For discussion **FCR(2002-03)64**
on 7 March 2003

ITEM FOR FINANCE COMMITTEE

HEAD 37 – DEPARTMENT OF HEALTH
Subhead 700 General other non-recurrent
Item 728 Studies on Chinese medicinal herbs

Members are invited to approve an increase in the approved commitment under Head 37 Department of Health Subhead 700 Item 728 from $8.1 million by $38.5 million to $46.6 million to develop Hong Kong Chinese Materia Medica standards for Chinese medicinal herbs

PROBLEM

Hong Kong lacks a set of regulatory standards for Chinese medicinal herbs (herbs) to safeguard public health as well as support the modernization and globalization of Chinese medicines, paving the way for Hong Kong to develop into an international centre for Chinese medicines.

PROPOSAL

2. Department of Health (DH), with the support of the Health, Welfare and Food Bureau, aims at developing the Hong Kong Chinese Materia Medica (HKCMM) standards for 200 commonly used herbs in Hong Kong. These herbs represent the majority number of herbs being prescribed by local Chinese medicine practitioners, and also make up the bulk of raw materials used in the manufacture of proprietary Chinese medicines in Hong Kong.

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3. In 2001, DH started a Pilot Study to develop HKCMM standards for eight herbs under a commitment of HK$8.1 million approved by the then Secretary for the Treasury under delegated authority. As good foundation and working connections have already been established, DH now proposes to increase the commitment from $8.1 million by HK$38.5 million to $46.6 million for the development of regulatory standards for another 52 herbs. Altogether, we aim at developing HKCMM standards for a total of 60 herbs in about three years. Thereafter, we will develop regulatory standards for the remaining 140 herbs whenever resources are identified.

JUSTIFICATION

Need for HKCMM Standards

4. Under the Public Health and Municipal Services Ordinance (Cap 132), all drugs for sale (including Chinese medicines) shall be fit for human consumption. In enforcing this ordinance with regard to Chinese medicines, we currently make reference to the Chinese Pharmacopoeia which describes for each herb its source and physical properties. The Chinese Pharmacopoeia does not document, however, such information as the safety levels of heavy metals, pesticide residues, aflatoxins and quantitative assays.

5. 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 herbs are the basic raw materials of proprietary Chinese medicines, their safety and quality will directly affect the safety and quality of the proprietary Chinese medicines concerned.

6. In our continuous effort to enhance public health and to facilitate research and trade in Chinese medicines, we have embarked on a study to develop the HKCMM standards that will serve as an authoritative tool or reference guide to a wide scope of potential users. The benefits are described in paragraphs 7 to 10 below.

7. First, Government authorities will be able to make use of the HKCMM standards to exercise more effective control on herbs and to take enforcement actions under the Public Health and Municipal Services Ordinance against the supply of substandard herbs harmful to public health. In due course, we

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may consider, in consultation with the trade, making it a licensing requirement under the Chinese Medicine Ordinance (Cap 549) that herbs shall comply with the HKCMM standards. However, we believe that the trade would make use of them voluntarily for their own benefits as explained in paragraph 8 below.

8. Secondly, the HKCMM standards will facilitate trade in Chinese medicines through harmonizing the names of commonly used herbs, standardizing the methods of processing, locating sources of efficacious herbs, identifying and differentiating herbs by objective methods. This will help boost the reputation of the local Chinese medicine industry and enhance their business worldwide. Furthermore, coupled with the adoption of Good Manufacturing Practice, assurance of the safety and quality of herbs in compliance with the HKCMM standards would ensure a high industry standard in the manufacture of proprietary Chinese medicines as a whole. This will enable local Chinese medicinal products to become more competitive in the international market.

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

10. Fourthly, universities and research institutions can make use of the HKCMM standards as the basis to initiate further in-depth studies on Chinese medicines, which in the long run may facilitate the development of new treatment methods or new medication. The HKCMM standards may also serve as an international standard for adoption and/or adaptation by other drug regulatory authorities in the control and management of Chinese medicines. Thus the establishment of HKCMM standards would facilitate the modernization and globalization of Chinese medicines, paving the way for Hong Kong to develop into an international centre for Chinese medicines.

