File Ref.: FHB/H/24/24

LEGISLATIVE COUNCIL BRIEF

Chinese Medicine Ordinance
(Chapter 549)

CHINESE MEDICINE (AMENDMENT) BILL 2017

INTRODUCTION

At the meeting of the Executive Council on 23 May 2017, the Council ADVISED and the Chief Executive ORDERED that the Chinese
A Medicine (Amendment) Bill 2017 ("the Bill"), at **Annex A**, should be introduced into the Legislative Council ("LegCo").

JUSTIFICATIONS

2. On 27 March 2014, the Department of Health ("DH") instructed a licensed wholesaler of proprietary Chinese medicines ("pCms") to recall two suspected unregistered pCms ("the Products") from the market on the grounds that the use of the Products may pose threats to public health as their safety, efficacy and quality have not been proven. The wholesaler concerned subsequently applied to the Court of First Instance ("the Court") for leave to challenge by way of judicial review the decisions of the Director of Health or the Deputy Director of Health (collectively and individually referred to as "the Director"), including the decision to issue the instruction to recall on 27 March 2014. Leave was then granted.

3. The judgment handed down by the Court on 21 May 2015[1] in the above judicial review case concluded that the Director had no lawful power under the Chinese Medicine Ordinance (Cap. 549) ("CMO") to instruct the wholesaler concerned to recall the Products in question on 27 March 2014 and thus the decision to issue the instruction was ultra vires.

4. 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

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

for pCms, Chinese herbal medicines ("Chms") and intermediate products[2] according to regulations 11(i), 16(q) and 20(g) of the Chinese Medicines Regulation (Cap. 549F) ("CMR"), the Court held in the above judicial review case that the Director did not have the statutory power to order recall. Moreover, we have reviewed the CMO and found that there is currently no provision under the CMO or its subsidiary legislation providing that an unlicensed trader must, as directed by the Director, carry out recall actions regarding pCms or Chms which may pose threats to public health, such as Chms being distributed without licence as well as unregistered pCms being distributed etc. In view of the aforementioned situation, we consider it necessary to amend the CMO and its subsidiary legislation to strengthen the control.

LEGISLATIVE PROPOSALS

(A) Chinese medicine safety order

5. The legislative proposal put forth by the Bill aims to confer on the Director the statutory power which is necessary to safeguard public health. The Director will be empowered to order any person (regardless of whether he/she is a licensed trader under the CMO or not) who has sold[3] Chms, pCms and/or intermediate products to recall Chms, pCms and/or intermediate products from the market, and to prohibit by order the sale of the same, should the Director have a reasonable cause to believe at the time of making the order that certain specified circumstances exist, including that such Chms, pCms and/or intermediate products may pose threats to public health. An order so made by the Director is referred to as a "Chinese medicine safety order" in the Bill.

6. Legislative amendments will also be made to the CMO and its subsidiary legislation to update and clarify certain provisions and to enable effective and smooth enforcement of Chinese medicine safety orders. Such provisions include provisions on service of notices and orders under the CMO and the setting up and maintenance of a system of control to enable the recall of pCms, Chms and intermediate products as required under the CMR. Relevant provisions relating to service in the Chinese Medicine

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[2] It refers to intermediate products generated in the course of manufacturing a pCm.

[3] The expression ***sell*** is defined in section 2(1) of the CMO 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.

Practitioners (Registration) Regulation (Cap. 549C) ("CMPRR") and the Chinese Medicine Practitioners (Discipline) Regulation (Cap. 549D) ("CMPDR") will also be repealed for the sake of consistency.

7. To ensure the fair and just handling of all cases, the Bill introduces an appeal mechanism to allow a person bound by a Chinese medicine safety order to appeal against the decision of the Director.

8. The proposed amendments will bring the regulatory regime for Chinese medicines of Hong Kong on par with the relevant regulatory regimes of other jurisdictions (e.g. the Therapeutic Goods Act in Australia and the Food and Drugs Act in Canada), where there are regulations in place with respect to recall of medicines to ensure safety in the administration of medications for public.

(B) Forms and effects of Chinese medicine safety order, variation order and revocation order

9. The Bill sets out clearly the forms and effects of a Chinese medicine safety order, variation order and revocation order with a view to facilitating traders' understanding of their responsibilities and the operational details of the orders.

