立法會
Legislative Council

LC Paper No. CB (2)940/14-15
(These minutes have been
seen by the Administration)

Ref : CB2/BC/4/13

Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014

Minutes of the eighth meeting
held on Tuesday, 25 November 2014, from 4:45 pm to 6:45 pm
in Conference Room 2B of the Legislative Council Complex

Members present	:	Prof Hon Joseph LEE Kok-long, SBS, JP, PhD, RN (Chairman) Hon LEUNG Yiu-chung Hon Emily LAU Wai-hing, JP Hon WONG Ting-kwong, SBS, JP Hon Mrs Regina IP LAU Suk-yee, GBS, JP Hon Alan LEONG Kah-kit, SC Hon Albert CHAN Wai-yip Hon Alice MAK Mei-kuen, JP Dr Hon Elizabeth QUAT, JP
Members absent	:	Hon Vincent FANG Kang, SBS, JP Dr Hon LEUNG Ka-lau Hon CHEUNG Kwok-che Hon Paul TSE Wai-chun, JP Hon LEUNG Kwok-hung Hon WONG Yuk-man Hon Claudia MO Hon CHAN Han-pan, JP Dr Hon KWOK Ka-ki Dr Hon Fernando CHEUNG Chiu-hung
Public Officers attending	:	Item I Miss Janice TSE, JP Deputy Secretary for Food and Health (Health) 1 Food and Health Bureau

Miss Fiona CHAU
Principal Assistant Secretary for Food and Health (Health) 1
Food and Health Bureau

Ms Linda WOO
Assistant Director of Health (Drug)
Department of Health

Mr Lot CHAN
Chief Pharmacist (1)
Department of Health

Mr Edwin LAM
Senior Pharmacist (Manufacturing Quality Assurance)
Department of Health

Miss Amy CHAN
Senior Assistant Law Draftsman (Acting)
Department of Justice

Ms Carmen CHAN
Senior Government Counsel (Acting)
Department of Justice

Clerk in attendance : Ms Maisie LAM
Chief Council Secretary (2) 5

Staff in attendance : Ms Wendy KAN
Assistant Legal Adviser 6

Ms Priscilla LAU
Council Secretary (2) 5

Ms Michelle LEE
Legislative Assistant (2) 5

Action

I. Meeting with the Administration

[LC Paper Nos. CB(2)328/14-15(01), CB(2)1344/13-14(02), CB(2)1735/13-14(03), CB(2)1810/13-14(02), CB(2)1943/13-14(02) and CB(3)511/13-14]

Action

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

Continuation of clause-by-clause examination of the Bill

2. The Bills Committee completed the clause-by-clause examination of the Bill and noted that it was the Administration's intention to propose, among others, the following Committee Stage amendments ("CSAs") to the Bill -

(a) to amend the proposed new regulation 30B(5) of the Pharmacy and Poisons Regulations (Cap. 138A) ("PPR") to the effect that the secretary to the Pharmacy and Poisons Board ("PPB") had to make the register of authorized persons available for inspection by the public free of charge at the secretary's office during normal office hours, and in any other manner the secretary thought fit; and

(b) to amend the proposed revised regulation 33 of PPR to provide certain flexibility for manufacturers in maintaining sample of finished products.

3. Pursuant to the decision of the Bills Committee at its meeting on 4 July 2014, members revisited whether there were any outstanding issues of concern with the legislative proposal to empower PPB to promulgate codes of practice for relevant licensed/registered drug traders and code of conduct for registered pharmacists under clause 6 of the Bill. The Administration was requested to relay to PPB the concern of some members that the arrangement to have the new Code of Practice for Authorized Seller of Poisons to take effect on 2 January 2015 to replace the existing one was undesirable, as the Bill might have not been passed by the Legislative Council at the time the new COP took effect.

Admin

II. Any other business

4. The Chairman said that he would discuss with the Clerk and the Administration on the date of the next meeting to consider the draft CSAs to be proposed by the Administration. Members would be informed of the meeting arrangements in due course.

(*Post-meeting note*: The notice of the ninth meeting of the Bills Committee scheduled for 16 December 2014 at 8:30 am was issued to members on 27 November 2014 vide LC Paper No. CB(2)354/14-15.)

