



中華人民共和國香港特別行政區政府總部食物及衛生局
Food and Health Bureau, Government Secretariat
The Government of the Hong Kong Special Administrative Region
The People's Republic of China

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22 March 2017

Ms Maisie LAM
Clerk to Panel
Legislative Council Panel on Health Services
Legislative Council Complex
1 Legislative Council Road
Hong Kong
(Fax : 2185 7845)

Dear Ms LAM,

Legislative Council Panel on Health Services

**Motion passed in relation to the Administration's proposal to amend
the Chinese Medicine Ordinance to confer power on
the Director of Health to issue recall order**

We refer to the discussions on the captioned subject at the meeting of the Legislative Council Panel on Health Services (the Panel) held on 28 February 2017. We thank the Panel for supporting in principle the Administration's legislative proposal. In response to the suggestions raised by Members at the meeting regarding the drafting of the legislative amendments, our reply is as follows.

To facilitate the trade to understand the legislative proposal, the Department of Health (DH) already conducted a series of briefings and consultations, including meeting with 16 Chinese medicines traders

associations and six briefing sessions for individual licensed Chinese medicines traders on the proposed legislative amendments in January 2017, and promulgating the consultation document in the websites of the Chinese Medicine Council of Hong Kong, the Chinese Medicine Division of the DH and the Business Consultation e-Platform of GovHK to gather opinion from the public and the trade. The consultation period ended on 26 February 2017. As revealed from the comments received, the public and the trade generally support the legislative proposal. The Administration will take into consideration their views and comments in finalising the proposal and preparing the legislative amendments.

On 27 February 2017, the DH also received a letter jointly signed by seven Chinese medicines traders associations. They supported in principle the proposed legislative amendments, while expressing their concerns on the matter. In this regard, the DH met with the representatives of the said associations and their members again on 2 March 2017. During the meeting, the associations indicated that they will cooperate with the DH and actively carry out recall when there is a problematic product being identified. The DH also shared with the industry that according to past records, traders were able to recall, in a systematic and effective manner, Chinese medicine products which might pose health threats. The DH also explained in detail the operating procedures of recall action and stressed that there is no procedural difference between the recall action in future and the existing recall system established by the trade.

The Administration should provide sufficient time for the trade to recall the products concerned when issuing a recall order

According to the Chinese Medicines Regulation (Cap. 549F), licensed wholesalers of Chinese herbal medicines (Chm), licensed manufacturers of proprietary Chinese medicines (pCm) and licensed wholesalers of pCm are required to set up and maintain a system of recall of Chm or pCm. This is to enable rapid and complete recall of, as far as practicable, any pCm or Chm sold or distributed by the traders concerned in the event that the pCm or Chm concerned are found to be dangerous, injurious to health or unfit for human consumption.

To minimise the risk posed by the problematic products, recalls are usually carried out as fast as practicable. Each recall action is considered as an independent exercise. When issuing a recall order, the DH will ensure adequate communication with the concerned trader. In deciding the appropriate manner of recall, there are a number of factors to be considered,

including the nature of the problem and sales networks. The problematic product should also be assessed on whether it would, when used by or in contact with human beings, cause short-term, curable or minor health problems, or cause severe adverse effect on human bodies, or even lead to death.

When a recall action is carried out, the concerned trader is advised to have sufficient communicate and cooperate with the DH so that the problematic Chinese medicine product can be recalled effectively and rapidly. This will ensure the quality and safety of the Chinese medicine products available in the market, thus safeguarding public health.

The Administration should specify that the criterion “to the extent reasonably possible” is only applicable to the recall of products that have already been supplied

The Administration proposes amending the Chinese Medicine Ordinance (Cap. 549) to empower the Director of Health (the Director) to make decision to order any person who has supplied Chm or pCm to recall such Chinese medicines product from the market, should the Director has reasonable cause to believe that the Chm or pCm may pose threats to public health. The proposed legislative amendments have already set out the concerned person should recall the Chm or pCm supplied in the market, and withdraw the same from being supplied.

The Administration should appropriately lower the penalty as the current penalty of a fine of \$100,000 and imprisonment for two years is too harsh

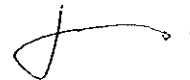
The Administration proposes a person who is bound by a recall order and fails or refuses to comply with any requirements set out in the recall order commits an offence, and is liable to a fine at level 6 (i.e. \$100,000) and to imprisonment for 2 years. The aforementioned is the maximum penalty.

Considering that a lenient penalty may not be able to achieve sufficient deterrent effect, the Administration has made reference to the existing penalties under the Chinese Medicine Ordinance in formulating the proposal. The aforementioned penalty is the same as the existing maximum penalties for not complying with other regulations for Chinese medicines under the Chinese medicine Ordinance. As indicated in paragraph 12 of LC Paper No. CB(2)859/16-17(06) submitted to the Panel on 28 February 2017, to ensure the fair and just handling of all cases, we propose introducing an appeal mechanism. A person bound by a recall order may appeal against the decision

of the Director.

We thank Members of the Panel for their attention to this matter.

Yours sincerely,



(Mr James LAM)
for Secretary for Food and Health

c.c. Director of Health
(Attn: Assistant Director (Traditional Chinese Medicine))