

立法會
Legislative Council

LC Paper No. CB (2)905/14-15

(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 seventh meeting
held on Monday, 3 November 2014, at 4:30 pm
in Conference Room 2A 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 Vincent FANG Kang, SBS, JP
Hon WONG Ting-kwong, SBS, JP
Hon Mrs Regina IP LAU Suk-yee, GBS, JP
Hon Paul TSE Wai-chun, JP
Hon Alan LEONG Kah-kit, SC
Hon LEUNG Kwok-hung
Hon Albert CHAN Wai-yip
Hon Claudia MO
Dr Hon Fernando CHEUNG Chiu-hung
Dr Hon Elizabeth QUAT, JP

Members absent : Dr Hon LEUNG Ka-lau
Hon CHEUNG Kwok-che
Hon WONG Yuk-man
Hon CHAN Han-pan, JP
Hon Alice MAK Mei-kuen, JP
Dr Hon KWOK Ka-ki

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 Edwin LAM
Chief Pharmacist (1) (Acting)
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)1344/13-14(02), CB(2)1735/13-14(03), CB(2)1810/13-14(02), CB(2)1943/13-14(02), CB(2)2374/13-14(01) and CB(3)511/13-14]

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

Action

Continuation of clause-by-clause examination of the Bill

2. The Bills Committee continued clause-by-clause examination of the Chinese text of the Bill up to clause 51.

Follow-up actions required of the Administration

3. Members noted the Administration's undertaking to, upon the gazettal of the notice identifying the Good Manufacturing Practice Guide or part revised, provide a copy of the Guide to the Panel on Health Services for information.

Admin

4. Members also noted that it was the Administration's intention to introduce the following Committee Stage amendments to the Bill -

- (a) to replace "委員會" with "管理局" before "在指明該日期前" in the Chinese text of the proposed new section 25(3B) of the Pharmacy and Poisons Ordinance (Cap. 138) ("the Ordinance") to align with the relevant English text;
- (b) to replace "及" with "或" after "並訂明註冊證明書" in the Chinese text of the proposed new section 29(1)(jb) of the Ordinance to align with the relevant English text; and
- (c) to replace "fine" in the proposed new section 34A(2) of the Ordinance with "civil debt" so that the sum ordered to be paid was recoverable in the same manner as a civil debt.

Admin

5. The Administration was requested to -

- (a) consider a suggestion that the monetary amounts of fine instead of fine levels should be specified in the relevant provisions in the Bill, and it should be clearly stipulated that the penalties specified therein were maximum penalties which the court might not apply fully;
- (b) review the drafting of the Chinese expression "名列該名單" in the proposed revised section 25(3) of the Ordinance in the light of members' views;
- (c) explain why an appeal against a decision made by the Pharmacy and Poisons Board ("PPB") under the proposed new section 25(3B) of the Ordinance as to a contravention of a condition imposed by PPR for suspending the operation of a

Action

direction made under the proposed revised section 25(3) of the Ordinance, was not covered under the proposed revised section 25(5) of the Ordinance;

- (d) explain why an appeal against a decision made by the Pharmacy and Poisons (Wholesale Licences) Committee under the proposed new regulation 26(5B) of the Pharmacy and Poisons Regulations (Cap. 138A) ("PPR") as to a contravention of a condition imposed by the Committee for suspending the operation of a decision made under the proposed new regulation 26(5)(a) of PPR was not covered under the proposed revised regulation 26(6) of PPR; and
- (e) consider making the register of authorized persons available for online inspection by the public.

II. Any other business

- 6. The Bills Committee agreed to hold the next meeting on Tuesday, 25 November 2014, at 4:45 pm.
- 7. There being no other business, the meeting ended at 6:31 pm.

Council Business Division 2
Legislative Council Secretariat
23 February 2015

**Proceedings of the seventh meeting of
the Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014
held on Monday, 3 November 2014, at 4:30 pm
in Conference Room 2A of the Legislative Council Complex**

Time marker	Speaker	Subject(s)/Discussion	Action required
<i>Agenda item I: Meeting with the Administration</i>			
001025 - 001119	Chairman	Opening remarks	
001120 - 001440	Chairman Admin	Briefing by the Administration on its response to issues raised at the meeting on 17 July 2014. [LC Paper No. CB(2)2374/13-14(01)]	
001441 - 001450	Chairman Admin	<u>Continuation of clause-by-clause examination of the Bill</u>	
001451 - 001958	Chairman Admin Ms Emily LAU	<u>Examination of clause 15</u>	
001959 - 002543	Chairman Admin Ms Emily LAU Mr LEUNG Yiu-chung	<u>Examination of clause 16</u> In response to Ms Emily LAU's enquiry, the Administration's advice that no adverse views had been received from the industry about the proposed amendment to section 16A(3) of the Pharmacy and Poisons Ordinance (Cap. 138) ("the Ordinance") which sought to increase the fine for failing to attend any inquiry, produce any document or answer any question as requested by the Disciplinary Committee appointed by the Pharmacy and Poisons Board ("PPB") from \$500 to a fine at level 3 (currently \$10,000). Mr LEUNG Yiu-chung's view that to enable members of the public to better understand the penalty provisions of the Ordinance upon enactment of the Bill, the monetary amounts of fine instead of fine levels should be specified. It should also be clearly stipulated that the penalties specified therein were maximum penalties, which the court might not apply fully. The Administration's advice that the current law drafting practice was to specify the fines by reference to the levels provided under Schedule 8 to the Criminal Procedure Ordinance (Cap. 221) ("CPO"). This would facilitate future revision of fines by a single legislative measure, as from time to time the existing maxima would become outdated because of the changing value of money. It should be noted that whether to impose a maximum penalty was a matter for the court to decide taking into account the circumstances of each individual case.	

