

立法會
Legislative Council

LC Paper No. CB (2)831/14-15
(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 fifth meeting
held on Friday, 4 July 2014, at 10:45 am
in Conference Room 3 of the Legislative Council Complex**

Members present : Prof Hon Joseph LEE Kok-long, SBS, JP, PhD, RN (Chairman)
Hon Emily LAU Wai-hing, JP
Hon Vincent FANG Kang, SBS, JP
Hon WONG Ting-kwong, SBS, JP
Hon Mrs Regina IP LAU Suk-ye, GBS, JP
Hon Alan LEONG Kah-kit, SC
Hon Albert CHAN Wai-yip
Hon Claudia MO
Hon CHAN Han-pan, JP
Hon Alice MAK Mei-kuen, JP
Dr Hon Elizabeth QUAT, JP

Members absent : Hon LEUNG Yiu-chung
Dr Hon LEUNG Ka-lau
Hon CHEUNG Kwok-che
Hon Paul TSE Wai-chun, JP
Hon LEUNG Kwok-hung
Hon WONG Yuk-man
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

Miss Emma WONG
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 : Miss Mimi CHANG
Assistant Legal Adviser 11

Mr YU Chun-ho
Research Officer 8

Ms Priscilla LAU
Council Secretary (2) 5

Ms Michelle LEE
Legislative Assistant (2) 5

Action

I. Meeting with the Administration

[File Ref.: IN19/13-14, LC Paper Nos. CB(2)1344/13-14(02), CB(2)1735/13-14(03), CB(2)1810/13-14(02), CB(2)1837/13-14(01), CB(2)1943/13-14(01) to (02) and CB(3)511/13-14]

Action

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

Clause-by-clause examination

2. The Bills Committee continued clause-by-clause examination of the Chinese text of the Bill starting from clause 6, and agreed to revisit the clause at a future meeting given the various concerns raised by members on the subject.

Admin

3. The Administration was requested to provide, in writing, the following information -

- (a) whether the drafting of the proposed new section 4B of the Pharmacy and Poisons Ordinance (Cap. 138) to empower the Pharmacy and Poisons Board to promulgate the code of conduct and codes of practice ("COPs") for registered pharmacists and relevant drug traders respectively was in line with the provisions of other existing ordinances which empowered the relevant authorities to issue COPs;
- (b) a summary of the meetings between the Administration and relevant deputations of the trade in relation to the Bill; and
- (c) the existing measures to govern the dispensing of drugs by medical practitioners.

II. Any other business

4. There being no other business, the meeting ended at 12:31 pm.

Council Business Division 2
Legislative Council Secretariat
10 February 2015

**Proceedings of the fifth meeting of
the Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014
held on Friday, 4 July 2014, at 10:45 am
in Conference Room 3 of the Legislative Council Complex**

Time marker	Speaker	Subject(s)/Discussion	Action required
<i>Agenda item I: Meeting with the Administration</i>			
001235 - 001351	Chairman	Opening remarks	
001352 - 001427	Chairman	Continuation of clause-by-clause examination of the Bill	
001428 - 001829	Admin Chairman	<p data-bbox="600 759 887 786"><u>Examination of clause 6</u></p> <p data-bbox="600 824 1302 1055">The Chairman's enquiry as to whether the drafting of clause 6 which empowered the Pharmacy and Poisons Board ("PPB") to issue code of conduct ("COC") for registered pharmacists and codes of practice ("COPs") for relevant licenced drug traders was in line with the provisions of existing legislation on empowering the regulatory authorities to issue COC and COPs.</p> <p data-bbox="600 1093 1302 1391">The Administration's advice that given the nature of COC and COPs which was to give practical guidance, the provision would provide PPB with the flexibility to draw up and revise the relevant codes with regard to local circumstances and changes. Reference had been made to other existing legislation, such as section 3 of the Broadcasting Ordinance (Cap. 562) and section 67 of the Insurance Companies Ordinance (Cap. 41) which empowered the relevant authorities to issue COPs.</p>	
001830 - 002728	Chairman Mr Albert CHAN Admin	<p data-bbox="600 1440 1302 1626">Mr Albert CHAN's concern as to whether the views and concerns raised by the deputations over the promulgation of COC and COPs by PPB had been addressed; and his enquiry as to whether reference was made to the practice in the European Union ("EU") in drafting the relevant COC and COPs.</p> <p data-bbox="600 1664 1302 1995">The Chairman's remarks that pursuant to members' request at the last meeting, the Secretariat had worked out a summary setting out the major issues of concern of the Bills Committee and the responses given by the Administration (LC Paper No. CB(2)1943/13-14(02)), in which item (c) was related to the concern over the promulgation of COC and COPs by PPB; and prepared an information note entitled "Regulations governing the definition, registration and manufacture of medicinal products in the European Union" (IN19/13-14).</p> <p data-bbox="600 2033 1302 2092">The Administration's advice that the process of revising and formulating the relevant COC and COPs was both</p>	

