, CM diagnosis consists of the four steps of observing the patient, listening to him, asking him questions and feeling his pulse 望聞問切.
- In WM symptoms are explained in terms of well-documented diseases. In CM symptoms are explained in terms of balance/imbalance of the human body as a whole.
- While WMPs can make use of standardized and ready-made drugs, CMPs have to put together individual formula for individual patients.

closer collaboration between CM and WM. In response to such demand, hospitals and clinics are already trying out CM/WM collaboration in different forms. Of the many modes of collaboration **CM health management with WM check-up** holds the greatest promise. As the population becomes more affluent and people become more health-conscious the demand for such services is expected to increase tremendously. The risks involved are relatively low.

- 4.9 Yet another area is **specialization** in CM services. Some of HK's clinics are going in this direction already by providing specialist services in various areas such as internal medicine, pediatrics and bone injury. Of the many specialist areas, **acupuncture** stands out as having the best potential immediately as a service industry both for local needs and attracting international clients. HK is also ready to provide acupuncture classes in English.

## **CHAPTER 5 - DISTRIBUTION AND DEVELOPMENT OF CM PRODUCTS: CURRENT SITUATION**

### **I. GENERAL**

5.1 In this chapter we are going to consider:

- regulation of CM products and the CM products trade in Hong Kong;
- development efforts of the Government;
- economic contribution of the industry; and
- recent developments in the industry.

### **II. REGULATION OF CM PRODUCTS AND THE CM TRADE IN HONG KONG**

#### **Regulation of CM products in Hong Kong**

5.2 CM products are regulated by the Medicines Board of the CM Council under the CM Ordinance. Under this Ordinance, CM products are classified into two categories for which there are two different sets of regulatory measures:

- Chinese herbal medicines 中草藥(CHMs); and
- Proprietary Chinese medicines 中成藥(PCMs)

#### ***Regulation of CHMs -***

5.3 The 600 or so CHMs commonly in use in HK are classified into two groups under two schedules:

- Schedule 1: contains 31 CHMs which may only be used or sold under prescription by registered CMPs. These are mainly medicines of high toxicity or strength such as medicinal mercury and arsenic trioxide;
- Schedule 2: contains 574 other CHMs which may be used or sold without prescription.

#### ***Regulation of PCMs -***

5.4 PCMs are defined as “any proprietary product-

- (a) composed solely of the following as active ingredients-
  - (i) any Chinese herbal medicines; or
  - (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.”

Under this definition, **PCMs include CM-based health products and CM granules as well as medicines.**

5.5 PCMs are required to be registered for safety, quality and efficacy. The Medicines Board has adopted a three-tier registration system:

- Group I registration: This represents the **minimum passing standard for all PCMs (except new medicines)**;
- Group II registration: This represents an intermediate standard;
- Group III registration: This represents a high standard and involves production of scientific evidence for efficacy claims. **New medicines are required to meet Group III standard** before registration.

PCMs which are not new medicines are required to meet Group I standard only; however, manufacturers or importers may choose to subject their products to more stringent tests and apply for Group II or III standards with a view to using these as a form of quality marking.

5.6 Registration of PCMs was implemented in 2003 with transitional arrangements for PCMs sold before March 1999. Up to late 2009 a total of 16,481 applications have been received, 8,772 or 53% have been approved, 5,196 or 32% have been rejected/withdrawn, and 2,513 or 15% are still under processing. A breakdown of the approved figures is given in the table below.

	<b>New PCMs</b>	<b>Non-new PCMs</b>
<b>Group I standard</b>	N.A.	8,772 PCMs under some form of registration: <ul style="list-style-type: none"> <li>• 7 PCMs with full registration</li> <li>• 8,765 PCMs under transitional registration</li> </ul>
<b>Group II standard</b>	N.A.	0 application
<b>Group III standard</b>	7 to 8 applications being processed	0 application

5.7 It can be seen that except for the seven to eight applications for new PCMs which are required to meet Group III standard, all other applications are for the minimum Group I standard. There may be three explanations for this. Firstly, the HK market is so small it is not worth going for a higher standard. Secondly, every country or area has its own standards for drugs and health products in order to protect its citizens; as the HK registration system is not compatible with those in other areas including the Mainland, meeting HK standards will not help export of PCMs elsewhere. Thirdly, most of the HK manufacturers and distributors are small and financially not strong.

