中華人民共和國香港特別行政區
Hong Kong Special Administrative Region of the People's Republic of China

立法會秘書處 法律事務部
LEGAL SERVICE DIVISION
LEGISLATIVE COUNCIL SECRETARIAT

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By Fax (2840 0467)

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Mr James LAM
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Food and Health Bureau
19/F, East Wing
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2 Tim Mei Avenue, Tamar
Hong Kong

Dear Mr LAM,

Chinese Medicine (Amendment) Bill 2017

To assist our scrutiny of the legal and drafting aspects of the above Bill, we should be grateful for your clarification of the following issues:

Clause 3 – proposed long title of the Chinese Medicine Ordinance (Cap. 549)

(a) Clause 3 seeks to amend 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". Since the main purpose of the Bill, as noted in its long title and Explanatory Memorandum, is to empower the Director of Health ("Director") to direct the recall of a Chinese medicine or related product ("Product"), is it necessary for the proposed amendment under clause 3 to refer expressly to "the manufacture, possession, sale *and recall* of Chinese medicines"?

Clause 4 – proposed Part XIVA of Cap. 549

(b) As noted in paragraph 9 of LC Paper No. CB(2)859/16-17(06) of February 2017 and paragraph 8 of the Legislative Council Brief (File Ref.: FHB/H/24/24) of 31 May 2017, the Administration has studied the drug recall regulation enacted by the China Food and

Drug Administration in December 2007, the *Therapeutic Goods Act 1989* of Australia (as amended in May 2003), and the *Food and Drugs Act* of Canada (as amended in November 2014). Please identify the relevant provisions of the Chinese, Australian and Canadian statutes on which the proposed Part XIVA of Cap. 549 is modelled, and provide a table comparing the proposed sections of the new Part XIVA against the corresponding provisions under the Chinese, Australian and Canadian statutes with regard to:

(i) types of medicinal or therapeutic products subject to recall;

(ii) grounds for prohibiting sale and/or directing recall;

(iii) types of persons bound by a recall order;

(iv) variation, revocation and appeal;

(v) sanctions and penalties for non-compliance; and

(vi) any defence available.

Clause 4 – proposed new sections 138C and 138D of Cap. 549

(c) Under clause 4, the proposed sections 138C(a)(ii), (b)(iv) and (c)(i) and 138D(a)(iii), (b)(iv) and (c)(i) of Cap. 549 refer to "unfit for use by human beings", rather than "unfit for human consumption" as currently referred to in sections 11(i), 16(q) and 20(g) of the Chinese Medicines Regulation (Cap. 549F). Please explain the difference in meaning, if any, between these two expressions.

Clause 4 – proposed new sections 138E, 138H and 138I of Cap. 549

(d) A Chinese medicine safety order ("CMSO") made under the proposed section 138B(1)(b) may direct the recall of a Product "and specify the way in which, and the period within which, the recall is to be conducted". The proposed section 138E(e) requires such a CMSO to state the period within which the recall is to be conducted, but does not require the CMSO to specify the manner in which the recall is to proceed. Please explain why such a requirement is omitted from the proposed section 138E.

(e) It is noted that the proposed sections 138H(2)(b) and 138I(2)(b) refer to the "order number" of the CMSO to be varied or revoked under those sections. However, the proposed section 138E, as drafted, does not seem to require a CMSO to state an "order number". Should an item relating to the order number of the CMSO be added to the proposed section 138E?

(f) Under the new sections 138H(2)(c) and 138I(2)(c), the reason for making a variation or revocation order must be stated in the order. In what circumstances and on what grounds would the Director vary or revoke a CMSO under the proposed sections 138H and 138I? Should these circumstances or grounds be set out in new provisions similar to the proposed sections 138C and 138D?

(g) In *Man Hing Medical Supplies (International) Ltd v Director of Health* [2015] 3 HKLRD 224 ("*Man Hing*") at 231, the applicant requested the Director to revoke or suspend the instruction to recall. Please consider whether it is necessary, despite section 46(a) of the Interpretation and General Clauses Ordinance (Cap. 1), for the Bill to provide expressly for the suspension of a CMSO by the Director.

