# *立法會*
# *Legislative Council*

LC Paper No. CB(2)1772/17-18
(These minutes have been seen by the Administration)

Ref : CB2/BC/6/16

**Bills Committee on Chinese Medicine (Amendment) Bill 2017**

**Minutes of the fourth meeting held on Tuesday, 21 November 2017, at 2:30 pm in Conference Room 2B of the Legislative Council Complex**

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| **Members present** | : | Hon Alice MAK Mei-kuen, BBS, JP (Chairman)<br>Hon CHAN Han-pan, JP<br>Hon KWOK Wai-keung, JP<br>Dr Hon Helena WONG Pik-wan<br>Dr Hon Elizabeth QUAT, BBS, JP<br>Dr Hon Junius HO Kwan-yiu, JP<br>Hon SHIU Ka-fai<br>Dr Hon Pierre CHAN |
| **Members absent** | : | Hon Mrs Regina IP LAU Suk-yee, GBS, JP<br>Dr Hon KWOK Ka-ki |
| **Public Officers attending** | : | Mr Howard CHAN, JP<br>Deputy Secretary for Food and Health (Health) 1<br>Food and Health Bureau<br><br>Miss Grace KWOK<br>Principal Assistant Secretary for Food and Health (Health) 1<br>Food and Health Bureau<br><br>Dr Edwin TSUI<br>Assistant Director (Traditional Chinese Medicine)<br>Department of Health |

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| | | Mr Stephen YUNG<br>Senior Pharmacist (Traditional Chinese Medicine) 2<br>Department of Health |
| | | Ms Mandy NG<br>Senior Government Counsel<br>Department of Justice |
| **Clerk in attendance** | : | Ms Maisie LAM<br>Chief Council Secretary (2) 5 |
| **Staff in attendance** | : | Mr Bonny LOO<br>Assistant Legal Adviser 4 |
| | | Ms Jasmine TAM<br>Senior Council Secretary (2) 8 |
| | | Miss Maggie CHIU<br>Legislative Assistant (2) 5 |

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**I. Meeting with the Administration**

[File Ref.: FHB/H/24/24, LC Paper Nos. LS75/16-17, CB(2)1883/16-17(02) to (05), CB(2)2141/16-17(02), CB(2)297/17-18(01) to (02) and CB(3)630/16-17]

The Bills Committee deliberated (index of proceedings attached at **Annex**).

Clause-by-clause examination of the Bill

2. The Bills Committee commenced clause-by-clause examination of the Chinese text of the Bill up to the proposed new section 138I of the Chinese Medicine Ordinance (Cap. 549) under clause 4 of the Bill.

Follow-up actions required of the Administration

Admin

3. The Bills Committee requested the Administration to:

(a) clarify whether Chinese herbal tea drinks sold at Chinese herbal tea shops would fall under the definition of "Chinese medicine or related product" and hence, would be subject to regulation

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under the Bill; and if not, advise whether any regulatory control was in place to ensure that such drinks were safe for human consumption; and

(b) provide information on the current legislation which governed the sale or supply of intermediate products generated in the course of manufacturing proprietary Chinese medicines, and review whether the existing regulation of such products was adequate for protecting public health.

Arrangements for the next meeting

4. Members agreed that the Bills Committee would receive deputations' views on the Chinese medicine safety order proposed under the Bill and continue discussion with the Administration at the next meeting to be scheduled.

(*Post-meeting note:* With the concurrence of the Chairman, the fifth meeting of the Bills Committee was scheduled for 22 January 2018 at 2:30 pm.)

## II. Any other business

5. There being no other business, the meeting ended at 4:19 pm.

Council Business Division 2
Legislative Council Secretariat
6 July 2018

**Annex**

# Proceedings of the fourth meeting of the Bills Committee on Chinese Medicine (Amendment) Bill 2017 held on Tuesday, 21 November 2017, at 2:30 pm in Conference Room 2B of the Legislative Council Complex