5.8 The Government had earlier said that PCM registration should be completed by 2006. The slow progress in PCM registration is now causing delay to enforcement action on:

- sale of unlicensed PCMs in the market (section 119 of CM Ordinance enacted in 1999 but not put into operation yet); and
- misleading or exaggerated medical advertising claims related to CM products (Undesirable Medical Advertisements Ordinance (Amendment) Ordinance enacted in 2005 but not put into operation yet).

### **Regulation of the CM products trade**

5.9 For CHMs, both wholesalers and retailers are required to be licensed. At present there are about 850 licensed CHM wholesalers and 4400 retailers in HK.

5.10 For PCMs, manufacturers and wholesalers are required to be licensed. At

present there are about 500 registered PCM manufacturers and 1250 wholesalers in HK. Of the PCM manufacturers only seven manufacturers have a Good Manufacturing Practice (GMP) Certificate issued by the Medicines Board.

### **Regulation of PCM testing**

- 5.11 The Medicines Board also regulates the standards of the laboratories conducting the safety, quality and efficacy tests for PCMs. Up to now, nine laboratories in HK have been accepted by the Board as meeting ISO/IEC 17025 standards for testing of PCMs. At the same time, the Board accepts test reports from 16 Mainland municipal testing institutes recommended by the State Food and Drug Administration of the Mainland (SFDA). We have been told that most manufacturers in HK are using the Mainland testing institutes as their charges are generally lower.

### **III. GOVERNMENT'S DEVELOPMENT EFFORTS**

- 5.12 In 1999 the Industry Department drew up a 10-year development plan for Chinese medicines. Shortly after Government departments underwent a reorganization exercise and the Industry Department was deleted. With its deletion the strategic plan was put aside.
- 5.13 In 2001 the JCICM was set up with a donation of \$500M from the HK Jockey Club "to serve as a focal point for action and coordination to steer the development of the Chinese medicines industry". In practice, the JCICM conducts its own research and funds research projects by others, mainly the universities. Its work lies mainly in two areas: firstly, research for herbal product innovations such as anti-depression herbal drugs; and secondly, research into standardization and other industry-wide applications such as production of chemical markers to support research, quality control and standard-setting. We have been given to understand that up to now only about 20% of the committed donation has been spent. The general feedback from the trade is that the JCICM is serving more as a research institute rather than as a coordinator to steer the development of the industry.
- 5.14 Since 2002, the Department of Health has been coordinating a project to develop standards for CHMs "to safeguard public health" and "to help

facilitate the trade”. Up to now standards for 60 commonly used CHMs have been completed and the results are published as the HK Chinese Materia Medica Standards. As announced by the Government in the Chief Executive’s Policy Address of 2009, the project will be expanded to cover a total of 200 CHMs by 2012.

- 5.15 In late 2009, the Government set up a HK Council for Testing and Certification. The Council will draw up a three-year development plan, one of the objectives of which is to promote the development of Chinese medicines and help establish HK as T&C centre.

#### **IV. ECONOMIC CONTRIBUTION OF THE SECTOR**

##### **Jobs and value added to economy**

- 5.16 According to Government statistics, the manufacture and distribution of CM products are providing employment to 10,466 persons or 0.3% of total employment in HK. Value added of the industry is \$2025M or 0.13% of HK’s GDP. However, it should be cautioned that these figures tend to understate the contribution of the industry as they have not taken into account people engaged in T&C, nor those engaged in R&D.

##### **External trade**

###### ***CHMs -***

- 5.17 HK’s imports of CHMs was \$1660M in 2008, and exports was \$731M. As HK does not grow any herbs, this suggests that about 50% of HK’s imports are retained and about 50% re-exported. In fact, retained imports of CHMs increased by 97% from 2001 to 2008. Discussions with the trade indicate that the increase was due not only to increased use of CHMs among the local population, but also to more Mainland visitors making purchases of CHMs in HK.
- 5.18 Mainland figures show that about 40% of Mainland’s CHMs exports are to HK. As noted above, about 50% of this amount is re-exported to other markets. Discussions with the trade show that HK has an edge in this re-export trade not only due to its experience in logistics and international trade, but also due to the screening and testing carried out by some distributors

in the re-export process. We do not have information on where HK exports CHMs to, but if Mainland figures are used as a reference, 80% are exported to other Asian areas and countries.

