立法會
Legislative Council

Ref : CB2/BC/1/19

LC Paper No. CB(2)1255/19-20
(These minutes have been seen by the Administration)

Bills Committee on Pharmacy and Poisons (Amendment) Bill 2019

Minutes of the second meeting held on Wednesday, 27 May 2020, at 8:45 am in Conference Room 2A of the Legislative Council Complex

Members present	:	Hon Alice MAK Mei-kuen, BBS, JP (Chairman) Hon Abraham SHEK Lai-him, GBS, JP Hon CHAN Han-pan, BBS, JP Hon SHIU Ka-fai, JP
Public Officers attending	:	Mr FONG Ngai, JP Deputy Secretary for Food and Health (Health) 3 Food and Health Bureau Ms Lily LEE Lee-man Principal Assistant Secretary for Food and Health (Health) 4 Food and Health Bureau Mr Lot CHAN Sze-tao Chief Pharmacist (1) Department of Health Mr Michael LAM Siu-chung Deputy Law Draftsman II (Acting) Department of Justice Miss Annet LAI Chau-mei Government Counsel Department of Justice
Clerk in Attendance	:	Ms Joanne MAK Chief Council Secretary (2) 3
Staff in attendance	:	Ms Wendy KAN Assistant Legal Adviser 6

Ms Jasmine TAM
Senior Council Secretary (2) 3

Mrs Fonny TSANG
Legislative Assistant (2) 3

Action

I. Meeting with the Administration

[File Ref: FHB/H/53/4 and LC Paper Nos. CB(3)44/19-20, LS16/19-20, CB(2)1067/19-20(01) and CB(2)1068/19-20(01)-(03)]

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

Written submissions on the Bill

2. Members noted that no written submissions on the Pharmacy and Poisons (Amendment) Bill 2019 ("the Bill") had been received.

Clause-by-clause examination of the Bill

3. The Bills Committee completed clause-by-clause examination of the Bill.

Proposed amendments to the Bill

4. Members noted that in response to the observations of the Legal Adviser to the Bills Committee, the Administration would propose amendments to clause 13(5) of the Bill to the effect that:

(a) when a specified person (i.e. the licensed wholesale dealer or licensed manufacturer concerned) was expected to terminate operation, the specified person should transfer the specified documents to the Pharmacy and Poisons Board ("PPB") pursuant to the proposed new regulation 39(2)(b) of the Pharmacy and Poisons Regulations (Cap. 138A) ("PPR"); and

(b) "債務人" in the Chinese text of the proposed new regulation 39(2)(b)(ii) of PPR be replaced by "債權人", as the Chinese rendition of "creditors" in the English text.

Admin

5. The Administration undertook to provide its proposed amendments to the Bill for members' consideration. The Administration also agreed to explain the reason(s) for not providing for, in the proposed new regulation 39(2)(b) of PPR, the return of the specified documents to the specified person concerned by PPB in the

event that the specified person, whether being a company or a natural person, subsequently became solvent again without proceeding to liquidation or bankruptcy; or in the event that the status of the specified person regarding winding up/dissolution/bankruptcy subsequently changed.

6. Members agreed that subject to their comments on the amendments proposed by the Administration, the Chairman would decide whether it was necessary to hold the next meeting scheduled for 1 June 2020 at 2:45 pm.

(*Post-meeting note*: Members were informed via LC Paper No. CB(2)1093/19-20 on 29 May 2020 that as directed by the Chairman, the meeting scheduled for 1 June 2020 at 2:45 pm had been cancelled. The Administration's proposed amendment to the Bill was issued to members for comments via LC Paper No. CB(2)1108/19-20 on 1 June 2020.)

II. Any other business

7. There being no other business, the meeting ended at 9:33 am.

Council Business Division 2
Legislative Council Secretariat
24 June 2020

Annex

Proceedings of the second meeting of the Bills Committee on Pharmacy and Poisons (Amendment) Bill 2019 on Wednesday, 27 May 2020, at 8:45 am in Conference Room 2A of the Legislative Council Complex

Time Marker	Speaker(s)	Subject(s)	Action required
0000524 - 0000935	Chairman Administration	Opening remarks Briefing by the Administration on the Pharmacy and Poisons (Amendment) Bill 2019 ("the Bill").	
000936 - 001250	Chairman Mr SHIU Ka-fai Administration	Mr SHIU Ka-fai sought details of the consultation conducted with relevant stakeholders (e.g. suppliers of advanced therapy products ("ATPs"), medical professionals and patients) on the Bill. The Administration said that during the public consultation exercise on the proposed regulatory framework for ATPs conducted from 3 April to 2 June 2018, it had engaged various organizations and stakeholders through briefing sessions and meetings. A total of 127 participants, including representatives of universities and academia, associations of medical professionals and pharmacists, public and private hospitals, industry and beauty organizations attended three briefing sessions to express their views. Another three briefing sessions were held for licensed wholesalers of pharmaceutical products, with a total of 393 representatives attending. Besides, 28 written submissions from organizations/institutions (including industry associations), industry and individuals were received. The Administration informed members that overall, there was broad support for the proposed regulatory regime for ATPs. The Administration further said that after the consultation report was published in October 2018, it had continued to hold meetings with relevant stakeholders to gauge their views in the course of drafting the Bill and preparing relevant guidelines. The views received had been suitably incorporated in the Bill.	
001251 - 002008	Chairman Administration	The Chairman said that the adverse incident that took place in 2012 whereby the deceased underwent infusion of processed blood products provided by a beauty service company had aroused wide public concern about the regulation of high-risk medical products and procedures advertised as "medical beauty services". While noting that the Bill contained provisions governing the manufacture of ATPs, the Chairman asked whether	

