

立法會
Legislative Council

LC Paper No. CB(2)1286/10-11

Ref : CB2/PL/HS

Paper for the House Committee meeting on 18 March 2011

**Proposal for activation of the Subcommittee on Registration of
Proprietary Chinese Medicines under the Panel on Health Services**

Purpose

This paper invites the House Committee to consider the proposal of the Panel on Health Services ("the Panel") to activate its Subcommittee on Registration of Proprietary Chinese Medicines ("the Subcommittee").

Background

2. The provisions in the Chinese Medicine Ordinance (Cap. 549) ("the Ordinance") related to the mandatory registration of proprietary Chinese medicines ("pCm") have commenced operation since 3 December 2010. The Panel held two special meetings on 17 January and 15 February 2011 to receive views from deputations on the subject. Many deputations have expressed great difficulties, in terms of technical and financial viability, in meeting the requirements for the registration of pCm. They have pointed out the substantial differences between Chinese medicines and Western medicines in terms of their principles and applications as well as trade practices, but the existing regulatory system for Chinese medicines has failed to take into account these differences. The deputations are also disappointed at the lack of support from the Government to assist the trade in meeting the testing requirements for the registration of pCm.

3. While agreeing that mandatory registration of pCm is conducive to safeguarding public health and consumer rights, members of the Panel have expressed grave concern about the lack of transparency and objectivity of the assessment criteria and procedure for the registration of pCm. Members are also dissatisfied with the inadequate support provided by the Government to the trade in meeting the registration

requirements for pCm. They consider it high time to conduct a review on the policy regulating Chinese medicines. To enable more focused discussion, the Panel agreed at its meeting on 14 March 2011 to set up a subcommittee to study the registration of pCm. Information relating to the Subcommittee as regards its terms of reference, work plan and time frame for completion of work is in **Appendix I**.

4. When considering the appointment of the Subcommittee at its meetings on 14 February and 14 March 2011, the Panel has noted Rule 26(a) of the House Rules which provides that the maximum number of subcommittees appointed by the House Committee and Panels to study policy issues that may be in operation at any one time is eight. If the number of such subcommittees has reached eight and new subcommittees have been appointed, a waiting list will be formed. As more than eight subcommittees on policy issues are currently in operation, two subcommittees, namely, the Subcommittee on Retirement Protection and the Subcommittee on Improving Barrier Free Access and Facilities for Persons with Disabilities appointed under the Panel on Welfare Services ("WS Panel"), are already on the waiting list. The House Committee has agreed at its meeting on 21 January 2011 that the former Subcommittee could be activated in late April 2011 and the latter Subcommittee be activated after the Subcommittee on Residential and Community Care Services for Persons with Disabilities and the Elderly under the WS Panel has completed its work. Members have noted that the Subcommittee to study the registration of pCm, if appointed by the Panel, will be placed on the waiting list. Members agreed that the Panel would continue to follow up the subject pending the approval of the House Committee for the activation of the Subcommittee.

Consideration for activation of subcommittees

5. In accordance with Rule 26 of the House Rules, if the number of Bills Committees in operation is less than 16, the House Committee may activate subcommittees on the waiting list after having considered the following –

- (a) the number of vacant slots for Bills Committee;
- (b) the number of bills likely to be introduced in the Council in the next three months;
- (c) the number of subcommittees on subsidiary legislation already or likely to be appointed by the House Committee and by Bills Committees; and

(d) the availability of resources in the Secretariat.

6. The staffing support in Council Business Divisions 1 and 2 can provide service to a total of 56 committees. As at 16 March 2011, the two Divisions are servicing a total of 50 committees including the House Committee, Finance Committee and its two subcommittees, 18 Panels, 12 Bills Committees, 10 subcommittees on policy issues, two other subcommittees under the House Committee and four subcommittees on subsidiary legislation. The Subcommittee on Retirement Protection under the WS Panel will commence its work in late April 2011. The remaining four slots for Bills Committees will shortly be taken up by four of the 14 Bills to be introduced in the coming three months. It is expected that at least eight subcommittees on subsidiary legislation will likely be appointed, making a total of 63 committees operating at the same time in the next three months. A position report on the existing and anticipated number of Bills Committees and subcommittees is in **Appendix II** to facilitate Members' consideration.

7. Given the existing and anticipated heavy workload, the Secretariat will not be able to absorb the servicing of the Subcommittee for the time being. The Secretariat will reassess its coping capacity when any one of the existing subcommittees on policy issues (discounting the Subcommittee on Residential and Community Care Services for Persons with Disabilities and the Elderly) has completed its work and when the number of Bills Committees in operation is less than 16.

8. Members may wish to note that proposals have also been made for the appointment of another two subcommittees to study issues relating to respectively combating poverty and insurance coverage for the transport trade.

Advice sought

9. The House Committee is invited to consider the Panel's proposal on the activation of the Subcommittee in paragraph 4 and the Secretariat's position report in paragraph 7.

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Ref : CB2/PL/HS

Panel on Health Services

**Proposal to appoint a Subcommittee on Registration of
Proprietary Chinese Medicines**

Proposed terms of reference, work plan and time frame

Proposed terms of reference

To review the mandatory registration of proprietary Chinese medicines and the implementation of the relevant provisions in the Chinese Medicines Ordinance (Cap. 549) and the Chinese Medicines Regulations (Cap. 549F).

