For discussion on
10 February 2003

Paper No. CB(2)1105/02-03(04)

Legislative Council Panel on Health Services
Meeting on 10 February 2003

Development of Regulatory Standards for Hong Kong Chinese Medicinal Herbs

Introduction

This paper seeks Members' views on the Administration' plan to develop regulatory standards for commonly used Chinese medicinal herbs (herbs) in Hong Kong.

Background

2. In 1997, the Chief Executive announced in his Policy Address the Government's commitment to establish a sound regulatory framework for Chinese medicine and to develop Hong Kong into an international centre for Chinese medicine. Following the enactment of the Chinese Medicine Ordinance in July 1999, the Chinese Medicine Council of Hong Kong was established under the Ordinance to devise and implement regulatory measures for the practice, use, trading and manufacture of Chinese medicine in Hong Kong. The registration of Chinese medicine practitioners has commenced since 2000 and the regulatory controls on Chinese medicines will be implemented by phases from 2003.

3. Although Chinese medicine has long been widely used in the community, there are presently no international standards regarding the safety and quality of the herbs. Given the large volume of trading

transactions with huge economic value, the authenticity, quality and safety of herbs are of great concern to the trade, the community and regulatory authorities. Moreover, as Chinese medicinal herbs are the basic raw materials of proprietary Chinese medicines, its safety and quality will directly affect the safety and quality of proprietary Chinese medicines concerned. In order to safeguard public health and to facilitate research and trade in Chinese medicines, objective safety and quality regulatory standards of Chinese medicinal herbs are necessary.

4. The regulatory standards will bring considerable benefits to various sectors of the community. First, with the introduction of the regulatory standards, Government authorities will be able to exercise more effective control on Chinese medicinal herbs, and take enforcement actions against substandard herbs that may be harmful to public health. The regulatory standards will provide an easy, readily available and authoritative reference to determine the authenticity, the safety level (as to the limits of pesticides residues and various heavy metal contents), and the quality (as to the purity and amount of marker ingredients) of the herbs in question.

5. Secondly, the regulatory standards will facilitate trade in Chinese medicines by harmonizing the names of the commonly used herbs; standardizing the methods of processing; locating sources of efficacious herbs; identifying and differentiating herbs by more objective methods. The adoption of regulatory standards in Hong Kong will help boost the reputation of local Chinese medicine industry and enhance their business worldwide. Furthermore, coupled with the adoption of Good

Manufacturing Practice (GMP), assurance of the safety and quality of herbs in compliance with the regulatory standards would ensure higher industry standards in the manufacturing of proprietary Chinese medicines as a whole. This will enable local Chinese medicinal products to become more competitive in the international market.

6. Thirdly, as efficacy and safety of a Chinese medicine prescription are largely determined by the safety and quality standards of the herbs concerned, the establishment of regulatory standards will enhance public confidence in the use of Chinese medicine.

7. Fourthly, universities and research institutions can make use of the regulatory standards as the basis to initiate in-depth studies on Chinese medicines, which in the long run may facilitate the development of new treatment methods or new medication. The regulatory standards may also serve as international standards for adoption and/or adaptation by other drug regulatory authorities in the control and management of Chinese medicines.

Development of the Regulatory Standards

8. As the development of regulatory standards for commonly used Chinese medicinal herbs is an entirely new initiative in Hong Kong, the Department of Health has in October 2001 set up a task force and launched a Pilot Study on eight Chinese medicinal herbs to test the feasibility of the initiative and to establish long term working connections with relevant institutions, experts and authorities. The regulatory standards will cover, among other things, sources and description of herbs,

identification (such as microscopic examination and chromatographic analysis), tests (such as on heavy metal and pesticide residues), extractive, assay and etc. Details of the content of the regulatory standards are set out at **Annex A**. The eight herbs listed at **Annex B** are selected according to the following criteria –

(a) the herbs should be commonly used in the local community;
(b) the herbs should be of high economic value in the local market; and
(c) the herbs should be of international concern in respect of their safety and quality.