#### ***PCMs -***

- 5.19 No figures on external trade of PCMs are available as there is no such classification in Government statistics. On the other hand, Mainland figures show that about 70% of Mainland's PCM imports (roughly \$1,014M) are from HK or have come through HK. HK has an advantage in this trade due to the tax concessions under CEPA. HK's reputation for genuine goods and quality control may also be another factor.
- 5.20 There is no further information on what our PCM exports to the Mainland comprise exactly. However, Eu Yan Sang, one of the largest manufacturers in HK, was recently reported on TV as saying that it experienced considerable difficulty in exporting PCMs as medicines to the Mainland. Judging from this, it would be reasonable to assume that most of HK's PCMs exports are food and health products rather than medicines.

#### **Mainland's external trade in CM products**

- 5.21 Para. 5.17 and 5.18 suggest that HK plays a significant role in Mainland's external trade in CM products. As HK's trade in CM products is closely connected to the Mainland, it would be useful for us to understand more about the Mainland's trade in CM products. In 2008 Mainland's imports of CM products was \$2620M and exports was \$9532M. Mainland's imports/exports in CM products is classified into the following three categories:
- CHMs (43% of total CM product exports): the main products exported are ginseng, cordyceps, wolfberry, chrysanthemum, Chinese angelica, licorice root, codonopsis and pinellia tuber.
  - CM extracts (43%): Extracts comprise mainly various plant juices and extracts, natural and synthetic glycosides; and Eucalyptus oil; and are used as dietary supplements and raw materials for cosmetics and health products. In recent years CM extracts experienced the highest increase among the three categories (+209% from 2002 to 2008).
  - PCMs (14%).



5.22 The main export markets are

- for CHMs: Asia (81%)(HK, Japan, Vietnam, Korea, Taiwan, Singapore and Malaysia);
- for CM extracts: Asia (51%) , Europe (23%) and US (14%); and
- for PCMs: Asia and Europe.

5.23 It is reported that in 2009 Mainland's CM products industry is facing two challenges:

- The transitional arrangements for registration of traditional herbal medicines in Europe will expire in end 2009; and
- Instead of importing PCMs from Mainland, more areas including Singapore and Europe are manufacturing their own herbal medicines and products using raw materials.

#### **Mainland's share in world trade in herbal medicines**

5.24 It is quoted in a number of reports that exports of Japan and Korea made up 70% of the world export market in 2002, followed by France and Germany, and that Mainland exports only accounted for about 5%.

5.25 These figures have to be interpreted with caution: even if accurate, they represent the situation in 2002 which is seven years ago; also, they refer to the whole herbal market, not just CM products. On the other hand, the general opinion of experts in the industry is that even if the figures present an exaggerated picture, it is correct to say that the Mainland is not yet a major player in world trade in herbal medicines.

5.26 One explanation for the small share of CM products in world trade in herbs is that safety and quality of CHMs are a continuing concern. Another possible reason is that up to now there is no scientific explanation of CM treatment mechanism in the language of modern science which is accepted by the Western world; also, the efficacy of Chinese medicines have not been proven by clinical trials as distinct from anecdotal evidence. These are serious hurdles which will have to be overcome if the CM products are to enter the Western medical market. Once these hurdles are overcome, the market potential would be considerable.

## V. RECENT DEVELOPMENTS IN HK

5.27 There have been a number of recent developments and trends in the production and distribution of CM products which are worthy of note, as given below:

- production of CM health supplements by the universities;
- added value export of CHMs;
- supplying PCMs to Mainland market; and
- exporting PCMs to Western markets as health products.

### Production of CM health supplements by the universities

5.28 In recent years apart from conducting research, at least four universities are also producing CM health supplements for the local market. They include BU (under its own brand BU Health), CU (under its brand NutriGreen), PolyU and HKU. In addition, BU has an ISO-accredited lab which conducts commercial testing and certification for PCMs from the Mainland for export to other countries and areas.

