

## **Consultation Document**

### **Proposal to amend the Chinese Medicine Ordinance to empower the Director of Health to direct a person to recall Chinese herbal medicine or proprietary Chinese medicine which may pose threats to public health**

#### **Introduction**

This document seeks the community's views on a proposal for empowering the Director of Health ("the Director") to direct a person to recall Chinese herbal medicine ("Chm") or proprietary Chinese medicine ("pCm") which may pose threats to public health.

#### **Background**

2. The Chinese Medicine Ordinance (Cap. 549) ("the Ordinance") was passed by the Legislative Council on 14 July 1999. The aims of the regulatory system for Chinese medicine established under the Ordinance are to enhance the protection of public health, accord a professional status for Chinese medicine practitioners and ensure the safety, quality and efficacy of Chinese medicines. The Ordinance provides for the regulatory system for Chinese medicine practitioners, which includes registration, examination and discipline of Chinese medicine practitioners; and the regulatory system for Chinese medicines, which includes licensing and regulation of Chinese medicines traders and registration of pCm. In addition, the Ordinance contains Schedule 1 of 31 types of potent/toxic Chm and Schedule 2 of 574 types of Chm.

3. The Chinese Medicine Council of Hong Kong ("the Council") is an independent statutory body established under the Ordinance. The Chinese Medicines Board set up under the Council is responsible for formulating and implementing various regulatory measures for Chinese medicines, and the Department of Health ("DH") is responsible for carrying out relevant regulatory measures.

4. According to the Ordinance, Chinese medicines traders who wish to conduct a business in the retail of Chm, wholesale of Chm, wholesale of pCm or manufacture of pCm shall first obtain a licence issued by Chinese Medicines Board. The DH conducts regular inspections to the premises of licensed Chinese medicines traders. To monitor the quality and safety of the Chinese medicines, the DH has put in place a market surveillance system under which samples of Chm and pCm would be collected from the market for testing on a regular basis. To safeguard public health, the DH has also established a mechanism for reporting adverse incidents relating to Chinese medicines to collate information through various channels, so as to conduct risk assessment, management and reporting. If any substandard Chinese medicines are found, the DH may take actions such as requesting the Chinese medicines traders concerned to recall the products and referring the cases to the Council for follow-up actions, and carry out risk communication by issuing relevant press statements.

5. The Chinese Medicines Regulation (Cap. 549F) is a subsidiary legislation of the Ordinance. It stipulates that wholesalers of Chm, wholesalers and manufacturers of pCm shall set up and maintain a recall system to enable the rapid, so far as practicable, complete recall of any Chm or pCm sold or distributed by them in the event that the product is found to be dangerous, injurious to health or unfit for human consumption. However, there is no provision under the Ordinance or its subsidiary legislations that the concerned person must carry out recall action regarding a Chm or pCm which may pose threats to public health, such as Chm which has been distributed without licence or unregistered pCm that the safety, quality or efficacy has not been proven. Therefore, the public health would be at risk if such Chinese medicine has not been recalled from the market in a systematic and effective manner.

### **Regulation of the Mainland and Overseas Countries**

6. There are regulations put in place in the Mainland and some overseas countries with respect to recall of medicines to ensure the safety in the administration of medications for public. In the Mainland, the China Food

and Drug Administration enacted the regulation governing drug recall in December 2007 which provides that when a drug manufacturer fails to initiate a recall of a drug which has safety concerns, the regulatory agency may order the concerned company to recall the drug. In Australia, the Therapeutic Goods Act 1989 was amended in May 2003 to include recall provisions for medicines which do not conform to applicable standards, unregistered medicines and medicines produced by unlicensed manufacturer. In Canada, the Food and Drugs Act was also amended in November 2014 regarding therapeutic products in order to protect public health and safety. The regulatory agency may order a person, who fails to voluntarily carry out a recall action, the removal of a therapeutic product from the market when a product presents an imminent or serious risk to health.

### **The Proposed Amendments**

7. Having reviewed the comparable drug regulations in the Mainland and overseas countries, to better protect public health, we propose amending the Ordinance to empower the Director to make a Chinese Medicine Safety Order (“Safety Order”) for immediate withdrawal of Chm or pCm from being supplied or the recall of such Chm or pCm already supplied to the extent reasonably possible. The Director should have reasonable cause to believe that such Chm or pCm may pose threats to public health at the time of making the Safety Order.

8. We propose setting out the manner of making and serving the Safety Order to facilitate an understanding of the operation detail across the trade.

9. We suggest that a person who is bound by a Safety Order and fails or refuses to comply with any requirements set out in the Safety Order commits an offence, and is liable to a fine at level 6 (\$100,000) and to imprisonment for 2 years. The proposed penalty is the same as the existing penalty for not complying with other offences under the Ordinance.

10. To ensure the fair and just handling of all cases, we propose introducing an appeal mechanism. A person bound by a Safety Order may appeal against a decision of the Director.

11. The making of this amendment to the Ordinance is in the common interest of the industry, the Government and the consumers. According to past record, the majority of medicines traders are willing to recall Chinese medicine products which may pose a health threat in a systematic and effective manner to safeguard public health. Therefore, the DH will make a Safety Order only when necessary.

12. To ensure the safety in the administration of medications for public, we preliminarily plan to introduce a bill to amend the legislation in mid-2017.

### **Views Sought**

13. We would like to invite your views and comments on the above proposed amendments. Please send us your views and comments on or before 26 February 2017:

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