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		<p>open and transparent. PPB had set up different working groups, with trade representatives and stakeholders as members, to provide comments in this regard. It had also gathered views on the relevant COC and COPs through a number of consultation meetings, public consultation and briefing sessions. Details of the consultation work carried out by PPB were set out in Annex 2 to LC Paper No. CB(2)1543/13-14(01). Under the proposed new section 4B(3) of the Pharmacy and Poisons Ordinance (Cap. 138) ("the Ordinance"), PPB would by notice published in the Gazette identify the COC and COPs issued or the part revised. It would, at the same time, inform relevant licensed drug traders or the registered pharmacists involved of the issuance or revision. While the draft COC and COPs took reference to overseas practice, no provisions of the relevant COC and COPs were directly adopted from that of overseas authorities.</p>	
002729 - 003539	Chairman Miss Alice MAK Admin	<p>Referring to the industry's grave concern about the proposed new section 4B(7) of the Ordinance which stipulated that COC and COPs promulgated by PPB were not subsidiary legislation and were therefore not subject to scrutiny by the Legislative Council ("LegCo"), Miss Alice MAK's view that the crux of the problem laid in the lack of representation of registered pharmacists from some professional bodies and drug traders in PPB. She called on the Administration to review the composition of PPB.</p> <p>The Administration's reiteration of the well-established mechanism put in place by PPB for consultation with the trade and relevant stakeholders in drafting, issuing and revision of any COC or COP; and its advice that -</p> <ul style="list-style-type: none"> (a) empowering PPB to issue or revise the relevant COC and COPs, which provided practical guidance for the industry in respect of the Ordinance and its subsidiary legislation, would provide PPB with the flexibility to revise the Codes in response to local circumstances and changes; (b) given that the contents of the relevant COC and COPs were not part of the legislation or its subsidiary legislation, no one would be deemed to have violated the Ordinance or its subsidiary legislation simply because he/she contravened COC or COPs (unless the matter concerned constituted an offence under the Ordinance or its subsidiary legislation); and (c) the Pharmacist Sub-group under the Steering Committee on the Strategic Review on Healthcare Manpower Planning and Professional Development ("the Steering Committee") would discuss the regulatory framework for registered pharmacists before the end of 2014. 	

