Introduction

Traditional Chinese Medicine (TCM) remains an integral part of Chinese culture. It is based on the basic principles of two opposite but interdependent aspects of “Yin” and “Yang,” working on an inner balance of human organs through different channels within the body.

TCM has been promoted for its effectiveness for treating sicknesses. There has been a great deal of governmental effort, especially in Hong Kong, Taiwan and Singapore, in promoting TCM research and related activities with the hope of raising the profile of TCM.

Regulatory Framework

Chinese Medicine Ordinance

The Hong Kong government has been active in promoting Chinese medicine as one of the key industries. Back in 1997, the Hong Kong Chief Executive stated his vision in his policy address of developing Hong Kong into an international center for manufacture and trading of TCM, research and development of TCM and promotion of TCM for medical care. Following this, the Chinese Medicine Ordinance (the “Ordinance”) was enacted in July 1999 for the purposes of:

1. setting up a Chinese Medicine Council for implementing regulatory measures for Chinese medicines, Chinese medicine practitioners and trading activities for Chinese medicines;
2. regulating registration of Chinese medicine practitioners;
3. licensing Chinese herbal medicine traders;
4. regulating registration of proprietary Chinese medicines; and
5. licensing proprietary Chinese medicine traders.

The provisions of the Ordinance are to be implemented in different phases and are set to revolutionize the practice of Chinese medicine in Hong Kong. Traditionally, Chinese medicine practitioners are mostly “family-trained” or trained “on-the-job” without any formal professional qualifications in the areas they practise. Prior to the Ordinance, anyone in Hong Kong could claim to be a “Chinese medicine doctor” and prescribe herbal medicines.

The Ordinance requires that no person can practise Chinese medicine without a licence. All TCM practitioners must now pass the Licensing Examination prescribed by the Chinese Medicine Council after having obtained a recognized undergraduate degree in Chinese
medicine. Transitional arrangements were available for those who practised Chinese medicine for a prescribed period as at 3 January 2000. Under such arrangements, an applicant would be exempted from the Licensing Examination upon satisfying the Chinese Medicine Council of certain criteria relating to experience, knowledge and skills in the practice of Chinese medicine.

The Ordinance lays down a licensing and registration regime for trading of TCM. When the relevant provisions are fully in operation, without a relevant licence, no one in Hong Kong can engage in wholesaling and retailing of Chinese herbal medicines, manufacturing and wholesaling of proprietary Chinese medicines, and all proprietary Chinese medicines must be registered before they can be sold, imported or possessed. However, there is no licensing regime for retailers of proprietary Chinese medicines. All these activities are under the supervision and control of the Chinese Medicine Council which has the power to deregister and revoke licences as it deems appropriate.

Classification of TCM Under Food or Drug Categories

In terms of regulatory control, products intended for human oral consumption can be broadly classified as “drug” or “food,” depending on their composition and claims on labels of products. A product containing Chinese medicine as active ingredients for the treatment or alleviation of disease is predominately regulated by the Ordinance. However, if a product containing Chinese herbal extracts or Chinese medicinal ingredients does not make any claims for diagnosis, treatment, prevention or alleviation of any disease or any symptom of a disease in human beings, it may fall outside the ambit of the Ordinance. The product may simply be classified as “food” thereby falling within the scope of the Public Health and Municipal Services Ordinance requiring the product to be fit for human consumption. Further, if a Chinese medicinal product contains pharmaceutical ingredients, it may fall within the meaning of “pharmaceutical products” and will thereby be regulated under the Pharmacy and Poisons Ordinance.

Health Supplements

Practically, the distinction between “drug” and “food” is not always clear. Hybrid products like “health foods,” “functional foods,” “dietary supplements,” “nutraceuticals” and “natural health products” carrying certain health-related claims are currently not regulated under a separate regulatory regime. Like drugs and foods, those health supplements are regulated by:

1. Public Health and Municipal Services Ordinance requiring drugs and foods to be fit for human consumption;

2. Import and Export Ordinance regulating the import and export of products to and from Hong Kong;

3. Trade Descriptions Ordinance prohibiting false trade descriptions, false marks and misstatements of goods provided in the course of trade;

4. Undesirable Medical Advertisements Ordinance prohibiting any advertisement likely to lead the public to the use of any medicine, surgical appliance or treatment for the purposes of treating or preventing human beings from contracting certain specified diseases;

5. Animals and Plants (Protection of Endangered Species) Ordinance restricting the importation, exportation and possession of certain animals and plants, and parts of such animals and plants;
(6). Pharmacy and Poisons Ordinance regulating and controlling medicines containing pharmaceutical ingredients;

(7). Antibiotics Ordinance controlling the sale and supply of certain antibiotic substances; and

(8). Dangerous Drugs Ordinance regulating the use and sale of dangerous drugs.

In recent years, there has been an increasing number of “health products” in Hong Kong claiming specific beneficial health or beautifying effects, such as regulation of blood lipid or cholesterol, detoxification and slimming. If the claims do not contain any wording for “prevention or treatment of certain specified diseases,” it is likely that those products may fall outside the ambit of the existing drug regulatory control. Realizing a need to control misleading or exaggerated claims on health products and to promote public awareness, the Hong Kong Government issued the Consultation Document on Regulation of Health Claims in Hong Kong in September 2003 (the “Document”) and the Public Consultation Paper on Proposed Labeling Scheme on Nutrition Information in November 2003 (the “Paper”).