| Time marker | Speaker | Subject(s)/Discussion | Action required |
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| *Agenda item I*: *Meeting with the Administration* | | | |
| 000631 - 000746 | Chairman | Opening remarks | |
| 000747 - 000910 | Admin | Briefing by the Administration on its response to the follow-up actions arising from the discussion at the meeting of the Bills Committee on 13 October 2017 [LC Paper No. CB(2)297/17-18(02)]. | |
| 000911 - 001523 | Chairman<br>Admin | The Chairman's enquiry and the Administration's response regarding whether the Administration would conduct an overall review of the Chinese Medicine Ordinance (Cap. 549) ("the Ordinance") to address the concerns raised by members and deputations at previous meetings over, among others, the development of Chinese medicine. | |
| 001524 - 001605 | Chairman<br>Admin | Commencement of clause-by-clause examination of the Bill | |
| 001606 - 001644 | Admin<br>Chairman | <u>Examination of the long title and clauses 1 to 3</u> | |
| 001645 - 002401 | Admin<br>Chairman<br>ALA4 | <u>Examination of clause 4</u><br><br>*Proposed section 138A of the Ordinance*<br><br>In respect of the proposed amended definition of "intermediate product" which read "a substance or component 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", the Administration advised that after having considered the views of the trade, it would move an amendment to replace the words "intended for use" with "to be used".<br><br>The Legal Adviser to the Bills Committee's remark that it seemed that the amendment was proposed in response to the concern raised by a deputation at a previous meeting about what would constitute "intermediate product" under the regulatory regime of Chinese medicine products. With the proposed amendment, the definition of "intermediate product" as provided for in the proposed section 138A of the Ordinance would be in line with that under section 2 of the Chinese Medicines Regulation (Cap. 549F) ("the Regulation").<br><br>In response to the Chairman's enquiry about the difference in meaning of the phrases "is to be used" and "is intended for use", the Legal Adviser to the Bills Committee advised that the phrase "is intended for use" carried a broader meaning and was less | |

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| | | certain than "is to be used", which might be the cause for concern to the said deputation. He had no particular views on the proposed amendment if it was the Administration's view that such amendment could better reflect its policy intent regarding what would constitute "intermediate product".<br><br>*Proposed section 138B of the Ordinance*<br><br>In response to the enquiry of the Legal Adviser to the Bills Committee, the Administration confirmed that the making of a Chinese medicine safety order ("CMSO") would have to be supported by evidence proving that the medicine or product concerned was a Chinese medicine or related product as defined under the Bill (i.e. a Chinese herbal medicine; a proprietary Chinese medicine ("pCm"); or an intermediate product). | |
| 002402 - 003128 | Chairman<br>Mr SHIU Ka-fai<br>Admin | In response to Mr SHIU Ka-fai's call for the Administration to take the opportunity of the current legislative exercise to address the beauty industry's concern that the provision of massage and manipulative therapy services might be regarded as "practising Chinese medicine" and hence be subject to regulation under the Ordinance, the Administration advised that the matter fell outside the scope of the Bill and should be followed up separately. | |
| 003129 - 004012 | Chairman<br>Mr CHAN Han-pan<br>Admin | Mr CHAN Han-pan pointed out that currently, when a pCm issued with a Notice of confirmation of transitional registration of pCm (i.e. HKP) was approved for formal registration and issued with a Certificate of registration of pCm (i.e. HKC), the product holder was required to replace new labels and package inserts for the pCm within a specified period such that the particulars of the pCm concerned for sale on the market were identical to the registered particulars of that pCm. In his view, as a pCm issued with HKP which was subsequently granted HKC status had met the registration requirements prescribed by the Chinese Medicine Board ("CMB"), the product holder should be allowed to sell out the stocks bearing a HKP label and package insert to avoid unnecessary wastage. He suggested that the Bills Committee should receive the trade's views in this regard.<br><br>The Administration explained that HKP and HKC could not co-exist for the same pCm under the law. In the light of the trade's concern, a transitional arrangement had been put in place under which a product holder who was granted HKC status had to indicate to CMB a preferred effective date for the HKC of the product, which should be within 12 months after being notified of the granting of the HKC status. A product holder who failed to complete the replacement before the effective date could apply to CMB for extending the deadline for up to another 12 months. CMB would consider such applications on a case-by-case basis. In the Administration's view, the transitional arrangement had struck a proper balance between the trade's interest and the need to safeguard public health. | |
| 004013 - 005020 | Chairman<br>Dr Helena WONG<br>Admin | Dr Helena WONG's request for the Administration to clarify in writing whether Chinese herbal tea drinks sold in Chinese herbal tea shops would fall under the definition of "Chinese medicine or | **Admin** |