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003540 - 004944	Chairman Mr Albert CHAN Admin	<p>Mr Albert CHAN's concern over the appropriateness to empower PPB to promulgate corresponding COC and COPs for registered pharmacists and relevant drug traders, and whether the Administration had addressed the concerns of the industry.</p> <p>The Chairman's remarks that given that some members and deputations held different views towards the general merits of the proposed amendment to empower PPB to issue or revise the relevant COC and COPs, it was agreed at an earlier meeting that the Bills Committee could revisit the issue when it examined the relevant clauses or at a future meeting.</p> <p>The Administration's explanation that the proposed amendment was originated from the recommendations put forth by the Review Committee on Regulation of Pharmaceutical Products in Hong Kong ("the Review Committee") in order to provide guidance and enhance monitoring for the conduct of the activities of registered pharmacists and various licensed and listed traders. At present, retailers, manufacturers, importers, exporters and wholesalers of pharmaceutical products were subject to different sets of licensing or registration control of PPB, and there were three individual sets of codes of ethics issued by the pharmacist professional associations. It should be noted that while some deputations had raised concerns towards the proposal, some other deputations, in particular the patient groups, had expressed support for the proposal, details of the stances of these deputations were set out in an earlier paper provided by the Administration for the Bills Committee (LC Paper No. CB(2)1810/13-14(01)).</p> <p>Given the controversy involved in the issue, Mr Albert CHAN's remarks that he might bring up the issue for further discussion at a future meeting.</p>	
004945 - 010128	Chairman Mr WONG Ting-kwong Admin	<p>While expressing support for the proposal to empower PPB to promulgate relevant COPs for the drug traders concerned in order to protect public health and ensure patient safety, Mr WONG Ting-kwong's view that the Administration should consider enhancing the representation of drug traders in PPB to ease the various concerns of the trade towards the proposal.</p> <p>The Administration's advice that the process of revising or formulating the relevant COPs or COC were both open and transparent. Trade representatives and stakeholders had been invited to be members of the working groups set up by PPB to provide comments on the revision or formulation of relevant COC and COPs. Details of the composition of each of the working groups and the consultation work carried out by the Administration were set out in Annex 2 to an earlier paper it provided for the Bills Committee (LC Paper No. CB(2)1543/13-14(01)).</p>	

Time marker	Speaker	Subject(s)/Discussion	Action required
		<p>The Chairman's request for the Administration to provide after the meeting information as to whether the drafting of the proposed new section 4B of the Ordinance to empower PPB to promulgate the relevant COC and COPs was in line with the provisions of other existing ordinances which empowered the relevant authorities to issue COPs.</p>	<p>Admin</p>
<p>010129 - 010828</p>	<p>Chairman Ms Emily LAU Admin</p>	<p>Taking into account that some deputations had expressed grave concerns on the Bill, Ms Emily LAU's view on the need of the Administration to maintain communication with the industry to ease their concerns.</p> <p>The Administration's advice that it had communicated with the trade and relevant stakeholders, including the deputations which had attended the meeting of the Bills Committee on 20 May 2014, on the drafting of the Bill. Following the meetings, some deputations had provided further submissions to the Bills Committee on their latest stance on the various legislative proposals. As regards the meeting between the Department of Health ("DH") and the Hong Kong Pharmacists Union originally scheduled for 20 June 2014, the Union had decided to call off the meeting as only representatives of DH, but not Government counsels, would attend the meeting.</p> <p>The Chairman's request for the Administration to provide in writing a summary of the meetings between the Administration and relevant deputations of the trade in relation to the Bill.</p>	<p>Admin</p>
<p>010829 - 012158</p>	<p>Chairman Mr Albert CHAN Admin</p>	<p>In response to the enquiries of Mr Albert CHAN and the Chairman, the Administration's advice on the following -</p> <p>(a) the existing licensing or registration control over the drug traders and the availability of three individual sets of codes of ethics issued by the respective pharmacist professional associations as explained earlier at the meeting; and</p> <p>(b) by virtue of the proposed new section 4B of the Ordinance, PPB would promulgate corresponding COPs for Authorized Seller of Poisons ("ASP"), Listed Seller of Poisons ("LSP"), holder of Wholesale Poisons Licence, holder of Certificate of Registration as an Importer and Exporter of Pharmaceutical Products, and holder of Pharmaceutical Manufacturer's Licence and Authorized Person, and a COC for registered pharmacists.</p> <p>Mr Albert CHAN's view that a separate statutory body should be set up to take over the existing function of PPB for regulating registered pharmacists, including the proposed power to be given to PPB to promulgate of a COC for the profession; and the Administration's reiteration that the Pharmacist Sub-group under the Steering Committee</p>	