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		advertisements of treatments involving the use of ATPs and the claims made in those advertisements would also be regulated under the Bill. The Administration said that in view of the high risks and complex nature of ATPs, it was proposed to require all facilities that manufactured ATPs to obtain a licence and comply with the Good Manufacturing Practice ("GMP") Guide and other standards set by the regulatory authority so as to ensure the safety, quality and efficacy of ATPs. Under the current proposals, manufacturing ATPs without a licence would be a criminal offence. The Administration further said that advertisements of ATPs which claimed to have properties for treating diseases and advertisements of treatments involving the use of such ATPs were already subject to the regulation of the Undesirable Medical Advertisements Ordinance (Cap. 231) ("UMAO"). The Chairman said that certain treatments (e.g. those claiming to have health maintenance effects) might not be regarded as "medicine" and thus the advertisements of these treatments might fall outside the scope of UMAO. She considered that apart from introducing legislation to regulate ATPs, the Administration should step up public education on how to differentiate low-risk and non-invasive cosmetic treatments from high-risk treatments involving the use of ATPs, as well as the importance of ensuring that the aforesaid high-risk treatments were performed only by qualified medical professionals, so as to further enhance protection for consumers/patients. She asked whether the Department of Health ("DH") would, after passage of the Bill, deploy more manpower to carry out relevant law enforcement (including conducting screening of advertisements and inspections) and public education work. The Administration said that additional resources had been allocated to DH to carry out relevant preparatory work for the current legislative exercise. Among others, DH had set up a dedicated website on advanced therapy to provide the public with information on cord blood banking and cell therapy as well as tips for finding trustworthy service providers, etc. Following the passage of the Bill, DH would launch a series of public education initiatives to enhance public understanding of ATPs and the risks involved in the use of ATPs. In doing so, DH would impress upon members of the public the importance of using ATPs and seeking relevant treatments only under the direction of qualified medical professionals.	

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		As regards law enforcement, the Administration advised that DH was responsible for enforcing UMAO, which prohibited the advertisements of medicines, surgical appliances or treatments for prevention or treatment of 14 diseases or bodily conditions. After passage of the Bill, DH would enhance screening of advertisements of ATPs and take necessary enforcement actions if warranted. DH would also conduct unannounced inspections and launch joint operations with the Police as necessary against premises suspected of involving in the provision of ATPs or relevant treatments.	
002009 - 002122	Chairman Administration	Commencement of clause-by-clause examination of the Bill Long title of the Bill **Part 1 – Preliminary** <u>Examination of clauses 1 and 2</u>	
002123 - 003145	Chairman Administration Assistant Legal Adviser ("ALA")	**Part 2 – Amendments to Pharmacy and Poisons Ordinance (Cap. 138)** <u>Examination of clauses 3 and 4</u> *Clause 3* ALA's enquiries about the reason(s) for not adopting entirely the definitions of "somatic cell therapy product" and "tissue engineered product" used in the relevant legislation of the European Union ("EU") as the proposed new definitions of "somatic cell therapy product" and "tissue engineered product" in the proposed section 2(1) of the Pharmacy and Poisons Ordinance (Cap. 138) ("PPO") (paragraphs 4 and 5 of the Annex to ALA's letter of 29 November 2019 to the Administration (LC Paper No. CB(2)1068/19-20(01) ("ALA's letter") referred). The Administration's explanation as set out in paragraphs 9 to 11 of its reply letter of 18 December 2019 to ALA (LC Paper No. CB(2)1068/19-20(02)) ("the Administration's reply letter"). The Chairman asked whether the proposed new definitions of "somatic cell therapy product" and "tissue engineered product" in the proposed section 2(1) of PPO were more or less stringent than the corresponding definitions adopted by EU. The Administration reiterated that in adapting the	

