立法會
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Paper for the House Committee Meeting
on 16 June 2017

Legal Service Division Report on
Chinese Medicine (Amendment) Bill 2017

I. SUMMARY

1.	**The Bill**	(a) The Bill seeks to amend the Chinese Medicine Ordinance (Cap. 549) and its subsidiary legislation by empowering the Director of Health ("Director") to issue a Chinese medicine safety order ("CMSO") to prohibit the sale or supply of Chinese medicines or related products or to recall such products if the Director believes that they are dangerous or injurious to health, are unfit for use by human beings, or pose a danger to public health. (b) A CMSO would be subject to variation or revocation by the Director, and subject to appeal to the Court of First Instance. (c) Any person who fails or refuses to comply with a CMSO would commit an offence and be liable to a fine at level 6 (i.e. $100,000) and to imprisonment for two years.
2.	**Public Consultation**	The Director conducted a seven-week public and trade consultation from January to February 2017 on the legislative proposal. The public and trade supported the proposal.
3.	**Consultation with LegCo Panel**	The Panel on Health Services was consulted on 28 February 2017. Members generally supported the legislative proposal but expressed certain concerns.
4.	**Conclusion**	Our scrutiny of the Bill is continuing. As the Bill seeks to confer new powers on the Director to direct the recall of Chinese medicines or related products, Members may wish to form a Bills Committee to study the Bill in detail.

II. REPORT

The date of First Reading of the Bill is 14 June 2017. Members may refer to the Legislative Council ("LegCo") Brief (File Ref.: FHB/H/24/24) issued by the Food and Health Bureau on 31 May 2017 for further details.

Object of the Bill

2. The Bill seeks to amend the Chinese Medicine Ordinance (Cap. 549) and its subsidiary legislation by empowering the Director of Health[1] ("Director") to issue a Chinese medicine safety order ("CMSO") to prohibit the sale or supply of Chinese medicines or related products or to recall such products if they are believed to be dangerous or injurious to health or unfit for use by human beings, or to pose a danger to public health.

Background

3. Cap. 549 establishes a statutory regime for, among others, the licensing of Chinese medicine traders and the registration of proprietary Chinese medicines[2] ("pCm"). Under section 146(2)(c) and (f) of Cap. 549, an inspector authorized by the Director may seize, remove and detain any article or pCm in connection with a relevant offence or in contravention of specified sections under Cap. 549. Under section 20(g) of the Chinese Medicines Regulation (Cap. 549F), a licensed wholesaler in pCm must set up and maintain a system of control to enable the rapid and, so far as practicable, complete recall of any pCm sold or distributed by him in the event that the pCm is found to be dangerous, injurious to health or unfit for human consumption.

4. In *Man Hing Medical Supplies (International) Ltd v Director of Health* [2015] 3 HKLRD 224, the Court of First Instance ("CFI") held that the Director had no implied power to instruct a licensed wholesaler to recall pCm under the aforesaid sections of Cap. 549 and Cap. 549F. Upon a review of Cap. 549 and its subsidiary legislation, the Administration has also found that there is at present no provision that an unlicensed trader must, as directed by the Director, recall any Chinese herbal medicine[3] ("Chm") or pCm which may pose threats to public health.

Provisions of the Bill

5. The Bill seeks to address the above lacuna by amending Cap. 549 and its subsidiary legislation to confer statutory powers on the Director to order any person to recall from the market any pCm or Chm which may pose threats to public health.

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1 Under section 2(1) of Cap. 549, "Director" also includes a Deputy Director of Health.

2 Under section 2(1) of Cap. 549, "proprietary Chinese medicine" includes any proprietary product composed of any Chinese herbal medicines or any materials of herbal, animal or mineral origin customarily used by the Chinese, formulated in a finished dose form, and known or claimed to be used for the diagnosis, treatment, prevention or alleviation of any human disease or symptom, or for the regulation of the functional states of the human body.

3 "Chinese herbal medicine" means any of the substances specified in Schedule 1 or 2 to Cap. 549.

Meaning of "Chinese medicine or related product" (clause 4 – new section 138A)

6. Clause 4 seeks to add a new Part XIVA to Cap. 549. Under the new section 138A, "Chinese medicine or related product" ("Product") would mean a Chm, a pCm or an "intermediate product" which is in turn defined as a substance or compound that is generated in the course of manufacture of a pCm and that is intended for use in the further preparation or production process of the medicine.