(C) Penalty

10. The Bill proposes that a person bound by a Chinese medicine safety order who fails or refuses to comply with any requirements set out in the Chinese medicine safety order commits an offence, and is liable to a fine at level 6 (i.e. $100,000) and to imprisonment for 2 years. The proposed penalty is the same as the existing penalty for not complying with most other provisions under the CMO.

OTHER OPTIONS

11. A systematic, swift and effective manner to recall Chinese medicines or products which may pose health hazards to the public is in the best interest of members of the public. In view of the Court's decision mentioned in paragraphs 2 and 3 above, we must amend the CMO and its subsidiary legislation in order to bring the above proposals into effect. There are no other options.

THE BILL

12. The key provisions of the Bill are set out as follows –

Amendments to the CMO

(a) **Clause 3** amends the long title of the CMO.

(b) **Clause 4** adds a new Part XIVA (Chinese Medicine Safety Order) to the CMO. The new Part empowers the Director to make a Chinese medicine safety order to prohibit the sale, and direct the recall, of a Chinese medicine or related product under specified circumstances, and provides for the grounds on which such an order may be made. It also empowers the Director to vary and revoke a Chinese medicine safety order by a variation order and revocation order respectively. The forms and effects of the Chinese medicine safety order, variation order and revocation order are set out in this Part. The legal consequences for failing or refusing to comply with a Chinese medicine safety order, the defence for the failure or refusal and the burden of proof are also provided for in this Part.

(c) **Clause 5** amends section 141 of the CMO to provide for a right to appeal against a Chinese medicine safety order or a variation order.

(d) **Clause 6** amends section 159 of the CMO to set out how service of notices or orders under the CMO is to be effected.

Amendments to the CMR

(e) **Clauses 8 to 10** amend sections 11(i), 16(1)(q) and 20(g) of the CMR respectively to adjust the system of control required to be maintained by licensed Chinese medicines traders to enable the rapid and, as far as practicable, complete recall of Chms, pCms and intermediate products as appropriate.

Related Amendments

(f) **Clauses 11 and 12** contain related amendments to the CMPRR and the CMPDR that relate to proving that

documents have been served.

B The existing provisions being amended are at **Annex B**.

LEGISLATIVE TIMETABLE

13. The legislative timetable will be as follows –

Publication in the Gazette	2 June 2017
First Reading and commencement of Second Reading Debate	14 June 2017
Resumption of Second Reading Debate, Committee Stage and Third Reading	To be notified

IMPLICATIONS OF THE PROPOSAL

14. The proposal is in conformity with the Basic Law, including the provisions concerning human rights. The amendments proposed in the Bill will not affect the binding effect of the existing provisions of the CMO and its subsidiary legislation. The financial, civil service, economic and sustainability implications of the proposal are set out at **Annex C**. The proposal does not have productivity, gender, family or environmental implications.

C

PUBLIC CONSULTATION

15. The DH conducted a seven-week public and trade consultation from January to February 2017 on the proposed legislative amendments, 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 generally recognize the need for the legislative amendments and support the legislative proposal. In particular, the DH received a letter jointly signed by seven Chinese medicines traders associations on 27 February 2017, which indicated support to the proposed amendments despite their concerns about the operational details. Subsequently, the DH met with the representatives of the said associations

and explained in detail the operating procedures of the proposal. The DH also stressed at the above meeting that there would be no substantive procedural difference between the proposed and the existing recall actions and the Bill would not require licensed traders to adjust their recall systems already established.

16. We briefed the LegCo Panel on Health Services ("the Panel") on the above legislative proposal at its meeting held on 28 February 2017. Members of the Panel were generally supportive of the proposed legislative amendments. Some Members expressed concern about the implementation details of the proposal such as readiness of the trade and the proposed penalty. In response, we have issued a reply letter to the Panel explaining that the licensed traders should have no problem complying with Chinese medicine safety orders as they have already put in place recall systems as currently required by the CMR, and that the penalty level proposed by the Bill is indeed the same as the existing penalty level applicable to conviction of most other offences under the CMO. We consider that the penalty level proposed by the Bill is reasonable and comparable to those other offences, and is necessary for achieving sufficient deterrent effect.