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		EU definitions of "somatic cell therapy product" and "tissue engineered product", a major consideration was to maintain consistency with the overall regulatory framework under PPO. The Administration considered that the proposed new definitions of the aforesaid two terms and the corresponding EU definitions constituted no material difference from regulatory point of view. ALA's enquiry about the reason(s) for proposing to adopt "對….的表述或其狀況顯示" as the Chinese renditions for "is presented" in paragraph (a)(i) of the proposed definition of "pharmaceutical product" in the English text and "presented as" in the proposed new definitions of "somatic cell therapy product" and "tissue engineered product" under the proposed section 2(1) of PPO in the English text respectively (paragraph 13 of the Annex to ALA's letter referred). The Administration's explanation as set out in paragraphs 18 and 19 of the Administration's reply letter.	
003146 - 003242	Chairman Administration	**Part 3 – Amendments to Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A)** <u>Examination of clauses 5 to 8</u>	
003243 - 003731	Chairman Administration ALA	<u>Examination of clause 9</u> *Clause 9(1)* In reply to the Chairman's enquiry about the proposed regulation 31(1)(d) of the Pharmacy and Poisons Regulations (Cap. 138A) ("PPR"), the Administration explained that when PPO was enacted back in 1970, it provided for a transitional arrangement that the Pharmacy and Poisons Board ("PPB") might make regulations to provide for the provisional registration of pharmaceutical products. However, as there was no operational need to issue provisional certificates, no provisions on provisional registration of pharmaceutical products were made under PPR. Opportunity of the current legislative exercise was thus taken to remove the existing reference to "provisional certificate" in regulation 31(1)(d) of PPR, which was no longer necessary, and to spell out clearly that for a pharmaceutical product registered under regulation 36 of PPR, its container would be required to be labelled with the number of the registration certificate issued under regulation 36(5) of PPR.	

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		Clause 9(4) ALA's enquiries regarding the requirement under the proposed new regulation 31(1)(g) of PPR for a licensed manufacturer to label or cause to be labelled the container of each ATP with, among other particulars, the unique donation identifier and unique recipient identifier assigned in accordance with the codes of practice issued by PPB, including whether the identity of the donor and recipient concerned would be disclosed (paragraph 7 of the Annex to ALA's letter referred). The Administration's explanation as set out in paragraphs 13 and 14 of the Administration's reply letter.	
003732 - 003852	Chairman Administration	<u>Examination of clauses 10 to 12</u>	
003853 - 004629	Chairman Administration ALA	<u>Examination of clause 13</u> *Clause 13* ALA's enquiry about the reason(s) for not prescribing in the proposed new regulation 39(2) of PPR the place where the books, records and documents relating to ATPs referred to in that regulation ("specified documents") must be preserved by the licensed wholesale dealer or licensed manufacturer concerned ("specified person"), as in the proposed regulation of 39(1) of PPR (paragraph 8 of the Annex to ALA's letter referred). The Administration's explanation as set out in paragraph 15 of the Administration's reply letter. In reply to the Chairman's enquiry, the Administration advised that failure to comply with the requirements under the proposed new regulation 39(2) of PPR would be an offence punishable by a fine at level 6 ($100,000) and imprisonment for two years. ALA's enquiry about the reason(s) for excluding the records and documents referred to in subparagraphs or proposed subparagraphs (d), (e), (f) and (g) of regulation 35(1) of PPR, which would be covered in the proposed regulation 39(1) of PPR, from the list of specified documents under the proposed regulation 39(2)(a) of PPR (paragraph 9 of the Annex to ALA's letter referred).	

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		The Administration's explanation as set out in paragraph 16 of the Administration's reply letter. Referring to ALA's observations set out in paragraphs 10 to 11 and paragraph 15 of the Annex to ALA's letter, the Administration said that it would propose amendments to clause 13(5) of the Bill with respect to the proposed new regulation 39(2)(b) of PPR. Regarding ALA's observation mentioned in paragraph 12 of the Annex to ALA's letter, the Administration agreed to explain, in the paper on its proposed amendments to the Bill to be provided to the Bills Committee, the reason(s) for not providing for, in the proposed new regulation 39(2)(b) of PPR, the return of the specified documents to the specified person concerned by PPB in the event that the specified person, whether being a company or a natural person, subsequently became solvent again without proceeding to liquidation or bankruptcy; or in the event that the status of the specified person regarding winding up/dissolution/bankruptcy subsequently changed.	**Admin** (paragraph 5 of minutes)
004630 - 004652	Chairman Administration	<u>Examination of clause 14</u>	
004653 - 005025	Chairman ALA Administration	ALA's enquiries regarding the Administration's target commencement date(s) of the Bill, if passed, and the expected timing for the issuance and coming into operation of the revisions, if any, required to be made to the relevant codes of practice and the GMP Guide (paragraph 1 of the Annex to ALA's letter referred). The Administration's explanation as set out in paragraphs 2 to 4 of the Administration's reply letter. The Chairman expressed concern about how the specified documents to be kept by the specified persons or transferred to and retained by PPB under the proposed new regulation 39(2) of PPRs would be dealt with upon the expiry of the proposed prescribed record-keeping period (i.e. 30 years after the expiry date of the product concerned). The Administration advised that upon the expiry of the proposed prescribed record-keeping period, the specified persons and PPB should dispose of the specified documents concerned in accordance with the relevant legal requirements and guidelines, including legislation relating to the protection of personal data.	

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005026 - 005144	Chairman ALA Administration	The Administration's undertaking that it would provide proposed amendments to the Bill for members' consideration. Arrangements for the next meeting	**Admin** (paragraph 5 of minutes)

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