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Legislative Council Panel on Health Services

Legislative Proposal for Conferring Power on the Director of Health to issue Recall Order under the Chinese Medicine Ordinance

PURPOSE

This paper briefs Members on the legislative proposal for conferring power on the Director of Health ("the Director") under the Chinese Medicine Ordinance (Cap. 549) ("the Ordinance") to make decision to order any person to recall from the market any proprietary Chinese medicine ("pCm") or Chinese herbal medicines ("Chm") under specified circumstances.

BACKGROUND

Existing Regulation

2. The Ordinance and its subsidiary legislation provide a legal framework for the regulation of practice, use, trading and manufacturing of Chinese medicine in Hong Kong. Based on the principle of professional self-regulation, the Chinese Medicine Council of Hong Kong ("CMCHK") has been established under the Ordinance to develop and implement these regulatory measures. Chinese Medicine Practitioners Board and Chinese Medicines Board ("CMB") have been set up under the CMCHK to assist the latter in pursuing its statutory functions.

3. Under section 119 of the Ordinance, all pCms must be registered by the CMB before they can be imported, manufactured or sold in Hong Kong. To be registered in Hong Kong, a pCm must fulfill the requirements regarding safety, quality and efficacy as prescribed by the CMB.

4. The Ordinance also stipulates that all Chinese medicines traders engaging in the retail and wholesale of Chm specified in Schedule 1 or 2 to the Ordinance, or the manufacture and wholesale of pCms are required to obtain the relevant Chinese medicines traders licence from the CMB before starting their business in Hong Kong.

5. According to regulations 11(i), 16(q) and 20(g) of the Chinese Medicines Regulation (Cap. 549F) , licensed wholesalers of Chm, licensed manufacturers of pCms and licensed wholesalers of pCms 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.

The Need for Amending the Legislation

6. On 27 March 2014, the Department of Health ("DH") instructed a licensed wholesaler of pCms to recall two unregistered pCms from the market on the grounds that the use of unregistered pCms may pose threats to public health as their safety, efficacy and quality have not been proven. The wholesaler concerned subsequently applied for leave to challenge by way of judicial review the decision of the Director to issue the instruction to recall on 27 March 2014. Leave was then granted.

7. The judgment of the judicial review handed down by the Court of First Instance, High Court, on 21 May 2015[1] concluded that there was no lawful power under the Ordinance for the Director to instruct the wholesaler concerned to recall the two unregistered pCms in question on

[1] Man Hing Medical Suppliers (International) Ltd v. The Director of Health and Another [2015] 3 HKLRD 224

27 March 2014 and that the decision to issue the instruction to recall was made without lawful power and thus ultra vires.

8. Despite the fact that relevant licensed traders of Chinese medicines have already been required by law to set up and maintain a system of recall of Chm or pCm (see paragraph 5 above), the judgement of the above judicial review points out that the Director does not have the statutory power to make decision on recalling pCms or Chm from the market. The Administration has also reviewed the Ordinance and found that there is currently no provision under the Ordinance or its subsidiary legislation that an unlicensed trader must carry out recall action regarding Chm or pCm which may pose threats to public health, such as Chm which has been distributed without licence as well as unregistered pCm being distributed etc.. In view of the foregoing lacuna in the Ordinance, the Administration considers it necessary to amend the Ordinance and its subsidiary legislation to strengthen the control by conferring statutory power on the Director to order any person to recall from the market any pCm or Chm which may pose threats to public health.

PROPOSED LEGISLATIVE AMENDMENTS

9. The Administration has researched into the legislation and regulatory regime in the Mainland and some overseas countries, including Canada and Australia, and found that there are regulations put in place in the Mainland and those 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 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 issue a statutory recall order to a person who refuses to

voluntarily recall from the market a therapeutic product which presents an imminent or serious risk to health.

10. Having reviewed the relevant drug regulations of the Mainland and overseas countries and considered the judgment (see paragraph 7 above) of the judicial review handed down by the Court of First Instance, High Court, for the purpose of further safeguarding public health, the Administration proposes amending the Ordinance to empower the Director to make decision to order any person (regardless of whether he/she is a licensed trader under the Ordinance or not) who has supplied Chm, pCm and/or intermediate product generated in the course of manufacturing a pCm ("intermediate product") to recall Chm, pCm and/or intermediate product from the market and to withdraw the same from being supplied should the Director has reasonable cause to believe that such Chm, pCm and/or intermediate product may pose threats to public health at the time of making the recall decision.

11. The proposed legislative amendments will set out the manner respectively relating to making and serving Chinese medicine recall order with a view to facilitating the trade to understand their responsibility and the operation details of the recall. Regulations 11(i), 16(q) and 20(g) of the Chinese Medicines Regulations will also be amended to the effect that the licensed traders of Chinese medicines concerned are required to set up and maintain a system of recall under the circumstances based on which a recall decision is made by the Director.

12. We suggest that 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 penalty is the same as the existing penalty for not complying with other regulations under the Ordinance. 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.

IMPLICATIONS OF THE PROPOSAL

Benefits to the Public

13. The proposed amendments to the Ordinance are in the common interest of the industry, the Government and the consumers. A systematic, swift and effective manner to recall Chinese medicine products which may pose health hazard to the public is in the best interest of members of the public.

Impact on the Industry

14. Relevant licensed traders of Chinese medicines have already been required under the Ordinance to set up and maintain a system of recall of Chm or pCm, as the case may be. According to past records, majority of licensed medicines traders are co-operative and willing to recall Chinese medicine products in a systematic and effective manner to protect public health. Therefore, the proposed legislative amendments which empower the Director to make a recall decision would not impose additional compliance burden to licensed traders. Moreover, to ensure the decision to recall is made in a justifiable manner, the legislative amendments will specify conditions under which the Director is empowered to make a recall order.

CONSULTATION

15. In January 2017, the DH has conducted a meeting with 16 Chinese medicines traders associations and 6 sessions of briefing forums for licensed Chinese medicines traders on the proposed legislative amendments. The comments received indicated general support for the legislative proposal. The DH has also commenced a public consultation exercise on the proposed legislative amendments which will last until 26 February 2017. The Administration will take into consideration their views and comments when finalising the proposal and preparing the necessary legislative amendments.

PROPOSED WAY FORWARD

16. The Administration plans to introduce the relevant legislative amendments into the Legislative Council in the current legislative session.

ADVICE SOUGHT

17. Members are invited to note and comment on the content of this paper.

Food and Health Bureau
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