Clause 4 – proposed new section 138K of Cap. 549

(h) The offence under the proposed section 138K would only apply to "a person bound by" a CMSO, i.e. a person to whom the CMSO is addressed and on whom it is served under the proposed section 138F(2) or 138H(4). Please consider whether there should also be a separate offence similar to that under section 146(3) of Cap. 549 which applies to *any person* who wilfully delays or obstructs a recall (e.g. if a retailer to whom the CMSO is not specifically addressed refuses or fails without reasonable excuse to return the Product to the wholesaler or manufacturer).

Clause 4 – proposed new section 138L of Cap. 549

(i) Please provide examples of what would constitute "a reasonable excuse" for the purposes of the defence under the new section 138L.

(j) The proposed section 138L(2) seeks to impose an evidential (rather than legal or persuasive) burden on the person charged to adduce sufficient evidence to raise an issue that he had a reasonable excuse for failing or refusing to comply with a CMSO. This deviates from the formulation of the existing defences under section 156 which requires the person charged "to prove" that he did not know, had no reason to suspect, and could not with reasonable diligence have discovered that the Chinese medicine was not supplied to him, or was not registered, in accordance with Cap. 549. Section 156 is couched in terms almost identical to the now repealed section 26(4) of the Trade Descriptions Ordinance (Cap. 362) which was read down by the Court of Final Appeal ("CFA") as imposing merely an

evidential burden on the accused to raise an issue, with the prosecution retaining the persuasive burden as to each element of liability throughout: *Lee To Nei v HKSAR* [2012] 15 HKCFAR 162 at 179. Please confirm whether section 156 of Cap. 549 must similarly be read down and, if so, whether it should be amended in line with the proposed section 138L.

Clause 5 – proposed section 141 of Cap. 549

(k) Clause 5 seeks to amend section 141 of Cap. 549 by adding new subsections (1A) and (1B) to allow a person aggrieved by a CMSO or a variation order to appeal to the Court of First Instance ("CFI"). Is it necessary for the Bill to add a similar provision to allow a person aggrieved by a revocation order (e.g. a competitor or a member of the public whose initial complaint prompted the making of the CMSO now revoked) to appeal against that order to CFI?

(l) The existing section 141(3) of Cap. 549 provides that the decision of CFI shall be final. Please confirm the Administration's view, with justifications, as to whether the finality clause in section 141(3) of Cap. 549 would satisfy the proportionality test referred to in *Mok Charles v Tam Wai Ho* [2010] 13 HKCFAR 762 at 781 insofar as section 141(3) purports to restrict or limit the power of final adjudication vested in CFA under Article 82 of the Basic Law.

Clause 6 – proposed section 159 of Cap. 549

(m) Clause 6 seeks to amend section 159 of Cap. 549 by providing for the methods of service of a "notice or order required to be served or given" under Cap. 549. Section 35 of the Chinese Medicine Practitioners (Registration) Regulation (Cap. 549C) and Part IV of the Chinese Medicine Practitioners (Discipline) Regulation (Cap. 549D), which clauses 11 and 12 of the Bill seek to repeal, refer to "a notice or *other communication*". Please consider whether the term "notice or order" in the proposed section 159 is broad enough to cover all forms of communication required to be served or given under Cap. 549 and its subsidiary legislation.

(n) The proposed section 159(1) of Cap. 549 prescribes the methods of service on an individual, a company and a body corporate. How would a notice be served on a partnership or an unincorporated association? In this connection, please refer to section 60(2)(d) and (e) of the Financial Reporting Council Ordinance (Cap. 588).

(o) The proposed section 159(1)(a)(i), (b)(i) and (c)(i) deals with personal service, but uses slightly different language in relation to an individual ("delivering it … personally") as opposed to an officer of a company or a body corporate ("delivering it by hand"). Please explain any difference between these two modes of service.

Clauses 8 to 10 – proposed sections 11(i), 16(1)(q) and 20(g) of Cap. 549F

(p) Clauses 8 to 10 propose amending sections 11(i), 16(q) and 20(g) of Cap. 549F to require a holder of a wholesaler or manufacturer licence to set up and maintain a system for the rapid and, so far as practicable, complete recall of any Product manufactured, sold or distributed by the licence holder. The existing requirement that the Product to be recalled must be "found to be dangerous, injurious to health or unfit for human consumption" is proposed to be omitted. In what circumstances and on what grounds would a licence holder be required to recall a Product under the amended sections? Please consider whether these circumstances or grounds should be set out in provisions similar to the proposed sections 138C and 138D of Cap. 549 in Cap. 549F itself or, alternatively, in the relevant practising guidelines or recall guidelines (collectively "Guidelines") issued by the Chinese Medicine Council of Hong Kong.