Infrastructure in the Development of HKCMM Standards

11. In late 2001, we established the International Advisory Board (IAB) to advise on the principles, methodology, parameters and analytical methods for developing the HKCMM standards. The IAB consists of 12 renowned local, Mainland and overseas (including Australia, Canada, Germany, Japan, Thailand and the United States) experts. Their support helps promote acceptance and recognition by regulatory authorities worldwide of the future HKCMM standards.

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12. The IAB has agreed that the HKCMM standards should cover, among other things, sources and description of herbs, identification methods (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 HKCMM standards are set out at Enclosure 1.

Encl. 1

13. In order to monitor the progress of the research and laboratory work, to work out solutions to technical problems and to examine the work results and findings, a Scientific Committee consisting of visiting IAB Members, representatives of participating universities and research institutions and Government officials has been established. The Committee has already finalized detailed Technical Guidelines on the research and laboratory work for the participating universities.

14. DH will collaborate closely with the Government Laboratory (GL) to make constructive use of its expertise, experience and facilities in Chinese medicine research. The GL will undertake the validation work on research and laboratory findings of the eight herbs.

Latest Development

15. The Chinese University of Hong Kong and Hong Kong Baptist University have been commissioned to conduct the research and laboratory work on eight herbs for completion in the last quarter of 2003. The universities are required to submit periodic progress report of their work. Meetings of the working groups and/or Scientific Committee will be held whenever necessary to discuss technical issues. The IAB will meet annually to examine the available results to be generated and to give general advice on the development of the standards. Upon completion of the necessary work such as drafting of provisional standards and trial run, we shall publish the HKCMM standards in early 2004.

16. With the solid foundation established in the current study, DH is planning to develop HKCMM standards for 60 herbs (inclusive of the eight herbs being studied under the Pilot Study) listed at Enclosure 2. The herbs are selected according to the following criteria –

Encl. 2

(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

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(c) the herbs should be of international concern in respect of their safety and quality.

The development work for the 52 herbs is scheduled to start in 2003, and will complete in 2005-06.

FINANCIAL IMPLICATIONS

17. The implementation of this proposal on regulatory standards requires funding of HK$46.6 million to cover the following costs –

		HK$'000
(a)	Staff cost (4 years):	11,328
(b)	Purchase of herb samples and herbarium specimens	3,000
(c)	Research and laboratory work	24,000
(d)	Meetings of International Advisory Board	
	Air passage	800
	Honorarium/Subsistence allowance	750
	Miscellaneous items	100
	Sub-total	1, 650
(e)	Purchase of equipment and reference materials	
	Storage and office equipment	500
	Reference materials	200
	Sub-total	700
(f)	Meetings of Scientific Committee	
	Air passage	600
	Honorarium/Subsistence allowance	168
	Sub-total	768
(g)	Inter-laboratory validation	1,800
(h)	Trial run of the provisional regulatory standards	600
(i)	Drafting and editing of the regulatory standards	600
(j)	Publication of the regulatory standards in forms of books and compact discs	800
	Total	45,246
(k)	Contingencies (3% of the total) to cover unforeseen expenses	1,360
	Grand-total	**$46,606**
	Say	**$46,600**

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18. As regards paragraph 17(a), the work of regulatory standards cannot be absorbed by existing staff in DH. The Department's Chinese Medicine Division is fully preoccupied with the registration of Chinese medicine practitioners and Chinese proprietary medicines as required by law while other divisions in DH have their own pledges and commitment in the delivery of essential health services. As such, in order to take up additional work and at the same time to maintain the existing provision of service and level of work effectiveness and efficiency, it is necessary to provide a team of seven staff to provide expert support to the project. The detailed breakdown of staff cost is set out at Table 1 of Enclosure 3.

Encl. 3

19. As regards paragraph 17(b), the estimated cost of HK$50,000 per herb is based on the information provided by the Mainland State Drug Administration which is assisting us in the collection of herbs samples and herbarium specimens, as well as identification and certification of the samples. The cost covers execution expenses, labour, the herbs samples and herbarium specimens, transportation, etc.

20. As regards paragraph 17(c), the fee charged by the participating universities for conducting the research and laboratory for each herb will vary depending on the amount of development work involved, the price level of the herb per se and the number of species of herb to be studied. Based on the experience of the Pilot Study, the estimated fee is $400,000 per herb. Details are set out at Table 2 of Enclosure 3.