PUBLICITY

17. We shall issue a press release on the Bill on 31 May 2017. A spokesperson will be available to answer media and public enquiries.

ENQUIRIES

18. Any enquiries on this brief can be addressed to Mr Lam Fong-tat James, Assistant Secretary for Food and Health (Health), at 3509 8956.

Food and Health Bureau
31 May 2017

Chinese Medicine (Amendment) Bill 2017

Contents

Clause Page

Part 1

Preliminary

1. Short title 1
2. Enactments amended 1

Part 2

Amendments to Chinese Medicine Ordinance (Cap. 549)

3. Long title amended 2
4. Part XIVA added 2

Part XIVA

Chinese Medicine Safety Order

Division 1—Preliminary

138A. Interpretation 2

Division 2—Making of Chinese Medicine Safety Order

138B. Chinese medicine safety order 3
138C. Grounds for prohibiting sale 3
138D. Grounds for directing recall 5
138E. Form of Chinese medicine safety order 6

Clause Page

138F. Person bound by Chinese medicine safety order 6

Division 3—Variation or Revocation of Chinese Medicine Safety Order

138G. Interpretation of Division 3 7
138H. Variation of Chinese medicine safety order 7
138I. Revocation of Chinese medicine safety order 8

Division 4—Offence Relating to Chinese Medicine Safety Order

138J. Interpretation of Division 4 8
138K. Non-compliance is an offence 8
138L. Defence 9

5. Section 141 amended (right of appeal to Court of First Instance) 9
6. Section 159 substituted 10

159. Service of notices and orders 10

Part 3

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

7. Section 2 amended (interpretation) 12
8. Section 11 amended (general duties of holders of wholesaler licences in Chinese herbal medicines) 12
9. Section 16 amended (general duties of holders of manufacturer licences) 12

Clause Page

10. Section 20 amended (general duties of holders of wholesaler licences in proprietary Chinese medicines) 13

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) 14

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

12. Part IV repealed (miscellaneous) 14

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.

Annex B

Extracts from Chinese Medicine Ordinance (Cap. 549)

Provisions to be amended by the Chinese Medicine (Amendment) Bill 2017

		Long title	L.N. 214 of 1999	06/08/1999

An Ordinance to make provisions for the registration of practitioners in Chinese medicine; the licensing of traders in Chinese medicines; the registration of proprietary Chinese medicines; and other related matters.

Section:	141	**Right of appeal to Court of First Instance**	L.N. 53 of 2003	30/04/2003

(1) A person aggrieved by any decision of the Medicines Board made under section 114, 115, 116, 121, 123, 124, 125, 129, 132, 135, 136, 139 or 140 may appeal to the Court of First Instance within 1 month from the date of service of the notice.
(2) The Court of First Instance may affirm, reverse or vary the decision appealed against.
(3) The decision of the Court of First Instance shall be final.

Section:	159	**Service of notices and orders**	L.N. 214 of 1999	06/08/1999

Any notice or order required to be served under this Ordinance may be served by delivering a copy -
(a) personally; or
(b) by post or by registered post addressed to the last known address of the business or residence of the person to be served or his address as recorded in the Register.

Extracts from Chinese Medicines Regulation (Cap. 549 sub. Leg. F)

Provisions to be amended by the Chinese Medicine (Amendment) Bill 2017

Section:	2	**Interpretation**	L.N. 130 of 2007	01/07/2007

intermediate product (中間產品) means a substance or compound generated in the course of manufacture of a proprietary Chinese medicine and which is to be used in further preparation or production process of the medicine;

Section:	11	**General duties of holders of wholesaler licences in Chinese herbal medicines**	L.N. 54 of 2003	30/04/2003

A holder of a wholesaler licence in Chinese herbal medicines shall ensure that-

(a) the premises to which the licence relates are maintained in sanitary condition;

(b) (i) adequate space; and
(ii) adequate and suitable facilities,
for storing Chinese herbal medicines are provided in the premises;

(c) the facilities for storing Chinese herbal medicines are maintained in good condition;