### Added value export of CHMs

5.29 In the CHMs trade safety and authenticity of the herbs are critical issues. To address the concerns of the market, the more enterprising distributors are now **adding value to the re-export trade of CHMs** by

- enhancing quality control over the farming process and
- testing the herbs for quality and authenticity.

5.30 Examples of related developments are given below:

- Zigen, a HK company, is planning to re-export high-value CHMs from Sichuan to Japan and other markets. The CHMs will be sourced from farms accredited under Good Agricultural Practice (GAP) and will be tested in HK for quality and authenticity before re-export.
- The Health Department has developed standards for 60 commonly used CHMs. The Government has recently announced that it will extend the exercise to cover 200 CHMs by 2012.
- JCICM is undertaking a project called “Authentication Studies of

Valuable Chinese Materia Medica” under which methodologies and guidelines will be developed for authentication of 30 species of valuable Chinese materia medica selected for their high sales volume, high value, and easy confusion with other herbs.

- However, while these two studies are certainly of value in themselves, many people in the trade have cast doubt on their relevance to trade facilitation. We have been given to understand that the standards developed by Health Department are generally too high to be of practical use in trading, and the standards being developed by the JCICM also tend to be on the high side.
- Meanwhile, updating of the Chinese Pharmacopoeia of the People’s Republic of China is near completion and is expected to be published in mid 2010. It has been suggested that there may be overlap between the work undertaken in HK and in the Mainland in developing standards.

#### **Supplying PCMs to the Mainland market**

5.31 With a population of 1.3 billion and the high acceptance of CM products among its people, the Mainland is the world’s largest market for CM products . In recent years a number of **HK companies have set up manufacturing facilities in the Mainland** under HK management and are now successfully supplying PCMs to the Mainland market under HK brand names. Examples include the following:

- Purapharm, a HK company, has set up manufacturing facilities in Guangxi to produce PCMs. It is now one of the six registered suppliers of CM granules on the Mainland and supplies about 25% of the market in CM granules.
- Lee Kam Kee is another HK company which has set up manufacturing facilities in the Mainland. Its facilities are in Guangdong and it produces mainly CM-based health foods. It is now supplying over 50 CM-based health products under a direct sales licence in 14 Mainland cities.

5.32 On the other hand, there are other companies which find it difficult to export PCMs manufactured in HK to the Mainland. Some of them have mentioned the different standards and registration requirements adopted in the two areas

as one of the main hurdles.

### **Export of PCMs to Western markets**

5.33 Traditionally PCMs exported to Western markets are sold within overseas Chinese communities. Access to mainstream consumers is limited. Little attention is paid to packaging and finishing and pricing is low-end. The situation is changing now. Some of the more enterprising companies are now **taking steps to enter the mainstream market** by meeting the quality standards of the importing countries.

Two examples of such developments are given below.

5.34 Example 1: Purapharm, a HK company, has recently obtained accreditation under the Dietary Supplement Verification Program of the United States Pharmacopoeia (USP-DSVP) for a yunzhi-based PCMs called Onco-z which is manufactured in its premises in Guangxi. With such accreditation Purapharm will be able to market the product as a dietary supplement with no therapeutic claims but with a quality label in the US mainstream market.

5.35 An explanation of what is meant by USP-DSVP would be in order here. The United States Pharmacopoeia (USP) is an official public standards-setting authority for all prescription and over-the-counter medicines and other health care products manufactured or sold in the United States. In order to qualify for a “USP-DSVP Verified” quality label, a product is required to undergo the following processes:

- laboratory testing of dietary supplement products against standards found in [The United States Pharmacopoeia and The National Formulary \(USP-NF\)](#);
- a manufacturing and quality control document review;
- an on-site manufacturing facility audit for compliance with USP standards and [FDA current Good Manufacturing Practices](#); and
- random off-the-shelf testing to confirm that USP Verified products continue to meet USP standards.

To the US consumer, the label carries the following meaning:

- the product contains the listed ingredients on the label, in the declared potency and amounts;
- it does not contain harmful levels of specified contaminants;
- it will break down and release into the body within a specified amount of time; and
- it has been made according to FDA current GMPs.

