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M E M O

To : Clerk to Panel on Health Services

From : Clerk to Bills Committee on Chinese Medicine (Amendment) Bill 2017

Our Ref : CB2/BC/6/16

Date : 29 March 2018

Bills Committee on Chinese Medicine (Amendment) Bill 2017

Referral to the Panel on Health Services

The Bills Committee on Chinese Medicine (Amendment) Bill 2017 has completed the scrutiny of the Bill and reported its deliberations to the House Committee.

2. In the course of scrutinizing the Bill, members are advised that the Administration is exploring amendments to the definition of proprietary Chinese medicines ("pCm") in the Chinese Medicine Ordinance ("the Ordinance") (Cap. 549) so as to strengthen the regulation. While agreeing with the need to introduce amendments to the definition of pCm, members have urged for a holistic review of the Ordinance within the term of the Sixth Legislative Council. The Administration has advised that it would need to further discuss with the Chinese medicine industry to understand the stakeholders' views on the current provisions of the Ordinance before a concrete timetable could be drawn up for a review of the Ordinance. The Bills Committee has requested the Administration to revert to the Panel on Health Services on the way forward in this regard.

3. An extract of the relevant parts of the report of the Bills Committee is attached.

(Maisie LAM)
CCS(2)5

Encl.

Extract from the report of the Bills Committee on Chinese Medicine (Amendment) Bill 2017

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9. Members are in principle supportive of the legislative proposal to confer power on the Director to make a CMSO to prohibit the sale of a Chinese medicine or related product and/or to recall such product in specified circumstances in order to further protect public health. They note that under the proposed new section 138A of the CM Ordinance, Chinese medicine or related product means a Chinese herbal medicine or a pCm (as currently defined in the CM Ordinance), or an intermediate product (the definition of which is proposed to be amended in the Bill[7]). Some members including Mr CHAN Han-pan, Dr KWOK Ka-ki and Mr SHIU Ka-fai have pointed out that registration of pCm is subject to a set of stringent registration requirements in respect of the safety, quality and efficacy of the product concerned. They are, however, concerned about the public health risk that might arise from the various orally consumed products composing mainly of Chinese herbal medicines but added other materials or substances (e.g. vitamins) as active ingredients being sold in the market and bottled drinks containing Chinese herbal medicines, such as Spica Prunellae bottled drinks or herbal teas claiming to have heat-clearing effect. Members note that these products are currently not regulated under the CM Ordinance and, if the Bill is passed, would not be subject to CMSO as they do not fall within the definition of pCm under the CM Ordinance.

10. The Administration has advised that the Public Health and Municipal Services Ordinance (Cap. 132) provides general protection for purchasers of food and drugs that do not fall within the definition of pCm under the CM Ordinance but fulfill the definition of "food" under the Public Health and Municipal Services Ordinance.[8] This apart, the labels and advertisements of products with health claims are regulated by the Undesirable Medical Advertisements Ordinance (Cap. 231), whereas the claims of health products are subject to the regulation of the Trade Descriptions Ordinance (Cap. 362). Separately, business operations involving the preparation of bottled drinks or

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[7] Please see paragraphs 14 and 15 below for details.

[8] Under the Public Health and Municipal Services Ordinance, "food" includes drink; ice; chewing gum and other products of a similar nature and use; smokeless tobacco products; and articles and substances used as ingredients in the preparation of food, but does not include live animals or live birds, other than live aquatic products; fodder or feeding stuffs for animals, birds or aquatic products; or medicine as defined by section 2(1) of the Pharmacy and Poisons Ordinance (Cap. 138) or Chinese herbal medicine or pCm as defined by section 2(1) of the CM Ordinance.

herbal teas are required to obtain the relevant food factory licences or restricted food permits from the Director of Food and Environmental Hygiene under the existing legislation. Applicants for the relevant licences or permits are required to submit to the Food and Environmental Hygiene Department ("FEHD") the formula of each type of herbal tea containing Chinese medicines ingredients to be sold on the premises and the dosage of each ingredient in the formula. FEHD will send the information to the Department of Health ("DH") for vetting to ensure that the formulae of these products are safe for human consumption. As at the end of December 2017, there were 398 valid Chinese Herb Tea Permits issued by FEHD. In 2017, the Centre for Food Safety took eight samples in these permitted premises for testing of plasticisers, pathogens, etc. All testing results were satisfactory.

11. Members have enquired about whether a licensed pCm manufacturer could manufacture health products (i.e. non-pCm products) in their licensed premises. According to the Administration, a pCm manufacturer licence only authorizes its holder to conduct the business of manufacturing pCms in the premises specified. A licensed pCm manufacturer who plans to manufacture non-pCm products in the licensed premises should make a declaration to CMB and provide objective justifications for the measures taken to prevent cross contamination as well as the effectiveness of these measures in order to ensure that the Chinese medicine products manufactured therein will be free from contamination.

12. The Administration has informed the Bills Committee that notwithstanding the safeguards set out in paragraphs 10 and 11 above, it is exploring amendments to the definition of pCm in the CM Ordinance so as to strengthen the regulation. CMB under CMCHK has established a working group, which comprises Chinese medicine experts, Chinese medicines industry representatives and representative from the Government Laboratory, to examine the issue and provide advice on the way forward. Subject to the recommendations to be made by the working group and the view of CMB, extensive consultations would be conducted on any proposed amendments to the definition of pCm in the CM Ordinance. The Administration would, as and when appropriate, propose the relevant legislative amendments in a separate legislative exercise.

13. While agreeing with the need to amend the definition of pCm in the CM Ordinance to cast the net wider for the protection of public health, some members including the Chairman, Mr CHAN Han-pan, Dr Helena WONG and Mr SHIU Ka-fai have urged for a holistic review of the CM Ordinance within the term of the Sixth Legislative Council. In particular, Mr CHAN Han-pan considers that there is an imminent need to introduce more classification categories of pCms with different levels of safety and quality

testing requirements. The Administration has advised that it would need to further discuss with the Chinese medicine industry to understand the stakeholders' views on the current provisions of the CM Ordinance before a concrete timetable could be drawn up for a review of the CM Ordinance. In view of members' strong views, the Administration has undertaken that it would keep the Panel on Health Services informed of the way forward in this regard.

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Follow-up actions by the Administration

52. The Administration has undertaken to study if a comprehensive review of the CM Ordinance should be conducted and inform the Panel on Health Services of the way forward in this regard (paragraph 13 refers).

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Council Business Division 2
Legislative Council Secretariat
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