Action

5. There being no other business, the meeting ended at 6:36 pm.

Council Business Division 2
Legislative Council Secretariat
2 March 2015

Annex

Proceedings of the eighth meeting of the Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014 held on Tuesday, 25 November 2014, from 4:45 pm to 6:45 pm in Conference Room 2B of the Legislative Council Complex

Time marker	Speaker	Subject(s)/Discussion	Action required
Agenda item I: Meeting with the Administration			
000345 - 000449	Chairman Admin	Opening remarks by the Chairman	
000450 - 000500	Chairman	<u>Continuation of clause-by-clause examination of the Bill</u>	
000501 - 002147	Chairman Admin Ms Emily LAU	<u>Examination of clause 52</u> The Administration's advice that in response to the suggestion made by Ms Emily LAU at the last meeting that the register of authorized persons ("APs") should be made available for public inspection via the Internet, it would move a Committee Stage amendment ("CSA") to amend the proposed new regulation 30B(5) of the Pharmacy and Poisons Regulations (Cap. 138A) ("PPR") to the effect that the Secretary to the Pharmacy and Poisons Board ("PPB") had to make the register available for inspection by the public free of charge at the Secretary's office during normal office hours, and in any other manner the Secretary thought fit. This would cover, among others, online inspection. The draft CSA was set out in Annex II to LC Paper No. CB(2)328/14-15(01). In response to Ms Emily LAU's enquiry on the qualification requirements of APs as specified in the proposed new regulation 30C of PPR, the Administration's advice that - (a) the proposal to allow registered pharmacists and any other person who held a qualification awarded on completion of a course recognised by the Pharmacy and Poisons (Manufacturers Licensing) Committee, who had at least three years' relevant experience in manufacturing pharmaceutical products in accordance with the Good Manufacturing Practice Guide, to act as an AP was in line with international practice, such as that adopted by the European Union; and (b) taking into account that only 24 licensed GMP pharmaceutical manufacturers in Hong Kong would be required to employ at least one AP under the proposed new regulation 30A of PPR, it was expected that the proposal would not significantly affect the job opportunities of registered pharmacists. The Chairman's remarks that while some members of the industry did not support the Administration's proposal, some	**Admin**

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		other members of the industry, such as those who made a joint submission to the Bills Committee (LC Paper No. CB(2)313/14-15(01)) on 6 October 2014, supported the positions of APs should be filled by persons who possessed relevant expertise and experience, and should not be restricted to registered pharmacists.	
002148 - 002511	Chairman Admin	Examination of clauses 53 and 54	
002512 - 002805	Chairman Admin	Examination of clause 55 The Administration's advice that it would move a CSA to amend the proposed revised regulation 33 of PPR to provide certain flexibility for manufacturers in maintaining sample of finished products. The draft CSA was set out in Annex II to LC Paper No. CB(2)328/14-15(01). In response to the Chairman's enquiry on the proposed revised regulation 33(4) of PPR, the Administration's advice that the reason for changing the specified period for a licensed manufacturer to maintain a control sample of each batch of finished products under conditions of storage suitable to that product to become "a period of not less than 1 year after the expiry date of the product" was to align with the PIC/S Good Manufacturing Practice requirement.	
002806 - 002959	Chairman Admin Ms Emily LAU	Examination of clause 56 Ms Emily LAU's enquiry as to the reason why the reference to "packaging" was proposed to be deleted from regulation 34 of PPR; and the Administration's advice that it was an amendment consequential to the proposed revised definition of manufacture under section 2(1) of the Pharmacy and Poisons Ordinance (Cap. 138) ("the Ordinance") which had expressly covered the packaging and repackaging of pharmaceutical products.	
003000 - 003126	Chairman Admin	Examination of clause 57	
003127 - 003904	Chairman Admin	Examination of clause 58 In response to the Chairman's enquiry, the Administration's advice that the amendment to replace "分銷" with "分發" in the Chinese text of regulation 36 of PPR as the word "distribute" included supply without payment . The Chairman's enquiry about whether registered chiropractors could possess or use any unregistered pharmaceutical product or substance for the purpose of treatment of a particular patient and, hence, be granted exemption under the proposed new regulation 36(1A)(ab) of PPR; and the Administration's reply in the negative.	

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		In response to the Chairman's enquiry about the proposed new regulation 36(7A) of PPR under which the renewal of registration certificate of pharmaceutical products was subject to any conditions the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee thought fit to impose, the Administration's advice that no adverse views from the trade had been received.	
003905 - 004404	Chairman Admin	Examination of clause 59 At the invitation of the Chairman, the Administration's advice that the proposed amendment to regulation 36B of PPR to extend the validity of clinical trial certificate or medicinal test certificate to not more than five years was to address the concern that the current two-year validity period was often too short for the completion of a clinical trial or medicinal test, so that the applicant did not need to apply for a certificate again if a trial or test lasted more than two years. The proposal would help enhance the capacity of drug research and development in Hong Kong. A number of deputations, including the Department of Pharmacology and Pharmacy of The University of Hong Kong, the School of Pharmacy of The Chinese University of Hong Kong and the Hong Kong Association of the Pharmaceutical Industry, were in support of the proposal.	
004405 - 004627	Chairman Admin	Examination of clauses 60 and 61	
004628 - 004734	Chairman Admin	Examination of clause 62 In response to the Chairman's enquiry, the Administration's confirmation that apart from making copies of the forms specified by an executive committee established under section 4A of the Ordinance available for inspection by the public free of charge at the office of the Secretary to PPB during normal office hours, the forms would also be made available for public inspection via the Internet.	
004735 - 004937	Chairman Admin	Examination of clauses 63 and 64	
004938 - 011229	Chairman Admin Mr Alan LEONG Mr WONG Ting-kwong	Examination of clauses 65 to 67 In response to Mr Alan LEONG's enquiry about the way of ordering of the substances in the First Schedule and the Third Schedule to PPR, the Administration's advice that the substances were arranged in alphabetical order in the English version and according to the number of strokes of the Chinese characters in the Chinese version. In response to the Chairman's enquiry, the Administration's confirmation that instead of labelled with the word "Poison 毒藥", medicine containing a poison included in the Third	