5.36 Example 2: Zigen, a HK company, is exploring with Huaxi Medical College the possibility of exporting a generic PCM with cardio-cerebral-vascular functions to Canada under the new Natural Health Product Regulations passed in Canada in 2004. The new Regulations allow PCMs to be imported into Canada under “Traditional Claims” provided certain requirements are met, and the requirements are relatively relaxed compared to those conventionally required for drugs. Basically:

- there must be evidence that the product is safe; and
- there has to be some clinical evidence of functional efficacy as a traditional medicine, but the level of efficacy evidence required is considerably lower than that conventionally required for drugs.

## CHAPTER 6 - DISTRIBUTION AND DEVELOPMENT OF CM PRODUCTS: OPPORTUNITIES AND CHALLENGES

### I. GENERAL

- 6.1 In this chapter we are going to consider:
- the supply chain of CM products;
  - HK's opportunities and challenges; and
  - development potential.

### II. THE SUPPLY CHAIN OF CM PRODUCTS

- 6.2 To assess HK's potential in the distribution of CM products it would be useful to examine the supply chain of CM products. Broadly speaking the supply chain is made up of the following elements:

- a) raw material production;
- b) manufacturing;
- c) testing and certification (T&C);
- d) research and development (R&D);
- e) branding, marketing and supply chain management; and
- f) raising finance.

*a) Raw materials -*

- 6.3 HK has little or no production of CM herbs.

*b) Manufacturing -*

- 6.4 HK's CM products manufacturing industry is not large. There is no pharmaceutical company in HK. Of the 500 PCMs manufacturers in HK, only seven have GMP certification. The larger manufacturers include well-known brand names such as Eu Yan Sang and Tong Ren Tang. Some of the local universities including BU and CU have also set up their own manufacturing arms to produce PCMs mainly for the local market.

- 6.5 On the other hand, HK's PCMs manufacturers enjoy a good reputation for genuine products and quality control. "Manufactured in HK" is a selling point for PCMs among consumers. As noted from the examples of

Purapharm and Lee Kam Kee in Chapter 5, even HK management of their manufacturing facilities in the Mainland (i.e. “managed by HK”) is regarded as an advantage.

*c) T&C -*

- 6.6 HK’s CM products T&C sector is small. There are only nine labs accredited by the CM Council for testing and registration of PCMs. Furthermore, most of HK’s commercial labs are technically limited – we have been told they are competent in testing when given standards and methodology; but would need assistance or back up if such are not given.
- 6.7 On the other hand the local universities, HACML and the JCICM do have labs which are capable of developing standards and methodology and undertaking research. For example the HACML labs undertake safety and authenticity testing for the CHMs used by its public sector CM clinics, and has developed a valuable knowledge base in the process.
- 6.8 It should be noted here that T&C of CM products is considerably more complicated than what the term usually implies, and often involves an element of research. For example, Western medicines usually comprise single chemical ingredient, and testing standards and methodology are well established. Chinese medicines are usually made up of multiple ingredients, and there are no complete or one universally accepted set of standards for Chinese medicines. Although there are many standards for herbs which can be used for reference (including the Chinese Pharmacopoeia of the People’s Republic of China, the HK Chinese Materia Medica Standards, the US standards, the UK standards, etc.), most of these standards are still being refined and updated and new discoveries are still being made.
- 6.9 A further complication here is that the HK market is small and any standards developed by HK will have to be recognized by our export markets (including the Mainland market) before they can help our export trade. Standards which are only accepted in HK can facilitate local consumer protection, but would give little direct benefit to our export trade.

*d) R&D -*

- 6.10 Where upstream basic research is concerned, six universities in HK (i.e. HKU, CU, BU, HK PolyU, HKUST and CityU) are undertaking various studies into

CM products. Their work is highly regarded academically and a lot of their research results have been published in world renowned journals. A study commissioned by the HK Science and Technology Parks in 2008 has found that HK accounts for 20% of the entire internationally documented biomedical research output of China; and ranks first of any city in China in terms of the number of peer-reviewed research papers in the life sciences (including but not limited to Chinese medicine). However, generally speaking their focus is mainly on academic results rather than commercial products.

6.11 For applied research, the JCICM has been set up by the Government as, amongst other things, an applied research centre for Chinese medicines. However, like the universities JCICM's research results are still some way from commercialization.