Proposed work plan

2. The Subcommittee will focus its work on the following major issues –
 - (a) policy on the regulation of proprietary Chinese medicines;
 - (b) progress of the processing of applications for registration of proprietary Chinese medicines; and
 - (c) implementation of the provisions in the Chinese Medicines Ordinance and the Chinese Medicines Regulations relating to the mandatory registration of proprietary Chinese medicines.

Proposed time frame

3. The Subcommittee will, in accordance with Rule 26(c) of the House Rules, complete its work within 12 months of its commencement and report to the Panel on Health Services.

**Existing and anticipated number of Bills Committees and subcommittees
(position as at 16 March 2011)**

<i>Estimated number of Bills Committees ("BCs") within the next three months</i> <i>(a)+(b) = (12 + 14), i.e. 26</i> <i>(The maximum number of BCs in operation is limited to 16; BCs formed exceeding this number will be put on a waiting list)</i>		<i>Estimated number of subcommittees ("SCs") on subsidiary legislation within the next three months</i> <i>(c)+(d) = (4 + 8), i.e. 12</i>		<i>Estimated number of SCs on policy issues / other SCs under House Committee ("HC") within the next three months</i> <i>(e)+(f) = (12 + 3), i.e. 15</i>	
BCs <i>(Maximum number in operation: 16)</i>		SCs on subsidiary legislation <i>(Notional maximum number : 2)</i>		SCs on policy issues/other SCs under HC <i>(Maximum number of SCs on policy issues : 8)</i>	
(a) BCs in action	(b) BCs expected to be formed in the next three months	(c) SCs on subsidiary legislation in action	(d) Subsidiary legislation expected to be gazetted in the next three months and on which SCs are expected to be formed	(e) SCs on policy issues/other SCs under HC in action	(f) SCs on the waiting list
Total : 12	14	Total : 4	8	Total : 12	4
Please refer to List A of the Position Report on Bills Committees and subcommittees (the Position Report) (LC Paper No. CB(2) 1278/10-11) for details of the BCs.	(i) Bills on the 2010-2011 Legislative Programme	1. SC on Securities and Futures Ordinance (Amendment of Schedule 5) Notice 2011 and Securities and Futures (Financial Resources) (Amendment) Rules 2011 2. SC on Public Revenue Protection (Dutiable Commodities) Order 2011 3. SC on Public Revenue Protection (Motor Vehicles First Registration Tax) Order 2011 4. SC on Mutual Legal Assistance in Criminal Matters (India) Order	1. Public Light Bus (Limitation on Number) Notice made under section 23(3) of the Road Traffic Ordinance (Cap. 374) 2. Subsidiary legislation relating to the Chief Executive Election and the Legislative Council Election in 2012 3. Subsidiary legislation to give effect to adjustment in the fares for the hiring of urban, New Territories and Lantau taxis 4. Subsidiary legislation to introduce amendments to the Fisheries Protection Regulations to ban trawling activities in Hong Kong waters 5. Revised Code of Practice on Employment under the Disability Discrimination Ordinance 6. Subsidiary legislation to implement the recommendations arising from the five-yearly review of the criteria for	(i) SCs on policy issues under HC	1. SC on Retirement Protection under the Panel on Welfare Services (HC agreed at its meeting on 21 January 2011 that the SC be activated in three months' time.) 2. SC on Improving Barrier Free Access and Facilities for Persons with Disabilities under the Panel on Welfare Services (HC agreed at its meeting on 21 January 2011 that the SC be activated after the SC on Residential and Community Care Services for Persons with Disabilities and the Elderly under the Panel on Welfare
	Of the 15 bills in the Administration's 2010-2011 updated Legislative Programme which have not yet been introduced into the Legislative Council, 13 BCs are expected to be formed in the next three months on the following Bills :			(ii) SCs on policy issues under Panels	
	1. Copyright (Amendment) Bill 2. Pyramid Selling Prohibition (Amendment) Bill 3. Trade Descriptions (Amendment) Bill 4. Electoral Arrangements (Miscellaneous Provisions) Bill 2011 5. Lifts and Escalators Bill 6. Fisheries Protection (Amendment) Bill 7. A bill to improve the regulatory regime for the financial market 8. Guardianship of Minors (Amendment) Bill			(iii) Others SCs under HC	

	<p>9. Protection of Wages on Insolvency (Amendment) Bill</p> <p>10. Immigration (Amendment) Bill 2011</p> <p>11. Road Traffic (Amendment) Bill</p> <p>12. Road Traffic (Amendment) (No. 2) Bill</p> <p>13. Enduring Powers of Attorney (Amendment) Bill</p> <p style="text-align: right;">Sub-total : 13</p> <hr/> <p>(ii) Members' Bill</p> <p>The Hong Kong Polytechnic University (Amendment) Bill 2011</p> <p style="text-align: right;">Sub-total : 1</p>		<p>assessing the financial eligibility of legal aid applicants</p> <p>7. Subsidiary legislation to revise the minimum and maximum levels of relevant income for Mandatory Provident Fund contributions</p> <p>8. Subsidiary legislation to implement proposals for expanding the Supplementary Legal Aid Scheme</p>		<p>Services has completed its work.)</p> <p>3. SC on Registration of Proprietary Chinese Medicines under the Panel on Health Services</p> <p>4. SC to study the subject of poverty alleviation (Subject to approval of its appointment)</p>
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