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		<p>would discuss the regulatory framework for registered pharmacists before the end of 2014.</p> <p>The Chairman's remarks that the objectives of the Bill were to amend the Ordinance and its subsidiary legislation to implement certain recommendations of the Review Committee and update the legislative provisions. The proposal to establish a separate statutory body for registered pharmacists was not directly relevant to the subject matter of the Bill.</p>	
012159 - 012805	Chairman Ms Claudia MO Admin	<p>Ms Claudia MO's concern as to whether the Administration would honour its undertaking to take forward the industry's proposal for establishing a separate regulatory body for registered pharmacists after the Bill, including the proposed amendment to empower PPB to promulgate COC for registered pharmacists, had been passed by LegCo.</p> <p>Referring to the view expressed by the Pharmacology and Pharmacy of The University of Hong Kong in its further submission dated 4 June 2014 (LC Paper No. CB(2)1767/13-14(01)) that the promulgation of COPs and COC for the trade and the pharmacists respectively would upgrade the standards of the pharmaceutical profession, the Administration's advice that no adverse views had been received from the industry on the promulgation of COC for registered pharmacists. The Administration understood that the call of the industry for establishing a separate regulatory body for registered pharmacists and it was open-minded on the proposal. That said, the details of the proposal would need thorough discussion and consensus by the parties concerned, and should be dealt with separately from the Bill.</p>	
012806 - 014553	Chairman Mr Vincent FANG Admin	<p>Mr Vincent FANG's enquiry as to whether the new COP for ASP had to take effect in January 2015 as scheduled given the concern of the drug traders towards the proposal to empower PPB to promulgate the relevant COPs; and his expression of doubt on the effectiveness of the proposal of requiring drug traders to place drug orders in written form in ensuring that private doctors would take adequate steps to verify whether the drugs received from the suppliers corresponded to the written order so as to prevent recurrence of the drug incident in 2005.</p> <p>The Administration's advice that -</p> <p>(a) the COP for ASP had existed for long and PPB would exercise its power under section 13(3) of the Ordinance to incorporate the revised COP as a registration condition for ASP's premises. The revision of the COP was not part of the current legislative proposals. It should also be noted that the drafting and revision of any of the COPs to be promulgated by PPB for the relevant drug traders</p>	

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		<p>would be carried out by the respective Working Groups set up under PPB in a transparent manner and with extensive consultation with the trade and relevant stakeholders. In addition, clause 6 of the Bill provided that if a COP was issued or revised, PPB had to identify the code or the part revised and the date on which the code or revision was to take effect in a Gazette notice;</p> <p>(b) while there was no panacea for preventing drug incidents, the proposed requirement of placing drug orders in written form would ensure that the relevant suppliers and corresponding parties (such as private doctors) would be able to check the written orders upon delivery and receipt of drugs. The proposed requirement would be incorporated into COPs for relevant drug traders. Apart from mail and fax, various kinds of retainable electronic records (e.g. e-mails and textual messages) would be acceptable means of placing orders in written form. To facilitate the trade to adapt to this requirement, PPB was considering implementing the requirement by phases; and</p> <p>(c) private doctors were encouraged to comply with the written order practice as recommended in the Good Dispensing Practice Manual issued by the Hong Kong Medical Association. As regards incidents concerning incorrect dispensing of drugs by doctors, as that might amount to professional misconduct, regulatory actions would be taken by the Medical Council of Hong Kong.</p> <p>The Chairman's request for the Administration to provide after the meeting information on existing measures to govern the dispensing of drugs by medical practitioners.</p>	<p>Admin</p>
014554 - 014757	Chairman Mr Vincent FANG	Closing remarks	