6.12 Where **R&D** is concerned, there are two critical issues to be overcome:

- reconciliation of CM treatment mechanism with the language of modern science or the principles of WM; and
- proof of efficacy of Chinese medicines through rigorous clinical research (as distinct from anecdotal evidence).

As far as we are aware, Chinese medicines are being sold overseas mainly as natural health products with no or limited claims of benefits and not as drugs with efficacy claims. There is ongoing research on development of drugs from CM formulations for overseas markets but so far no major breakthrough. For example, Professor Tommy YC Cheng of Yale University and his partners have been researching into PHY 906 with more than US\$20M funding since 1999 and has yet to obtain approval of the US Food and Health Administration (FDA) for the drug. PHY 906 is a 4-herb Chinese traditional formulation with a history of over 1500 years of human use. It is developed to enhance the therapeutic effects of cancer chemotherapy and is at present in Clinical Trial Phase II. [Sources: Dr Daniel Sze, Secretariat of Consortium for Globalization of Chinese Medicine; <http://phytoceutica.com> ]

*e) Branding, marketing and supply chain management -*

6.13 With long experience and expertise in serving as an entrepot, branding, marketing and supply chain management are traditionally HK's strong points. Supply chain management is particularly important in the CM products trade as it involves long supply chains over different areas (e.g. CHMs grown in Sichuan, manufactured into PCMs in Guangdong and tested in HK).



*f) Raising finance -*

- 6.14 Drug development requires heavy investment which is high-risk and long in payback period, although return may also be high.
- 6.15 In general, public sector funding of R&D in HK is lower than in many neighbouring areas. In HK R&D funding (including all sectors, not only CM) is 0.75% of GDP, in the Mainland this figure is 1.42%, in Singapore 2.39% and in Taiwan 2.58%. However, where Chinese medicines are concerned, R&D funding is not a particularly limiting factor as explained below. In HK, public sector funding for R&D in Chinese medicines may come from the following sources:
- JCICM. We understand that up to December 2009 only about 20% of its committed funding of \$500M has spent;
  - Innovation and Technology Commission; and
  - Research Grants Council of the University Grants Committee (mainly for basic research).
- 6.16 Where private funding is concerned, HK has good infrastructure for raising finance and efficient supporting services including a sound legal system. However, there is at present not much investor interest in Chinese medicines development. There is a lack of venture capital funding for the commercialization of R&D results.

### **III. OPPORTUNITIES AND CHALLENGES**

- 6.17 HK's **advantages and opportunities in the CM products industry** include those of CM products in general and those specific to HK.
- 6.18 Advantages of CM products in general include the following:
- Traditional CM formulae have been proven by experience and are waiting to be marketed to the world provided their safety, quality and efficacy can be "scientifically" proven.
  - There is increasing worldwide acceptance of herbal medicines and health products.
- 6.19 Where advantages specific to HK is concerned, we can see that HK can play a

complementary role to the Mainland in the supply chain of CM products :

- Mainland's strengths lie in raw material production, manufacturing, and its large local market; while
- HK excels mainly in downstream functions such as marketing and distribution. Other strengths include modernized management, quality control, and professionalism and creditability in T&C and the strong R&D capacity of our universities. In the CM products trade, being manufactured or managed by HK companies is a selling point.

6.20 **Limiting factors and challenges** facing HK include those applicable to CM in general and those specific to HK.

6.21 Challenges for CM products in general include the following:

- The most critical issue facing CM products is that its treatment mechanism has yet to be fully explained in modern science terms, and the efficacy of most CM products is not supported by clinical research. It will take very strong commitment to R&D and heavy investment in product development to overcome this challenge.
- Safety and authenticity of CHMs is another concern. To overcome this quality control over the production process, standard-setting and T&C are required.

6.22 Limiting factors specific to HK include the following:

- HK has only a niche advantage in the supply chain and this advantage is being eroded as the Mainland develops further.
- Although Government has made efforts in developing Chinese medicines, these efforts are largely uncoordinated and focused on regulation rather than development. Even Government-funded research is being undertaken for the sake of research with insufficient regard to its practical value.<sup>4</sup> One of the reasons for the lack of coordination is the fact that **responsibilities for CM are scattered** among two policy bureaus (Food

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<sup>4</sup> An example is the development of CHM standards by Government. Feedback from various sources indicates that the 60 standards developed are too high to be of practical application. In other words, while this project may be of scientific value, it is of little direct benefit to the export of Chinese medicines.

and Health Bureau and Commerce and Economic Development Bureau) and three executive agencies (Department of Health, Hospital Authority Chinese Medicine Limited (HACML), and Innovation and Technology Commission) in the Government.