9. An International Advisory Board (IAB) consisting of 12 renowned local, Mainland and overseas (including Australia, Canada, Germany, Japan, Thailand and the United States) experts was established in late 2001 to give advice on the development of the regulatory standards. At the first Board meeting held in February - March 2002, the IAB discussed and determined the principles, methodology, parameters and analytical methods for the Pilot Study. The support of IAB members will promote acceptance and recognition by overseas regulatory authorities worldwide of the future regulatory standards.

10. A Scientific Committee consisting visiting IAB Members, representatives of participating universities and research institutions and Government officials has been established to monitor the progress of the laboratory and research work, to work out solutions to technical problems and also to examine the research and laboratory findings. The Committee

has already finalized detailed Technical Guidelines on the research and laboratory work for the participating universities.

11. The Department of Health will collaborate closely with the Hong Kong Government Laboratory to make use of its expertise, experience and facilities in Chinese medicine research. The Government Laboratory will undertake the validation work on research and laboratory findings on the eight herbs.

Latest Development

12. The Chinese University of Hong Kong and the Hong Kong Baptist University have been commissioned to conduct the research and laboratory work on the eight herbs selected for the Pilot Study for completion in the last quarter of 2003. The universities will be required to submit periodic progress reports of their work. Meetings of the working group and/or the Scientific Committee will be held whenever necessary to discuss technical issues. The IAB will meet annually to examine the available results and to give general advice on the development of the regulatory standards.

13. Upon completion of the necessary work on validation, drafting and trial run, we shall publish the regulatory standards of the eight herbs in early 2004 in the form of books and CD roms for distribution to interested parties, including Chinese medicines traders, Chinese medicine practitioners, local, Mainland and overseas universities and research institutions, Government departments, other overseas regulatory bodies in drugs and members of the public.

The Way Forward

14. In view of the practical needs for regulatory standards for the protection of public health and other benefits as well as the solid foundation established by the Pilot Study, we propose to start the development of regulatory standards for another 52 commonly used herbs from 2003. The development of regulatory standards for these 52 herbs will require funding of $38.5 million. The proposal will be submitted to the Finance Committee of the LegCo for approval in due course.

Members' Advice

15. Members are invited to comment on the proposal in para. 14 above. After the completion of the study on 60 herbs (including the eight herbs of the Pilot Study) in 2005-6, we shall review the progress and consider developing regulatory standards for more herbs.

Department of Health

February 2003

Annex A

Content of the Regulatory Standards

1. **Name of Chinese Materia Medica**
   a. Official name
   b. Chinese name
   c. Chinese phonetic name

2. **Source of Chinese Materia Medica**
   a. The taxonomical classification of the plant and animals including its genus, family, species and variety
   b. The part of plant or animal used and its conditions
   c. Time for harvest/collection
   d. The source of the material
   e. The preliminary treatment on the spot of collection
   f. Other related information

3. **Description of the Chinese Materia Medica**
   a. Appearance
   b. Colour
   c. Texture
   d. Gross internal structure (include fracture characteristics)
   e. Odour/smell
   f. Taste
   g. Other related information

4. **Identification**
   a. Organoleptic tests
   b. Microscopic examination
   c. Physical and chemical testing
   d. Chromatographic analysis

e. Spectroscopic analysis
f. Other identification tests

5. **Test**
   a. Heavy metals
   b. Pesticide residues
   c. Mycotoxins
   d. Foreign Matter
   e. Ash (total ash and acid-insoluble ash)
   f. Determination of water
   g. Other tests

6. **Extractive**
   a. Water-soluble extractive
   b. Alcohol-soluble extractive
   c. Other extractive tests

7. **Assay**

   The name, limit and molecular formula of active ingredients or marker compounds of the herb

Annex B

List of the Eight Herbs in the Pilot Study

1. Cortex Moutan (牡丹皮)
2. Radix Ginseng (人參)
3. Radix Notoginseng (三七)
4. Radix Salviae Miltiorrhizae (丹參)
5. Radix Angelicae Sinensis (當歸)
6. Rhizoma Alismatis (澤瀉)
7. Cortex Phellodendri (黃柏)
8. Radix Astragali (黃芪)