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		Schedule to PPR would be required to label with the text "Prescription Drug 處方藥物", whereas medicine containing a poison included in Part I of the Poisons List contained in the proposed new Schedule 10 to PPR but not included in the Third Schedule to PPR would be required to label with the text "Drug under Supervised Sales 監督售賣藥物".	
011230 - 011618	Chairman Admin Mr Alan LEONG	<u>Examination of clause 68</u> In response to the Chairman's enquiry about the reason for proposing to delete Forms 1 to 16 from the Eighth Schedule to PPR, the Administration's advice that the proposed amendment would provide PPB with the flexibility to revise the relevant forms as and when necessary. The Chairman's concern that the proposal to remove from Form 17 the specifications on the size of the "℞" logo displayed by the authorized seller of poisons ("ASP") would result in these logos came in different sizes and cause confusion to the public; and the Administration's explanation that the proposed amendment would enable enforcement against the display of the "℞" logo, regardless of its size, at premises not being the registered premises of an ASP.	
011619 - 012657	Chairman Admin Mr Alan LEONG	In response to Mr Alan LEONG's concern as to whether the defendant's claim that the substance or product with Chinese name that did not correspond exactly to that stipulated in the First and Third Schedule to PPR would affect enforcement action, the Administration's advice that there was no cause for such concern, as all pharmaceutical products which were composed of particular substances had to be registered with PPB before they could be sold in Hong Kong. The registered particulars covered, among others, the Chinese and/or English names of the substances contained in the products which had to be the same as those stipulated in the Schedules.	
012658 - 013259	Chairman Admin	<u>Examination of clauses 69 to 72</u>	
013300 - 013327	Chairman Admin	Completion of clause-by-clause examination of the Bill	
013328 - 013723	Chairman Mr WONG Ting-kwong Admin	Mr WONG Ting-kwong's enquiry as to whether, and if so, how the Administration would address the concern of drug manufacturers over the proposed new requirement of keeping samples of each batch of finished products as keeping samples of expensive drugs was costly. The Administration's elaboration of the details of the CSA that it proposed to move to amend the proposed revised regulation 33 of PPR was to provide certain flexibility for licensed manufacturers in maintaining sample of finished products. For instance, they would only be required to retain a sample of the additional package insert, the replacing package insert or the label affixed, as the case might be, if the	

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		pharmaceutical products involved were enclosed in a primary container and the process of manufacture that the manufacturers carried out in respect of the products only involved adding a package insert, replacing a package insert or affixing a label to any labelled container of the products. The draft CSA was set out in Annex II to LC Paper No. CB(2)328/14-15(01).	
013724 - 015048	Chairman Mr LEUNG Yiu-chung Admin	Mr LEUNG Yiu-chung's view that the arrangement of PPB to have the new Code of Practice ("COP") for ASP, that was previously endorsed by PPB, to take effect in January 2015 was undesirable, as the Bill might have not been passed by the Legislative Council at the time the new COP took effect. The Administration's clarification that the revision of the existing COP for ASP, which was introduced in 1997 as a condition for registration of premises under section 13 of the Ordinance, was not part of the legislative proposals under the Bill. It should be noted that the drafting of the new COP was conducted by the Working Group on the Code of Practice for Authorized Seller of Poisons. A number of consultation meetings and briefing sessions had also been held to collect views from the trade and other stakeholders on the draft of the new COP. Based on the comments received during the consultation exercise, the new COP for ASP was finalized and subsequently endorsed by PPB for replacing the existing one with effect from 2 January 2015. The Chairman's advice that the Bills Committee would need to hold another meeting to consider the draft CSAs to be proposed by the Administration. A time slot on 16 December 2014 had been reserved for the purpose. Hence, the resumption of the Second Reading debate of the Bill could only take place at the Council meeting of 21 January 2015 the earliest. In the light of this, the Administration was requested to relay members' concern to PPB for consideration.	**Admin**
Agenda item II: Any other business			
015049 - 015219	Chairman Ms Emily LAU Admin	Date of next meeting Closing remarks by the Chairman	

Council Business Division 2
Legislative Council Secretariat
2 March 2015