(d) where any Schedule 1 medicine is stored in the same premises with any Schedule 2 medicine or material of herbal, animal or mineral origin customarily used by the Chinese for medicinal purpose, the Schedule 1 medicine is stored effectively separated from the Schedule 2 medicine or material;

(e) each type of Chinese herbal medicine stored in the premises is stored in a separate container;

(f) each container referred to in paragraph (e) is sufficiently stout to prevent leakage and contamination arising from the ordinary risks involved in handling the Chinese herbal medicine stored in it;

(g) where any Chinese herbal medicine or mixture of Chinese herbal medicines is processed in the premises-

(i) equipment and facilities suitable for processing are provided in the premises;

(ii) the equipment and facilities for processing are maintained in good condition;

(iii) the processed medicine or mixture is examined by the licence holder to ensure its quality before it is offered for sale or supplied to or used by any other person;

(iv) the following particulars in relation to each processing are recorded-

(A) the name and quantity of each type of material (including the Chinese herbal medicine or mixture of Chinese herbal medicines to be processed) used in the processing;

(B) the name and quantity of the processed medicine or mixture;

(C) the name or a description of the processing method;

(D) the date of the completion of the processing;

(E) the result of the examination referred to in subparagraph (iii); and

(F) the name of the person who supervises the processing;

(v) the particulars mentioned in subparagraph (iv) are recorded within 72 hours after the completion of the processing; and

(vi) the record prepared pursuant to subparagraph (iv) is retained in the premises to which the licence relates for a period of not less than 2 years from the date of the completion of the processing;

(h) no Chinese herbal medicine in his possession is consigned for transport unless suitable arrangements have been made to prevent leakage and contamination arising from the ordinary risks involved in the delivery and transport of the medicine; and

(i) a system of control is set up and maintained, which will enable the rapid and, so far as practicable, complete recall of any Chinese herbal medicine sold or distributed by him in the event of the medicine being found to be dangerous, injurious to health or unfit for human consumption.

Section:	16	**General duties of holders of manufacturer licences**	L.N. 54 of 2003	30/04/2003

A holder of a manufacturer licence shall ensure that-

(a) the premises to which the licence relates are maintained in sanitary condition;

(b) where ingredients or packing materials, or both, used for manufacturing proprietary Chinese medicines are stored in the premises-

(i) adequate space; and

(ii) adequate and suitable facilities,

for storing the ingredients or packing materials, or both, as the case may be, are provided in the premises;

(c) the facilities (if any) for storing ingredients or packing materials, or both, as the case may be, are maintained in good condition;

(d) where any Schedule 1 medicine is stored in the same premises with any Schedule 2 medicine or material of herbal, animal or mineral origin customarily used by the Chinese for medicinal purpose, the Schedule 1 medicine is stored effectively separated from the Schedule 2 medicine or material;

(e) fittings and equipment suitable for use in the manufacturing process specified in the licence are provided in the premises;

(f) the fittings and equipment used in the manufacturing process are maintained in good condition;

(g) where intermediate products generated or proprietary Chinese medicines manufactured in the course of manufacture, or both, are stored in the premises-

(i) adequate space; and

(ii) adequate and suitable facilities,

for storing the products or medicines, or both, as the case may be, are provided in the premises;

(h) the facilities (if any) for storing intermediate products or proprietary Chinese medicines, or both, are maintained in good condition;

(i) the humidity, lighting, temperature and ventilation of the part of the premises provided for-

(i) storing ingredients or packing materials;

(ii) manufacturing proprietary Chinese medicines; or

(iii) storing intermediate products or proprietary Chinese medicines,

are suitable for their respective purposes;

(j) where any ingredient is used in the manufacturing process, the ingredient is examined by a responsible person before it is used to ensure its identity and quality;

(k) no manufacturing process is carried out in the premises otherwise than under the supervision of a responsible person;

(l) adequate steps have been taken to prevent contamination of any ingredient or packing material used, any intermediate product generated or any proprietary Chinese medicine manufactured in the course of manufacture;

(m) each batch of intermediate product generated or proprietary Chinese medicine manufactured in the course of manufacture, or both, is examined by a responsible person before it is sold or distributed by the holder of the licence to ensure its quality;