- In undertaking research and development (R&D) into Chinese medicines, HK is also hampered by the fact that it has **no CM hospital, its small patient base, its small local market and lack of significant investor interest at this stage.**
- Given that the Mainland is the world's largest producer of CM products as well as the largest consumer market, HK is heavily dependent on the Mainland in developing such products. However, there has been **insufficient collaboration with the Mainland.** For example, HK's registration system for proprietary Chinese Medicines (PCM) is not compatible with the Mainland system, making it necessary for a manufacturer to meet two sets of registration requirements if he wants to sell his product in the two adjacent markets.

#### **IV. DEVELOPMENT POTENTIAL**

6.23 In the light of these opportunities, challenges, and recent developments in the industry, there is development potential in the following areas.

- further expansion into the Mainland market;
- adding value to the export of CHMs through T&C; and
- development of PCMs as high-quality health products for export.

##### **Further expansion into the Mainland market**

6.24 The Mainland market is both acceptive of CM products and receptive of HK branding, and presents tremendous potential to HK manufacturers and distributors. Purapharm and Lee Kam Kee, with their manufacturing facilities on the Mainland under HK management, represent success stories. Other companies which try to export to the Mainland PCMs manufactured in HK, have reported difficulties with the different standards and the registration requirements adopted in the two areas. This is an area where Government assistance may be required and greater collaboration between HK and the Mainland authorities would be helpful.

### **To add value to the export of CHMs through T&C**

- 6.25 Traditionally HK has been an important entrepot for export of CHMs from the Mainland to other markets. There is potential for enterprising distributors to **add value** to the export of CHMs from the Mainland through (a) quality control of the farming process and (b) testing and certifying the CHMs against authenticity and quality standards. For this to happen, HK will need to build up the capability of its T&C sector and to obtain recognition of accredited labs in HK by the regulatory authorities in our export markets.

### **Development of PCMs as high-quality health products for export**

- 6.26 There is potential to **add value** to this trade and to upgrade it from the “Chinatown” market to the mainstream market. To achieve this, the entrepreneur will need to be able to (a) exercise quality control over the farming and manufacturing processes and (b) to test and certify the PCMs against quality standards of the markets, such as the Dietary Supplement Verification Program of the US Pharmacopeia (mentioned in Chapter 5).

### **Development of PCMs as drugs**

- 6.27 This can be pursued as a long term goal. As explained above, the development of PCMs as drugs acceptable to overseas markets require strong commitment in R&D and heavy investment. At this stage there is a gap between university research and industry in HK; also there is apparently insufficient investor interest in this sector.

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## Abbreviations

BU	Hong Kong Baptist University	香港浸會大學
CHMs	Chinese herbal medicines	中草藥
CityU	City University of Hong Kong	香港城市大學
CM	Chinese medicine	中醫藥
CMP	Chinese medical practitioner	中醫師
CU	The Chinese University of Hong Kong	香港中文大學
GAP	Good Agricultural Practice	優良農業規範
GDP	Gross Domestic Product	國內生產總值
GMP	Good Manufacturing Practice	優良製造規範
HACML	Hospital Authority Chinese Medicine Limited	醫管局中醫藥有限公司
HK	Hong Kong	香港
HKU	University of Hong Kong	香港大學
JCICM	Hong Kong Jockey Club Institute of Chinese Medicine Limited	香港賽馬會中藥研究院有限公司
NGO	Non-government organization	非政府組織
PCMs	Proprietary Chinese medicines	中成藥
PolyU	Hong Kong Polytechnic University	香港理工大學
R&D	Research and development	科研
SFDA	State Food and Drug Administration of Mainland	國家食品藥品監督管理局
T&C	Testing and certification	檢測認證
WM	Western medicine	西藥
WMP	Western medical practitioner	西醫