21. As regards paragraph 17(d) and (f), the honorarium/subsistence allowance payable to members of the IAB and Scientific Committee is comparable to that offered by local research institutions.

22. As regards paragraph 17(e), it is planned that one-third of the herbs samples will be distributed to the participating universities to carry out the research and laboratory work, one-third will be reserved for inter-laboratory validation and the remaining one-third will be kept for future reference. Since herbs will perish easily and quickly if they are not kept properly, it is necessary to procure suitable equipment for proper storage and management of the herbs samples and herbarium specimens.

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23. As regards paragraph 17(g), it is estimated that the amount of validation work is no more than 10% of the research and laboratory work conducted by the participating universities.

24. As regards paragraph 17(h), the estimated cost of $10,000 per herb for the trial run of the provisional HKCMM standards is based on information provided by GL. In the trial run period, samples of herbs collected from retailers and wholesalers on random basis will be put to laboratory tests to see whether the herbs currently on sale in the market can meet the required standards.

25. As regards paragraph 17(i), it is necessary to hire an experienced expert on part-time contract basis to undertake the drafting and editing work of the HKCMM standards. Currently, we do not have expert staff who is experienced to take up the task.

26. As regards paragraph 17(j), the HKCMM standards will be published in forms of books and compact discs for use by concerned and interested parties in the field of Chinese medicine as authoritative reference. DH intends to recover the publication cost by sale of the books and compact discs which is estimated to generate about $0.8 million. Although Government owns the intellectual property rights of the research results, we would encourage the participating universities to publish the findings so as to enhance international recognition of the study and its results. The main returns of having regulatory standards will be the intangible benefits in the enforcement of laws, upgrading the quality and safety standards of herbs for protection of public health and promoting the development of Hong Kong as an international centre of Chinese medicine.

27. The estimated cash flows of the project will be as follows –

Financial year	**$ million**
2001-2002 (actual)	0.7
2002-2003	6.0
2003-2004	20.4
2004-2005	15.5
2005-2006	4.0
Total	46.6

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28. If Members approve the proposal, we shall provide supplementary provision required in 2003-04 under delegated authority, and include provisions required in 2004-05 and 2005-06 in the draft Estimates of these two years.

CONSULTATION

29. We have consulted the Health Services Panel on the proposal to develop regulatory standards for commonly used Chinese medicinal herbs in Hong Kong at its meeting on 10 February 2003. Members have indicated support for the proposal.

BACKGROUND INFORMATION

30. 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 in September 1999 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. The licensing requirements for retailers and wholesalers of herbs focus on the hygienic conditions and facilities in warehouse, shops and factories, and the practising conditions including requirements for proper packaging, labeling, storage and sales records. The safety aspects of Chinese medicines are covered by the Public Health and Municipal Services Ordinance which requires that all drugs for sale shall be fit for human consumption.

31. With the Chief Executive's vision, both DH and the Hong Kong Jockey Club Institute of Chinese Medicine Limited (HKJCICM) have been promoting the development of Hong Kong as an international centre of Chinese medicine although their work has different emphasis. DH concentrates its effort in establishing a viable legal framework for the regulation of Chinese medicine in protection of public health while the HKJCICM aims to spearhead the development of Chinese medicine as a high value added industry for Hong Kong through promotion and coordination of related activities and strategic support for scientific and evidence-based development programmes.

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32. The proposed HKCMM standards will be mainly used for law enforcement and regulation targeting the safety and quality aspects of commonly used herbs in Hong Kong. With this clear objective, DH has been controlling, steering and coordinating this project with the support and collaboration of GL, local / Mainland / overseas universities and research institutions, and international experts. It is anticipated that the regulatory standards will help generate more data and information as well as stimulate more ideas for the further research and development of Chinese medicines and products for the sharing and consideration of the HKJCICM.