(q) The existing section 16(q) of Cap. 549F refers to the recall of *any intermediate product* ("IP") *generated or proprietary Chinese medicine* ("pCm") *manufactured in the course of manufacture which has been sold or distributed* without specifying by whom:

(i) the IP must have been generated;

(ii) the pCm must have been manufactured; or

(iii) the IP or pCm must have been sold or distributed.

By virtue of the proposed section 16(1)(q) and (2) as amended by clause 9, the "specified product" (i.e. IP or pCm) to be recalled must be generated or manufactured and sold or distributed by the same licence holder. If multiple manufacturers (e.g. A, B and C) are involved in the manufacture of a pCm, please advise which party would be required, under the proposed section 16(1)(q), to recall any IP generated by A in the following circumstances:

(i) the IP is delivered to B who keeps it in B's premises without using it for the preparation or production of any pCm;

(ii) B uses the IP in manufacturing a pCm which B then sells or distributes to the market; or

(iii) B sells or supplies the IP to C for use in manufacturing a pCm which C then sells or distributes to the market.

(r) How and when (if at all) would the relevant provisions of the Guidelines (e.g. the definitions of "recall") be amended to reflect the changes sought to be made by the Bill? In this regard, please see paragraphs 68 and 69 of CFI's judgment in *Man Hing* at 244.

(s) Regulations 28(8) and 33(5) of the Pharmacy and Poisons Regulations (Cap. 138A) require a licensed wholesale dealer or manufacturer to set up and maintain a system for the rapid and, so far as practicable, complete recall of any pharmaceutical substance or product from sale to the public *in the event of the substance or product being found to be dangerous or injurious to health*.

(i) Please explain the present regime, if any, for the recall of pharmaceutical substances or products under the Pharmacy and Poisons Ordinance (Cap. 138). Does the Director have any power to direct or instruct a licensed wholesale dealer or manufacturer to recall a pharmaceutical substance or product? If not, is it necessary to amend Cap. 138 and/or its subsidiary legislation so as to confer such power on the Director?

(ii) In view of the proposed amendments to sections 11(i), 16(q) and 20(g) of Cap. 549F, please consider whether similar amendments should also be made to regulations 28(8) and 33(5) of Cap. 138A to remove the italicised words above.

<u>Chinese text</u>

(t) The proposed sections 138B(1)(b), 138D and 138E(e) (as well as the existing section 124(5)) of Cap. 549 and the proposed sections 11(i), 16(1)(q) and 20(g) of Cap. 549F render "recall" as "收回", whereas Cap. 549F has hitherto referred to "回收". Please explain any difference in meaning between these two renditions.

(u) The proposed sections 138F, 138H and 138I render "addressed" as "致送" in relation to a CMSO, variation order or revocation order, but the same term is rendered as "致予" in relation to a food safety order under section 31 of the Food Safety Ordinance (Cap. 612). Please explain any difference in meaning between these renditions.

(v) The proposed section 138L of Cap. 549 renders "establish" and "established" as "證明", contrary to paragraph 6.2.18 of *Drafting Legislation in Hong Kong – A Guide to Style & Practices* which states that "prove" or "證明" should not be used for imposing an evidential burden. Please refer to section 542(2) of the Companies Ordinance (Cap. 622) which renders "establish" as "確立" in relation to a statutory defence. Please consider which Chinese term is more appropriate in the context of the proposed section 138L.

(w) Under clause 6, the proposed section 159(3) of Cap. 549 renders "the second day after the day" as "當日起計的第三日", while the same expression is literally rendered as "當日後的第二日" in section 166(2)(a) of the Competition Ordinance (Cap. 619) which similarly provides for the time at which a notice sent by post is taken to have been served. While the two Chinese renditions appear to be synonymous, please consider whether the inconsistent use of language in similar contexts is likely to confuse readers.

We look forward to receiving your reply in both languages as soon as possible.

Yours sincerely,

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