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| | | related product" and hence, would be subject to regulation under the Bill; and if not, advise whether any regulatory control was in place to ensure that such drinks were safe for human consumption.<br><br>Dr Helena WONG's enquiry and the Administration's reply regarding what follow-up actions would be taken by the Department of Health ("DH") upon receiving complaints or referrals involving decoctions of Chinese herbal medicines prepared by Chinese medicine dispensaries. | |
| 005021 - 010551 | Chairman<br>Mr SHIU Ka-fai<br>Admin<br>Dr Helena WONG<br>Dr Junius HO<br>Mr KWOK Wai-keung | Mr SHIU Ka-fai's reiteration of his concern about the lack of a proper forum for members of the beauty industry to raise their views and concerns about the Ordinance; and his agreement with Mr CHAN Han-pan's proposal for the Bills Committee to receive deputations' views on issues relating to the Ordinance.<br><br>Mr SHIU Ka-fai's enquiries and the Administration's replies regarding DH's market surveillance system to monitor the quality and safety of Chinese herbal medicines available in the market.<br><br>Members' agreement that the Bills Committee would receive deputations' views on the proposed CMSO and continue discussion with the Administration at the next meeting. | |
| 010552 - 011409 | Chairman<br>Mr KWOK Wai-keung<br>Admin | Mr KWOK Wai-keung's enquiries and the Administration's replies regarding whether the Director of Health ("the Director") would seek the views of relevant professionals in deciding whether the making of a CMSO was warranted and the time required for taking such a decision. | |
| 011410 - 011452 | Chairman<br>Admin | *Proposed section 138B of the Ordinance*<br><br>Members raised no further questions. | |
| 011453 - 011919 | Chairman<br>Admin<br>ALA4 | *Proposed section 138C of the Ordinance*<br><br>The Legal Adviser to the Bills Committee enquired about the reason why the proposed sections 138C(a)(ii), b(iv) and (c)(i) and 138D(a)(iii), (b)(iv) and (c)(i) of the Ordinance referred to "unfit for use by human beings", rather than "unfit for human consumption" as currently referred to in section 11(i), 16(q) and 20(g) of the Regulation.<br><br>The Administration explained that since the proposed sections would apply to both external use (such as cream and plaster) and internal use (such as tablets and capsules), "unfit for use by human beings" would be wide enough to cover both scenarios. | |
| 011920 - 014604 | Chairman<br>Admin<br>ALA4 | *Proposed section 138D of the Ordinance*<br><br>In reply to the Chairman's enquiry, the Administration confirmed that those products with a HKP label and package insert which were available for sale on the market after its HKC status had come into effect would be subject to a CMSO under the proposed sections 138C(b)i and 138D(b)(i) of the Ordinance. | |

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| | | In response to the enquiry of the Legal Adviser to the Bills Committee, the Administration advised that examples whereby a Chinese medicine or related product would be regarded as being "dangerous or injurious to health" included wrongly labelled products (e.g. Unprocessed Radix Aconiti Lateralis being labelled as Processed Radix Aconiti Lateralis) and deficient products deviating from the quality specifications which could result in serious health consequences. A Chinese medicine product containing industrial dye was an example of products that were "unfit for use by human beings". A product with incorrect dosage labelling and an improper storage of products which would cause a danger to public health (e.g. asbestos-containing Chinese medicines) were respective examples whereby a CMSO was necessary in order to prevent or reduce a possibility of danger to public health, or to mitigate any adverse consequence of a danger to public health.<br><br>On the Chairman's enquiry about the regulatory measures to monitor the safety and quality of intermediate products that might be generated in the course of manufacturing pCms, the Administration advised that sections 16 to 19 of the Regulation had provided for the general duties of holders of pCm manufacturer licence in respect of the storage, production and sale of intermediate products.<br><br>In response to the enquiry of the Legal Adviser to the Bills Committee, the Administration explained that as an intermediate product which had been stored, produced or sold in contravention of sections 16, 17, 18 or 19 of the Regulation did not necessarily pose a public health risk and warrant the making of a CMSO, it did not consider it necessary or appropriate to stipulate in the proposed section 138D(c) of the Ordinance that the Director might make a CMSO under the proposed section 138(B)(1)(b) if he had reasonable grounds to believe that an intermediate product had been stored, produced or sold in contravention of the relevant sections of the Regulation.<br><br>The Chairman's request for the Administration to provide information on the current legislation which governed the sale or supply of intermediate products, and review whether the existing regulation of such products was adequate for protecting public health. | **Admin** |
| 014605 - 014937 | Chairman<br>Admin<br>ALA4 | *Proposed section 138E of the Ordinance*<br><br>In reply to the enquiry of the Legal Adviser to the Bills Committee, the Administration advised that the way in which the recall was to be conducted would be covered by "action required under the order" provided for under the proposed section 138E(d) of the Ordinance.<br><br>The Chairman's enquiry and the Administration's reply on how the requirement under the proposed section 138E(a) of the Ordinance for a CMSO to state the person or persons intended to be bound by the order would be applied in cases where the | |

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| | | party to which a CMSO was addressed was a company.<br><br>The Legal Adviser to the Bills Committee's advice that as defined under section 3 of the Interpretation and General Clauses Ordinance (Cap. 1), a person included any public body and any body of persons, corporate or unincorporate. | |
| 014938 - 015300 | Chairman<br>Admin | *Proposed sections 138F, 138G, 138H and 138I of the Ordinance* | |
| *Agenda item II: Any other business* | | | |
| 015301 - 015312 | Chairman | Closing remarks | |

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