Under the Document, it is proposed that the list of prohibited claims in the Undesirable Medical Advertisements Ordinance should be expanded to include claims relating to (1) body sugar or glucose; (2) blood pressure; (3) blood lipid or cholesterol; (4) prevention, elimination or treatment of breast lumps; (5) function of genitourinary system; (6) endocrine system; (7) slimming or fat reduction; (8) body immune system; and (9) promotion of detoxification.

Whereas under the Paper, it is proposed that a mandatory nutrition labeling scheme on food products be implemented in phases. The proposed scheme requires all suppliers of food products carrying nutrient-related claims or other nutrition information to list out the contents of energy, core nutrients, other nutrients and the amount of any nutrient for which a claim is made on the pre-packaged food products. The presentation of nutrition information will need to be expressed in a standardized manner so as to facilitate easy understanding of information. There are additional requirements for nutrient-related claims.

The Hong Kong Government intends to bring its drug- and food-related legislation in line with other advanced countries, but a balance has to be struck between protection of public health and freedom of choice by customers. With the popularity of using TCM products in boosting the body’s immune system, detoxification and slimming, it is likely that TCM producers and distributors will strongly oppose the extent of the prohibited claims under the Document.

Investment Framework

The Hong Kong government and a number of non-governmental organizations have been funding numerous TCM research projects with industry collaborators working alongside. For instance, the Innovation and Technology Commission of the government (the “Commission”) operates various funding schemes to assist universities and companies in developing and promoting technology-based research programs. One of its schemes, the University-Industry Collaboration Program, provides a dollar-for-dollar funding match, while another of the Commission’s funding arms, the Applied Research Fund, provides venture capital funding to support technology ventures undertaken by local companies.

With the support of the government appointed University Grants Committee (UGC), the Research Grant Council advises the government in relation to academic research and distribution of funding undertaken by academic staff of UGC-funded institutions. On the other hand, the
private sector through a number of listed and other enterprises has been collaborating with universities/research institutes from Hong Kong, Mainland China and overseas on TCM-related projects.

The Hong Kong Jockey Club Charities Trust and the government have both seen the need to have a dedicated organization to promote TCM in Hong Kong. This resulted in the establishment of the Hong Kong Jockey Club Institute of Chinese Medicine which supports scientific- and evidence-based TCM development programs, which Institute boasts financial support of HK$500 million (US$64.2 million) from the Hong Kong Jockey Club Charities Trust.

Commercialization of TCM Projects
As a TCM project progresses to commercialization, capturing intellectual property rights (IPR) and know-how remains a primary concern if the TCM project is to succeed commercially. Great care should be taken to identify the ownership of IPR from the beginning and the capacity of each of the participating researchers, as the IPR developed may not belong totally to the research institute. For projects involving a university, investors should be aware that it is not in all cases that a university in Hong Kong can directly enter into a pure profit-oriented commercial transaction.

Like many life sciences/biotech projects, the success of a TCM spin-off and to some extent licensing deal depends on the inventors or main research scientists involved in the technology transferred, since knowledge and know-how for controlling consistency and achieving standardization of products are often locked inside inventors’ or researchers’ heads. This is particularly important if the investor contemplates to market the products internationally. In order to satisfy foreign regulatory requirements, TCM products at the very least have to meet the three basic criteria of “quality,” “safety” and “efficacy” with the support of proven clinical research data and documentation. This will require an array of clinically tested proprietary technology and extensive dossiers with research results and manufacturing details supported by Good Agricultural Practice, Good Laboratory Practice and Good Manufacturing Practice. Overcoming problems such as correct identification of crude herbal products, controlling wide harvest materials and maintaining consistency of standards due to seasonality are just other challenges facing any TCM manufacturers.

Deriving value and credit enhancing a TCM project is an art all in itself and can be achieved with the active participation of quality advisors and other industry participants. In truth, a TCM IPR may not be patentable because of its inherent characteristics but that does not necessarily mean the project is not valuable commercially. Having the correct mix of TCM products, investors and advisors is a key ingredient to successful commercialization.

Opportunities Ahead
No doubt, TCM projects in Hong Kong require active participation of both financial and strategic investors. The Hong Kong government has been trying to open up more investment opportunities in this respect. The Closer Economic Partnership Arrangement (CEPA) signed by Mainland China and Hong Kong in 2003 grants preferential treatment to Hong Kong companies in a number of areas and promotes an earlier liberalization of China’s existing World Trade Organization (WTO) commitments. Among other things, CEPA promotes the industrialization of Chinese medicine and serves to advance its modernization and internationalization through cooperation and support. The expertise, supply of raw materials and manufacturing facilities
available in Mainland China will greatly support Hong Kong TCM projects which will, in turn, boost their commercialization prospects.

While the concerted effort of the Hong Kong government, universities, research institutes, investors and industry collaborators has put Hong Kong on the map to becoming a world center for TCM development, at this stage it is difficult to tell how far Hong Kong can go as it ultimately depends on many variables. It is true that Hong Kong does have a competitive edge over its neighbors in the TCM sector, but this position is changing as China continues to overcome its shortcomings in this sector. Getting the right blueprint to enable the TCM industry to take off in Hong Kong is one thing, getting sufficient investor interest and high quality TCM projects for investment is another. Time will tell whether Hong Kong will succeed in its TCM initiatives.

About the Author

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