Health, Welfare and Food Bureau
February 2003

An Outline Content of HKCMM Standards

1.	Name of Chinese Medicinal Herbs
	a. Official name b. Chinese name c. Chinese phonetic name
2.	Source of Chinese Medicinal Herbs
	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. The time for harvest/collection d. The location of source material e. The preliminary treatment on the spot of collection f. Other related information
3.	Description of the Chinese Medicinal Herbs
	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

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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

Enclosure 2 to FCR(2002-03)64

List of the 60 Target Chinese Medicinal Herbs

1	Cortex Moutan (牡丹皮)	31	Folium Ginkgo (銀杏葉)
2	Cortex Phellodendri (黃柏)	32	Fructus Evodiae (吳茱萸)
3	Radix Angelicae Sinensis (當歸)	33	Fructus Forsythiae (連翹)
4	Radix Astragali (黃芪)	34	Fructus Ligustri Lucidi (女貞子)
5	Radix Ginseng (人參)	35	Fructus Psoraleae (補骨脂)
6	Radix Notoginseng (三七)	36	Herba Andrographitis (穿心蓮)
7	Radix Salviae Miltiorrhizae (丹參)	37	Herba Desmodii Styracifolii (廣金錢草)
8	Rhizoma Alismatis (澤瀉)	38	Herba Ephedrae (麻黃)
9	Radix Platycodi (桔梗)	39	Herba Leonuri (益母草)
10	Processed Radix Aconiti (制川烏)	40	Herba Taxilli (桑寄生)
11	Radix Angelicae Pubescentis (獨活)	41	Medulla Junci (燈心草)
12	Radix Bupleuri (柴胡)	42	Radix Achyranthis Bidentatae (牛膝)
13	Radix Codonopsis (黨參)	43	Radix Aucklandiae (木香)
14	Radix et Rhizoma Rhei (大黃)	44	Radix Glehniae (北沙參)
15	Radix Gentianae (龍膽)	45	Radix Ophiopogonis (麥冬)
16	Radix Glycyrrhizae (甘草)	46	Radix Panacis Quinquefolii (西洋參)
17	Radix Paeoniae Alba (白芍)	47	Radix Polygalae (遠志)
18	Radix Paeoniae Rubra (赤芍)	48	Radix Pseudostellariae (太子參)
19	Radix Polygoni Multiflori (何首烏)	49	Radix Puerariae (葛根)
20	Radix Saposhnikoviae (防風)	50	Radix Rehmanniae (地黃)
21	Rhizoma Chuanxiong (川芎)	51	Radix Scutellariae (黃芩)
22	Rhizoma Coptidis (黃連)	52	Rhizoma Anemarrhenae (知母)
23	Rhizoma et Radix Notopterygii (羌活)	53	Rhizoma Atractylodis Macrocephalae (白朮)
24	Bulbus Fritillariae Thunbergii (浙貝母)	54	Rhizoma Belamcandae (射幹)
25	Bulbus Fritillariae Ussuriensis (平貝母)	55	Rhizoma Cimicifugae (升麻)
26	Caulis Clematidis Armandii (川木通)	56	Rhizoma Curcumae (莪朮)
27	Cortex Eucommiae (杜仲)	57	Rhizoma Gastrodiae (天麻)
28	Cortex Magnoliae Officinalis (厚樸)	58	Semen Cassiae (決明子)
29	Cortex Mori (桑白皮)	59	Semen Vaccariae (王不留行)
30	Flos Magnoliae (辛夷)	60	Spica Prunellae (夏枯草)

Table 1: Staff cost

	Post	Staff Cost (4 years) $ 000’
1.	Senior pharmacist (1)	3,732
2.	Pharmacist / Chemist (2)	2,810
3.	Mainland expert (1)	1,944
4.	Executive officer (1)	1,834
5.	Project assistant (2)	1,008
	Total:	**11,328**

Table 2: Breakdown of work fees on each herb

	Items	Cost ($)
1.	Hiring research personnel for conducting analytic tests to ascertain the quality and safety standards of Chinese medicinal herbs (12 months)	216,000
2.	Consumables including chemical, solvents, gases, chromatographic supplies etc.	100,000
3.	Laboratory supplies including small tools, replacement parts, maintenance, etc.	15,000
4.	Plant materials	3,000
5.	Office supplies, photocopying, and miscellaneous expenses, etc	6,000
6.	Overhead charge (15%) by UGC-funded institutions	60,000
	Total	**400,000**