Chinese Medicine (Amendment) Bill 2017

Contents

A BILL

To

Amend the Chinese Medicine Ordinance and the Chinese Medicines Regulation to confer powers on certain public officers to prohibit, in specified circumstances, the sale of Chinese medicines and other substances or compounds generated in the course of manufacture of proprietary Chinese medicines and to recall, in specified circumstances, the medicines, substances or compounds that have been sold; and to provide for related matters.

Enacted by the Legislative Council.

Part 1

Preliminary

1. Short title

This Ordinance may be cited as the Chinese Medicine (Amendment) Ordinance 2017.

2. Enactments amended

The enactments specified in Parts 2, 3 and 4 are amended as set out in those Parts.

Part 2

Amendments to Chinese Medicine Ordinance (Cap. 549)

3. Long title amended

The long title—

Repeal

everything after "to"

Substitute

"provide for the regulation of activities or matters relating to Chinese medicines, including the registration of practitioners of Chinese medicine, the licensing of traders in Chinese medicines, the registration of proprietary Chinese medicines and the manufacture, possession and sale of Chinese medicines.".

4. Part XIVA added

After Part XIV—

Add

"Part XIVA

Chinese Medicine Safety Order

Division 1—Preliminary

138A. Interpretation

In this Part—

Chinese medicine or related product (中藥或相關產品) means—

(a) a Chinese herbal medicine;

(b) a proprietary Chinese medicine; or

(c) an intermediate product;

Chinese medicine safety order (中藥安全令) means an order made under section 138B(1);

intermediate product (中間產品) means a substance or compound that is generated in the course of manufacture of a proprietary Chinese medicine and that is intended for use in the further preparation or production process of the medicine.

Division 2—Making of Chinese Medicine Safety Order

138B. Chinese medicine safety order

(1) The Director may, by order in writing, do either or both of the following—

(a) prohibit the sale of a Chinese medicine or related product;

(b) direct that a Chinese medicine or related product that has been sold be recalled and specify the way in which, and the period within which, the recall is to be conducted.

(2) The grounds on which a Chinese medicine safety order may be made are set out in sections 138C and 138D.

138C. Grounds for prohibiting sale

The Director may make an order under section 138B(1)(a) only if the Director has reasonable grounds to believe that—

(a) for a Chinese herbal medicine—

(i) the medicine has been sold or distributed in contravention of section 109(2) or 111(2);

(ii) the medicine is dangerous or injurious to health, or unfit for use by human beings; or

(iii) the order is necessary to prevent or reduce a possibility of danger to public health, or to mitigate any adverse consequence of a danger to public health;

(b) for a proprietary Chinese medicine—

(i) the medicine has been sold in contravention of section 119(1), 143 or 144;

(ii) the medicine has been sold or distributed in contravention of section 134;

(iii) the medicine has been manufactured in contravention of section 131;

(iv) the medicine is dangerous or injurious to health, or unfit for use by human beings; or

(v) the order is necessary to prevent or reduce a possibility of danger to public health, or to mitigate any adverse consequence of a danger to public health; and

(c) for an intermediate product—

(i) the product is dangerous or injurious to health, or unfit for use by human beings; or

(ii) the order is necessary to prevent or reduce a possibility of danger to public health, or to mitigate any adverse consequence of a danger to public health.

138D. Grounds for directing recall

The Director may make an order under section 138B(1)(b) only if the Director has reasonable grounds to believe that—

(a) for a Chinese herbal medicine—

(i) the medicine has been sold or dispensed in contravention of section 109(1) or 111(1);

(ii) the medicine has been sold or distributed in contravention of section 109(2) or 111(2);

(iii) the medicine is dangerous or injurious to health, or unfit for use by human beings; or

(iv) the order is necessary to prevent or reduce a possibility of danger to public health, or to mitigate any adverse consequence of a danger to public health;

(b) for a proprietary Chinese medicine—

(i) the medicine has been sold in contravention of section 119(1), 143 or 144;

(ii) the medicine has been sold or distributed in contravention of section 134;

(iii) the medicine has been manufactured in contravention of section 131;

(iv) the medicine is dangerous or injurious to health, or unfit for use by human beings; or

(v) the order is necessary to prevent or reduce a possibility of danger to public health, or to mitigate any adverse consequence of a danger to public health; and

(c) for an intermediate product—

(i) the product is dangerous or injurious to health, or unfit for use by human beings; or

(ii) the order is necessary to prevent or reduce a possibility of danger to public health, or to mitigate any adverse consequence of a danger to public health.

138E. Form of Chinese medicine safety order

A Chinese medicine safety order must be in the specified form and state the following—

(a) the person or persons intended to be bound by the order;

(b) the particulars of the Chinese medicine or related product that is the subject of the order;

(c) the reason for making the order;

(d) the prohibition or action required under the order;

(e) for an order made under section 138B(1)(b), the period within which the recall is to be conducted;

(f) the provision under which the order is made; and

(g) the consequences of failing or refusing to comply with a requirement of the order.

138F. Person bound by Chinese medicine safety order

(1) A Chinese medicine safety order—

(a) may be addressed to a particular person or particular persons; and

(b) must be served on each person to whom it is addressed.

