

立法會
Legislative Council

LC Paper No. CB(2)859/16-17(08)

Ref : CB2/PL/HS

Panel on Health Services

**Information note prepared by the Legislative Council Secretariat
for the meeting on 28 February 2017**

**Legislative proposal for conferring power on the Director of Health
to issue recall order under the Chinese Medicine Ordinance (Cap. 549)**

The Chinese Medicine Ordinance (Cap. 549) ("the Ordinance"), enacted in July 1999, provides a statutory framework for the regulation of the practice, use, trading and manufacturing of Chinese medicines in Hong Kong. Based on the principle of professional self-regulation, the Chinese Medicine Council of Hong Kong ("CMCHK") is established under the Ordinance to, among others, develop and implement these regulatory measures. The Chinese Medicines Board set up under CMCHK is responsible for regulatory measures regarding proprietary Chinese medicine ("pCm").

2. As stipulated under section 2 of the Ordinance, pCm is defined as any proprietary product:

- (a) composed solely of the following active ingredients:
 - (i) any Chinese herbal medicines; or
 - (ii) any materials of herbal, animal or mineral origin customarily used by the Chinese; or
 - (iii) any medicines and materials referred to in subparagraphs (i) and (ii) respectively;
- (b) formulated in finished dose form; and

- (c) known or claimed to be used for the diagnosis, treatment, prevention or alleviation of any disease or any symptoms of a disease in human being, or for the regulation of the functional states of the human body.

3. Under the Ordinance, all products fall within the definition of pCm must be registered before they can be imported, manufactured or sold in Hong Kong. To get registered in Hong Kong, a pCm must fulfill the registration requirements regarding safety, quality and efficacy as prescribed by the Chinese Medicine Board. Separately, all Chinese medicines traders who engage in a business of retail and wholesale of Chinese herbal medicines, or manufacture or wholesale of pCms are required under the Ordinance to obtain the relevant Chinese medicines traders licence from the Chinese Medicines Board before the commencement of their business.

4. Following an investigation into a complaint concerning the sale of suspected unregistered pCms, the Director of Health ("the Director") instructed on 27 March 2014 the licensed wholesaler of pCms concerned to recall from consumers two suspected unregistered pCms. The public announcement issued by the Administration on the same day stating that the wholesaler concerned was ordered by the Director to recall the products is in the **Appendix**. The pCm wholesaler had complied with the instruction to recall and recalled the products from the market, but also applied for leave to challenge by way of judicial review the Director's decisions to (a) issue the instruction to recall on 27 March 2014; (b) issue the public announcement; and (c) refuse to revoke or recall the instruction to recall and to return the retained suspected unregistered pCms. The judgment handed down by the Court of First Instance on 21 May 2015 concluded that the Director's decisions were made without lawful power and thus ultra vires.

5. According to the Administration, given the lacuna in the law that the Director has no lawful power to issue recall order, it is necessary to amend the Ordinance to strengthen the legislative control by conferring statutory power on the Director to order any relevant person to recall from the market any product or substance presented as pCm or Chinese herbal medicine which may pose threats to public health. The Administration's plan is to introduce the Chinese Medicine (Amendment) Bill into the Legislative Council in the second half of the 2016-2017 legislative session.

6. On 27 January 2017, the Administration launched a one-month public consultation on the legislative proposal. The consultation period will end on 26 February 2017.

7. The Administration will brief the Panel on Health Services on the legislative proposal on 28 February 2017.

Council Business Division 2
Legislative Council Secretariat
22 February 2017

Press Releases 27 March 2014

Recall of two unregistered proprietary Chinese medicines (with photo)

The Department of Health (DH) today (March 27) instructed a licensed wholesaler of proprietary Chinese medicines (pCms), Man Hing Medical Suppliers (International) Ltd, located at 13/F, So Hong Commercial Building, 41-47 Jervois Street, Central, Hong Kong, to recall from consumers two suspected unregistered pCms, namely RYUKAKUSANDIRECT Stick Peach Flavor and RYUKAKUSANDIRECT Stick Mint Flavor.

The appeal followed the DH's investigation into a complaint related to the above pCms. Preliminary investigation by the DH revealed that both pCms were imported from Japan by Man Hing for sale in Hong Kong and have not been registered with the Chinese Medicine Council of Hong Kong (CMCHK).

"The use of unregistered pCms may pose threats to public health as their safety, efficacy and quality have not been proven. While the DH's investigation is ongoing, no related adverse reports have been received so far. Man Hing has set up a hotline at 2544 8005 for related enquiries. The DH will closely monitor the recall," a DH spokesman explained.

"According to Section 119 of the Chinese Medicine Ordinance (Cap 549), no person shall sell, import or possess any pCm unless the pCm is registered. The maximum penalty is \$100,000 and two years' imprisonment. Upon completion of the investigation, the DH will work with the Department of Justice on prosecution matters. The DH will also refer this case to the CMCHK for consideration of possible disciplinary action," the spokesman added.

The spokesman urged members of the public who have purchased the unregistered pCms to stop using them immediately and submit the products to the Chinese Medicine Division of the DH on 16/F, AIA Kowloon Tower, Landmark East, 100 How Ming Street, Kwun Tong, during office hours for disposal. They should consult health-care professionals if they feel unwell.

Members of the public may visit the website of the CMCHK (www.cmchk.org.hk/pcm/eng/#main_dis.htm) for the list of registered pCms.

Ends/Thursday, March 27, 2014
Issued at HKT 19:05

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