Time marker	Speaker	Subject(s)/Discussion	Action required
		The Chairman's request for the Administration to consider reviewing the drafting of the proposed revised section 16A(3) of the Ordinance and other relevant provisions in the Bill having regard to the views of members.	Admin
002544 - 002616	Chairman Admin	<u>Examination of clause 17</u>	
002617 - 003512	Chairman Admin Mr LEUNG Yiu-chung Mr WONG Ting-kwong Ms Emily LAU	<u>Examination of clause 18</u> Mr LEUNG Yiu-chung's concern about whether "裁斷" was an appropriate Chinese rendition for "finding" in the proposed revised section 19 of the Ordinance and whether the term was commonly used in local legislation; and the Administration's advice that the same Chinese rendition was used in the subsidiary legislation of the Ordinance relating to the disciplinary procedure of pharmacists and in other existing ordinances. Mr LEUNG Yiu-chung's view that legislation should be comprehensible to the general public. While sharing Mr LEUNG's view, Ms Emily LAU's opinion that it was not practicable to change the use of "裁斷" as the Chinese rendition for "finding" as it was used in a number of legislation; and Mr WONG Ting-kwong's remarks that he accepted the use of "裁斷" and the law drafting practice to specify the fines by reference to the levels of fines.	
003513 - 003559	Chairman Admin	<u>Examination of clause 19</u>	
003600 - 004800	Chairman Admin Mr WONG Ting-kwong Mr LEUNG Yiu-chung ALA6	<u>Examination of clause 20</u> In response to Mr WONG Ting-kwong's enquiry, the Administration's advice that the existing annual fee for retaining the name and the existing fee for altering the entry relating to the person on the list of listed sellers of poisons were \$430 and \$250 respectively. Mr LEUNG Yiu-chung's view that the Chinese expression "名列該名單" in the proposed revised section 25(3) of the Ordinance failed to convey the meaning of "on the list"; and the Administration's undertaking to advise if it was necessary to revise the drafting of the Chinese rendition. At the advice of ALA6, the Administration's undertaking to move a Committee Stage amendment ("CSA") to replace "委員會" with "管理局" before "在指明該日期前" in the Chinese text of the proposed new section 25(3B) of the Ordinance to align with the relevant English text.	Admin Admin

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		ALA6's enquiry about the reason why an appeal against a decision made by PPB under the proposed new section 25(3B) of the Ordinance as to a contravention of a condition imposed by PPB for suspending the operation of a direction made under the proposed revised section 25(3) of the Ordinance was not covered under the proposed revised section 25(5) of the Ordinance as in the proposed revised section 16(3) of the Ordinance; and the Administration's undertaking to provide a response.	Admin
004801 - 005007	Chairman Admin	<u>Examination of clauses 21 and 22</u>	
005008 - 005733	Chairman Admin ALA6	<u>Examination of clause 23</u> At the advice of ALA6, the Administration's undertaking to move a CSA to replace "及" with "或" after "並訂明註冊證明書" in the Chinese text of the proposed new section 29(1)(jb) of the Ordinance to align with the relevant English text.	Admin
005734 - 010109	Admin	<u>Examination of clauses 24 to 29</u>	
010110 - 010532	Admin Mr WONG Ting-kwong	<u>Examination of clause 30</u> Referring to some traders' concern over the proposed new section 34A of the Ordinance which provided for the recovery of the costs and expenses reasonably incurred by the Government in relation to the collection, analysis or examination of a poison, pharmaceutical product or any other substance for the purpose of the criminal proceedings, Mr WONG Ting-kwong's view that the proposal was reasonable as it applied only to persons convicted of an offence under the Ordinance. The Administration's advice that it would move a CSA to replace "fine" in the proposed new section 34A(2) of the Ordinance with "civil debt" so that the sum ordered to be paid was recoverable in the same manner as a civil debt. This was in line with the concept on recovery of costs that the amount to be granted would be compensatory in nature.	Admin
010533 - 011025	Chairman Admin	<u>Examination of clauses 31 and 32</u> At the invitation of the Chairman, the Administration's advice that while some deputations had different views on the qualification requirements for an authorized person ("AP"), the proposal to allow a registered pharmacist 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	