(n) no proprietary Chinese medicine that he manufactures is sold or distributed by him after its expiry date;

(o) each container or package of intermediate product generated or proprietary Chinese medicine manufactured in the course of manufacture is sufficiently stout to prevent leakage and contamination arising from the ordinary risks involved in handling the products or medicines, as the case may be;

(p) no intermediate product generated or proprietary Chinese medicine manufactured in the course of manufacture is consigned for transport unless suitable arrangements have been made to prevent leakage and contamination arising from the ordinary risks involved in the delivery and transport of the product or medicine, as the case may be;

(q) a system of control is set up and maintained, which will enable the rapid and, so far as practicable, complete recall of any intermediate product generated or proprietary Chinese medicine manufactured in the course of manufacture which has been sold or distributed in the event of the product or medicine, as the case may be, being found to be dangerous, injurious to health or unfit for human consumption;

(r) a control sample of each batch of intermediate product (if any) generated in the course of manufacture which has been sold is retained, under suitable conditions of storage, in the premises from the date on which the batch of product is generated until the expiry of 2 years from the date of the last transaction in the batch of product; and

(s) a control sample of each batch of proprietary Chinese medicine (if any) manufactured in the course of manufacture is retained, under suitable conditions of storage, in the premises from the date of the manufacture until the expiry of 2 years from the expiry date of the batch of medicine.

Section:	20	**General duties of holders of wholesaler licences in proprietary Chinese medicine**	L.N. 54 of 2003	30/04/2003

A holder of a wholesaler licence in proprietary Chinese medicines shall ensure that-

(a) the premises to which the licence relates are maintained in sanitary condition;

(b) (i) adequate space; and

(ii) adequate and suitable facilities,

for storing proprietary Chinese medicines are provided in the premises;

(c) the facilities for storing proprietary Chinese medicines are maintained in good condition;

(d) no proprietary Chinese medicine in his possession is sold or distributed after its expiry date;

(e) all proprietary Chinese medicines sold or distributed by him are packed using materials that are sufficiently stout to prevent leakage and contamination arising from the ordinary risks involved in handling the medicine;

(f) no proprietary Chinese medicine in his possession is consigned for transport unless suitable arrangements have been made to prevent leakage and contamination arising from the ordinary risks involved in the delivery and transport of the medicine; and

(g) a system of control is set up and maintained, which will enable the rapid and, so far as practicable, complete recall of any proprietary Chinese medicine sold or distributed by him in the event of the medicine being found to be dangerous, injurious to health or unfit for human consumption.

Extracts from Chinese Medicine Practitioners (Registration) Regulation (Cap. 549 sub. Leg. C)

Provisions to be amended by the Chinese Medicine (Amendment) Bill 2017

Section:	35	**Proof of service of documents**	L.N. 252 of 2000	16/08/2000

Service of a notice or other communication on an applicant mentioned in Parts I to Iv may be proved by means of a sworn statement made by the Board secretary or the person responsible for effecting the service.

Extracts from Chinese Medicine Practitioners (Discipline) Regulation (Cap. 549 sub. Leg. D)

Provisions to be amended by the Chinese Medicine (Amendment) Bill 2017

Part:	IV	**Miscellaneous**	L.N. 253 of 2000	16/08/2000
Section:	24	**Proof of service of document**	L.N. 253 of 2000	16/08/2000

Service of a notice or other communication on any person under this Regulation may be proved by means of a sworn statement made by the Board secretary or the person responsible for effecting the service

Annex C

Financial, Civil Service, Economic and Sustainability Implications

Financial and civil service implications

The Department of Health would endeavour to absorb within its existing resources as far as possible the additional workload arising from implementing the legislative proposal, including enforcement, prosecution and appeal handling. Additional manpower and resources, if required, would be sought with justifications in accordance with the established mechanism.

Economic and sustainability implications

2. As regards the economic and sustainability implications, the proposal would help strengthen the regulatory regime for Chinese medicines, thereby safeguarding the health of the public. Since licensed traders of Chinese medicines have already been required under the Chinese Medicine Ordinance (Cap. 549) to set up and maintain a system of recall, the additional compliance burden and costs should be minimal.