(2) A Chinese medicine safety order is binding on a person to whom it is addressed only from the time it is served on the person.

Division 3—Variation or Revocation of Chinese Medicine Safety Order

138G. Interpretation of Division 3

In this Division, a reference to a Chinese medicine safety order includes a Chinese medicine safety order that is varied under section 138H(1).

138H. Variation of Chinese medicine safety order

(1) The Director may, by order in writing, vary a Chinese medicine safety order.

(2) An order made under subsection (1) (***variation order***) must be in the specified form and state the following—

(a) the person or persons to whom the variation order is addressed;

(b) the order number of the Chinese medicine safety order to which the variation order relates;

(c) the reason for making the variation order;

(d) the details of the variation;

(e) the provision under which the variation order is made; and

(f) the consequences of failing or refusing to comply with a requirement of the Chinese medicine safety order.

(3) A variation order must be addressed to and served on each person bound by the Chinese medicine safety order.

(4) A variation order is binding on a person to whom it is addressed only from the time it is served on the person.

138I. Revocation of Chinese medicine safety order

(1) The Director may, by order in writing, revoke a Chinese medicine safety order.

(2) An order made under subsection (1) (***revocation order***) must be in the specified form and state the following—

(a) the person or persons to whom the revocation order is addressed;

(b) the order number of the Chinese medicine safety order to which the revocation order relates;

(c) the reason for making the revocation order; and

(d) the provision under which the revocation order is made.

(3) A revocation order must be addressed to and served on each person bound by the Chinese medicine safety order.

(4) A revocation order has effect on a person to whom it is addressed only from the time it is served on the person.

Division 4—Offence Relating to Chinese Medicine Safety Order

138J. Interpretation of Division 4

In this Division, a reference to a Chinese medicine safety order includes a Chinese medicine safety order that is varied under section 138H(1).

138K. Non-compliance is an offence

If a person bound by a Chinese medicine safety order fails or refuses to comply with a requirement of the order, the person commits an offence and is liable to a fine at level 6 and to imprisonment for 2 years.

138L. Defence

(1) It is a defence for a person charged under section 138K to establish that the person had a reasonable excuse for the failure or refusal.

(2) The person is to be taken to have established that the person had a reasonable excuse for the failure or refusal if—

(a) sufficient evidence is adduced to raise an issue that the person had such a reasonable excuse; and

(b) the contrary is not proved by the prosecution beyond reasonable doubt.".

5. Section 141 amended (right of appeal to Court of First Instance)

(1) After section 141(1)—

Add

"(1A) A person aggrieved by a Chinese medicine safety order may appeal to the Court of First Instance against the order within 1 month from the date of service of the order on the person.

(1B) A person aggrieved by a variation order may appeal to the Court of First Instance against the order within 1 month from the date of service of the order on the person.".

(2) After section 141(3)—

Add

"(4) In this section—

Chinese medicine safety order (中藥安全令) means an order made under section 138B(1);

variation order (更改令) means an order made under section 138H(1).".

6. Section 159 substituted

Section 159—

Repeal the section

Substitute

"**159. Service of notices and orders**

(1) A notice or order required to be served or given (however described) under this Ordinance may be served or given—

(a) for an individual—

(i) by delivering it to the individual personally;

(ii) by leaving it at the individual's usual place of residence or business, or at the individual's last known address; or

(iii) by sending it by post or registered post to the individual's usual place of residence or business, or to the individual's last known address;

(b) for a company as defined by section 2(1) of the Companies Ordinance (Cap. 622)—

(i) by delivering it by hand to an officer of the company as defined by that section;

(ii) by leaving it at the company's registered office within the meaning of that Ordinance (***registered office***), at a place at which the company carries on business, or at the company's last known address; or

(iii) by sending it by post or registered post to the registered office, to a place at which the company carries on business, or to the company's last known address; or

(c) for a body corporate (other than a company described in paragraph (b))—

(i) by delivering it by hand to a director, chairperson, president, manager, secretary or other similar officer of the body corporate;

(ii) by leaving it at a place at which the body corporate carries on business, or at the body corporate's last known address; or

(iii) by sending it by post or registered post to a place at which the body corporate carries on business, or to the body corporate's last known address.

(2) In the absence of evidence to the contrary, a notice or order served or given under subsection (1)(a)(ii), (b)(ii) or (c)(ii) is taken as having been served or given on the day immediately following the day on which it was left at the place or address mentioned in that subsection.

(3) In the absence of evidence to the contrary, a notice or order served or given under subsection (1)(a)(iii), (b)(iii) or (c)(iii) is taken as having been served or given on the second day after the day on which it was posted.".

Part 3

Amendments to Chinese Medicines Regulation (Cap. 549 sub. leg. F)

7. Section 2 amended (interpretation)

Section 2—

Repeal the definition of *intermediate product*

Substitute

"***intermediate product*** (中間產品) has the meaning given by section 138A of the Ordinance;".

8. Section 11 amended (general duties of holders of wholesaler licences in Chinese herbal medicines)

Section 11(i)—

Repeal

everything after "recall of"

Substitute

"a Chinese herbal medicine sold or distributed by the licence holder.".