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		<p>Manufacturing Practices Guide ("the GMP Guide"), to act as an AP was in line with international practice, such as that adopted by the European Union. 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 the Pharmacy and Poisons Regulations (Cap. 138A) ("PPR"), it was expected that the proposal would not significantly affect the job opportunities of registered pharmacists.</p> <p>In response to the Chairman, the Administration's advice that the courses to be recognised by the Committee were not offered locally at the time being.</p>	
011026 - 011052	Chairman Admin	<u>Examination of clauses 33 and 34</u>	
011053 - 011231	Chairman Admin Mr WONG Ting-kwong	<u>Examination of clause 35</u> In response to Mr WONG Ting-kwong's enquiry, the Administration's advice that the respective monetary amounts of the six levels of fines (from level 1 to level 6) provided in Schedule 8 to CPO were \$2,000, \$5,000, \$10,000, \$25,000, \$50,000 and \$100,000.	
011232 - 011319	Chairman Admin	<u>Examination of clause 36</u>	
011320 - 011446	Chairman Admin	<u>Examination of clause 37</u> In response to the Chairman's enquiry on the labeling of pharmaceutical products listed in Part I of the Poisons List of the Poisons List Regulations (Cap. 138B) (which was proposed to be merged into PPR), the Administration's advice that for pharmaceutical products, the text "Poison 毒藥" would be replaced by "Prescription Drug 處方藥物" or "Drug under Supervised Sales 監督售賣藥物" depending on the sale restriction stipulated by PPR so as to avoid confusion that the pharmaceutical products might be harmful and unsuitable for use or consumption.	
011447 - 011659	Chairman Admin	<u>Examination of clause 38</u> The Administration's advice that the proposed amendments set out to extend the control stipulates by regulation 19(2) of PPR to all Part I Poisons and did not introduce any change to the existing requirement that only registered pharmacists should retain the key to the locked receptacle for the storage of these poisons in the registered premises of an authorized seller of poisons.	
011700 - 012037	Chairman Admin	<u>Examination of clauses 39 to 45</u>	

Time marker	Speaker	Subject(s)/Discussion	Action required
012038 - 012709	Chairman Admin ALA6	<p><u>Examination of clause 46</u></p> <p>Referring to section 3 of the Interpretation and General Clauses Ordinance (Cap.1) which provided that an "Ordinance" also included any subsidiary legislation made under it, ALA6's enquiry about the need to state "or any of the regulations made under section 29" in the proposed new regulation 26(5A)(b)(i) of PPR. It should be noted that the proposed new section 15(1)(c)(i) of the Ordinance had not made such provision.</p> <p>The Administration's explanation that given that references to a particular regulation made under section 29 of the Ordinance were made under PPR, it was considered desirable to use the above expression to clearly set out that the scope of the provision covered all the regulations made under section 29 of the Ordinance.</p> <p>In response to ALA6's enquiry, the Administration's undertaking to provide a response regarding the same observation mentioned in respect of the proposed revised section 25(5) of the Ordinance on the proposed revised regulation 26(6) of PPR.</p>	Admin
012710 - 013049	Chairman Admin	<u>Examination of clauses 47 and 48</u>	
013050 - 015147	Chairman Admin Ms Emily LAU ALA6 Mr LEUNG Yiu-chung	<p><u>Examination of clause 49</u></p> <p>Ms Emily LAU's view that the Administration should consult the Panel on Health Services before the finalization of any revision to the GMP Guide which would not be a subsidiary legislation, and therefore not subject to the scrutiny of the Legislative Council.</p> <p>Mr LEUNG Yiu-chung's view that all licensed drug manufacturers should be fully consulted on any revision made to the GMP Guide.</p> <p>The Administration's advice that GMP was a quality assurance approach used by the drug manufacturing industry worldwide. PPB would revise the GMP Guide, which served as a licensing condition for licensed pharmaceutical drug manufacturers, from time to time taking into account the latest GMP standards adopted by the World Health Organization and other overseas countries, as well as the views and capacity of local drug manufacturers. PPB had put in place a well-established mechanism for consultation with the licensed drug manufacturers in revising the GMP Guide. If the GMP was revised, PPB had to, by notice published in the Gazette, identify the Guide or part revised. The Administration would, upon the gazettal of the notice, provide a copy of the GMP Guide to the Panel for information.</p>	Admin

Time marker	Speaker	Subject(s)/Discussion	Action required
015148 - 015610	Chairman Admin	<u>Examination of clauses 50 and 51</u>	
015611 - 020129	Chairman Admin Ms Emily LAU	<u>Examination of clause 52</u> The Administration's undertaking to consider Ms Emily LAU's suggestion to make available the register of AP for online inspection by the public, in addition to making it available for public inspection at the office of the Secretary to PPB as set out in the proposed new regulation 30B(5) of PPR. The Administration's reiteration of the justifications for the qualification requirements for AP as set out in the proposed new regulation 30C(2) of PPR. The Chairman's remarks that the Bills Committee would continue to examine clause 52 at the next meeting.	Admin
<i>Agenda item II: Any other business</i>			
020130 - 020234	Chairman Ms Emily LAU	Date of next meeting Closing remarks	

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23 February 2015