Chinese medicine safety order (clauses 4 and 5 – new sections 138B to 138I and 141)

7. Under the new sections 138B to 138D, the Director would be empowered to issue a CMSO in writing to prohibit the sale or supply of a Product, or to direct the recall of such Product, if the Director has reasonable grounds to believe:

(a) that the Product has been manufactured, dispensed, sold or distributed in contravention of a requirement under Cap. 549 relating to trader licences, prescriptions for Chm, or the registration or packaging of pCm;[4]

(b) that the Product is dangerous or injurious to health, or unfit for use by human beings; or

(c) that the CMSO is necessary to prevent or reduce a possibility of danger to public health, or to mitigate any adverse consequence of such danger.

8. A CMSO must be in the specified form (new section 138E) addressed to and served on each person intended to be bound (new section 138F). A CMSO would be subject to variation or revocation by the Director who must state the reason for making the variation or revocation order (new sections 138H and 138I). Under the proposed section 141 as amended by clause 5, a person aggrieved by a CMSO or a variation order may appeal to CFI within one month from the date of service of the respective order on the person.

Consequences of non-compliance (clause 4 – new sections 138K and 138L)

9. If a person bound by a CMSO fails or refuses to comply with a requirement of the CMSO, he would commit an offence and be liable to a fine at level 6 (i.e. $100,000) and to imprisonment for two years (new section 138K). The person charged would have a defence if sufficient evidence is adduced to raise an issue that the person had a reasonable excuse for the failure or refusal, and the contrary is not proved by the prosecution beyond reasonable doubt (new section 138L).

Other amendments

10. Clause 3 proposes amending the long title of Cap. 549 by expressly referring to "the regulation of activities or matters relating to Chinese medicines, including … the manufacture, possession and sale of Chinese medicines".

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[4] The relevant requirements are set out in sections 109, 111, 119(1), 131, 134, 143 and 144. The maximum penalty for contravening these sections is a level 6 fine and two years' imprisonment.

11. Clause 6 seeks to amend section 159 of Cap. 549 by providing for the methods of service of notices or orders required to be served or given under Cap. 549 on an individual, a company and a body corporate, and the time at which such service is taken to have been effected. As these provisions would be of general application to Cap. 549 and its subsidiary legislation, section 35 of the Chinese Medicine Practitioners (Registration) Regulation (Cap. 549C) and Part IV of the Chinese Medicine Practitioners (Discipline) Regulation (Cap. 549D), which permit proof of service by a sworn statement, would be repealed (clauses 11 and 12).

12. Clauses 7 to 10 propose amending sections 2, 11(i), 16(q) and 20(g) of Cap. 549F in relation to a licensed wholesaler or manufacturer's obligation to set up and maintain a system for the rapid and, so far as practicable, complete recall of any Product sold or distributed by the wholesaler or manufacturer. These amendments seek to dispense with the present requirement that the Product sought to be recalled must be found to be dangerous, injurious to health or unfit for human consumption.

Commencement

13. The Bill does not contain a commencement provision. By virtue of section 20(2)(a) of the Interpretation and General Clauses Ordinance (Cap. 1), the Bill, if passed, would come into operation on the day on which the enacted Ordinance is published in the Gazette.

Public Consultation

14. According to paragraph 15 of the LegCo Brief, the Director conducted a seven-week public and trade consultation on the proposed legislative amendments from January to February 2017, during which a meeting with 16 Chinese medicines traders associations and six briefing sessions for individual licensed Chinese medicines traders were convened. The public and trade supported the proposal.

Consultation with LegCo Panel

15. As advised by the Clerk to the Panel on Health Services, the Panel was briefed on 28 February 2017 on the proposed amendments to Cap. 549. Members generally supported the legislative proposal, but raised various concerns, such as the grounds for making a CMSO and the time given for the traders to recall the Products.

Conclusion

16. Our scrutiny of the Bill is continuing. As the Bill seeks to confer new powers on the Director to direct the recall of Chinese medicines or related products, Members may wish to consider forming a Bills Committee to study the Bill in detail.

Prepared by
LOO Chi-pong, Bonny
Assistant Legal Adviser
Legislative Council Secretariat
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