9. Section 16 amended (general duties of holders of manufacturer licences)

(1) Section 16—

Renumber the section as section 16(1).

(2) Section 16(1)(q)—

Repeal

everything after "recall of"

Substitute

"a specified product;".

(3) After section 16(1)—

Add

"(2) In this section—

specified product (指明產品), in relation to a holder of a manufacturer licence, means—

(a) an intermediate product that is generated in the course of manufacture of a proprietary Chinese medicine by the licence holder and that is sold or distributed by that licence holder; or

(b) a proprietary Chinese medicine that is manufactured and sold or distributed by the licence holder.".

10. Section 20 amended (general duties of holders of wholesaler licences in proprietary Chinese medicines)

Section 20(g)—

Repeal

everything after "recall of"

Substitute

"a proprietary Chinese medicine sold or distributed by the licence holder.".

Part 4

Related Amendments

Division 1—Amendment to Chinese Medicine Practitioners (Registration) Regulation (Cap. 549 sub. leg. C)

11. Section 35 repealed (proof of service of documents)

Section 35—

Repeal the section.

Division 2—Amendment to Chinese Medicine Practitioners (Discipline) Regulation (Cap. 549 sub. leg. D)

12. Part IV repealed (miscellaneous)

Part IV—

Repeal the Part.

Explanatory Memorandum

The main purpose of this Bill is to amend the Chinese Medicine Ordinance (Cap. 549) (***Ordinance***) to empower the Director to prohibit, in specified circumstances, the sale of Chinese medicines and intermediate products and to recall, in specified circumstances, the medicines and intermediate products that have been sold.

Notes—

The expression ***Director*** is defined in section 2(1) of the Ordinance to mean the Director of Health or a Deputy Director of Health.

The expression ***sell*** is defined in section 2(1) of the Ordinance to include—

(a) offer or expose for sale;

(b) supply without payment; and

(c) offer or expose for supply without payment,

and ***sale*** and ***seller*** are to be construed accordingly.

2. The Bill is divided into 4 Parts.

Part 1—Preliminary

3. Clause 1 sets out the short title.

Part 2—Amendments to Ordinance

4. Clause 3 amends the long title of the Ordinance.

5. Clause 4 adds a new Part XIVA to the Ordinance. The new Part XIVA consists of 12 sections, new sections 138A to 138L.

6. The new section 138A defines terms used in the new Part XIVA.

7. The new section 138B(1) empowers the Director to make an order (***Chinese medicine safety order***)—

(a) to prohibit the sale of a Chinese medicine or related product; and

(b) to direct the recall of a Chinese medicine or related product.

8. The grounds on which the Director may make a Chinese medicine safety order to prohibit the sale, or to direct a recall, of a Chinese medicine or related product are provided for in the new sections 138C and 138D.

9. The new section 138E provides for the form of a Chinese medicine safety order.

10. The new section 138F further provides for the persons bound by a Chinese medicine safety order.

11. The new section 138H empowers the Director to make an order to vary a Chinese medicine safety order (***variation order***) and provides for the form of a variation order and its effect. The new section 138I empowers the Director to make an order to revoke a Chinese medicine safety order (***revocation order***) and provides for the form of a revocation order and its effect. These 2 new sections also apply to a Chinese medicine safety order that has been varied by a variation order.

12. The new section 138K provides for the legal consequences for failing or refusing to comply with a Chinese medicine safety order or a Chinese medicine safety order that has been varied under the new section 138H(1). The new section 138L provides for a defence for the failure or refusal and the burden to fall on the defendant to establish the defence.

13. Clause 5 amends section 141 of the Ordinance to provide for a right to appeal against a Chinese medicine safety order or a variation order.

14. Clause 6 replaces the existing section 159 of the Ordinance with a new section 159. The new section 159 sets out the way in which a notice or order required to be served or given under the Ordinance may be served or given (see the new section 159(1)). It also provides for the time at which such a notice or order is taken as having been served or given in specified circumstances (see the new section 159(2) and (3)).

Part 3—Amendments to Chinese Medicines Regulation

15. Clause 7 amends section 2 of the Chinese Medicines Regulation (Cap. 549 sub. leg. F) (***Regulation***). That section is an interpretation provision.

16. Clause 8 amends section 11(i) of the Regulation to adjust the system of control required to enable the rapid and, so far as practicable, complete recall of Chinese herbal medicines.

17. Clause 9 amends section 16(1)(q) of the Regulation to adjust the system of control required to enable the rapid and, so far as practicable, complete recall of intermediate products and proprietary Chinese medicines.

18. Clause 10 amends section 20(g) of the Regulation to adjust the system of control required to enable the rapid and, so far as practicable, complete recall of proprietary Chinese medicines.

Part 4—Related Amendments

19. Clauses 11 and 12 repeal provisions of the Chinese Medicine Practitioners (Registration) Regulation (Cap. 549 sub. leg. C) and the Chinese Medicine Practitioners (Discipline) Regulation (Cap. 549 sub. leg. D) that relate to proving that documents have been served.