

立法會
Legislative Council

LC Paper No. CB (2)370/14-15
(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 first meeting
held on Thursday, 24 April 2014, at 4:30 pm
in Conference Room 3 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
Dr Hon LEUNG Ka-lau
Hon CHEUNG Kwok-che
Hon Paul TSE Wai-chun, JP
Hon LEUNG Kwok-hung
Hon Albert CHAN Wai-yip
Hon Claudia MO
Hon CHAN Han-pan
Hon Alice MAK Mei-kuen, JP
Dr Hon Fernando CHEUNG Chiu-hung
Dr Hon Elizabeth QUAT, JP
- Member attending** : Hon LEE Cheuk-yan
- Members absent** : Hon Mrs Regina IP LAU Suk-ye, GBS, JP
Hon Alan LEONG Kah-kit, SC
Hon WONG Yuk-man
Dr Hon KWOK Ka-ki

Public Officers : Item II
attending

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

Ms Lonnie NG
Senior Assistant Law Draftsman (Acting)
Department of Justice

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

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

Staff in : Ms Wendy KAN
attendance Assistant Legal Adviser 6

Ms Priscilla LAU
Council Secretary (2) 5

Ms Michelle LEE
Legislative Assistant (2) 5

Ms Louisa YU
Clerical Assistant (2) 5

Action

I. Election of Chairman

Mr LEUNG Yiu-chung, member who had the highest precedence in the Council among members of the Bills Committee present, presided over the election of the Chairman.

2. Mr LEUNG Yiu-chung invited nominations for the chairmanship of the Bills Committee. Prof Joseph LEE was nominated by Mr WONG Ting-kwong and the nomination was seconded by Ms Emily LAU, Mr Vincent FANG, Mr CHEUNG Kwok-che and Miss Alice MAK. Prof Joseph LEE accepted the nomination. As there was no other nomination, Mr LEUNG Yiu-chung declared Prof Joseph LEE elected as the Chairman of the Bills Committee.

3. Members agreed that the election of Deputy Chairman was not necessary.

II. Meeting with the Administration

[File Ref.: FHB/H/23/1 Pt.9, LC Paper Nos. LS41/13-14, CB(2)1344/13-14(02) and (03) and CB(3)511/13-14]

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

Admin

5. The Bills Committee requested the Administration to -

- (a) provide, in tabular form, information on the concerns raised by the trade and relevant stakeholders on the legislative amendments, the actions taken by the Administration to address their concerns, and the areas which the trade remained concern;
- (b) provide the membership of all working groups set up by the Pharmacy and Poisons Board on the revision or formulation of the Codes of Practice for relevant licensed/registered drug traders and the Code of Conduct for registered pharmacists; and
- (c) revert to the Bills Committee the outcomes of discussions after meeting with the Hong Kong Pharmacists Union and the Hong Kong General Chamber of Pharmacy Limited to gauge their views on the Bill.

III. Any other business

Invitation of public views

6. Members agreed to receive views from the public on the Bill at the next meeting to be scheduled. In line with usual practice, a general notice would be posted on the Legislative Council website and invitation letters would be issued to the 18 District Councils for the purpose.

(Post-meeting notes: With the concurrence of the Chairman, the next meeting of the Bills Committee was scheduled for 20 May 2014 at 2:30 pm to receive views from the public.)

7. There being no other business, the meeting ended at 6:27 pm.

Council Business Division 2
Legislative Council Secretariat
28 November 2014

**Proceedings of the first meeting of
the Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014
held on Thursday, 24 April 2014, at 4:30 pm
in Conference Room 3 of the Legislative Council Complex**

Time marker	Speaker	Subject(s)/Discussion	Action required
000115 - 000344	Mr LEUNG Yiu-chung Mr WONG Ting-kwong Ms Alice MAK Prof Joseph LEE	Election of Chairman	
000345 - 001203	Chairman Admin	Briefing by the Administration on the Pharmacy and Poisons (Amendment) Bill 2014 ("the Bill")	
001204 - 002349	Chairman Mr Vincent FANG Admin	<p>Mr Vincent FANG's view that the Bills Committee should receive views from the trade on the Bill at a future meeting as there was no consensus amongst the trade on certain legislative proposals; and his enquiries about -</p> <p>(a) how the proposal of requiring drug traders to place drug orders in written form could avoid recurrence of the drug incident in 2005 whereby a private doctor prescribed inappropriate medications to 153 patients over a period of five months due to his failure to take adequate steps to verify whether the drugs received from the supplier (who had erroneously taken the drug order placed verbally) corresponded to the order and to ensure accuracy of the prescriptions given to patients;</p> <p>(b) whether consideration could be given to allowing, at times when a registered pharmacist was not present at the part of the authorized seller of poisons ("ASP") where poisons were kept for the purpose of retail sale, the rest of the premises of ASP be remained open for sale of goods not classified as poisons;</p> <p>(c) the steps to be taken by the Administration to eliminate the misconception of the public that "藥坊" (or "medicine stores") were subject to the same regulatory framework of "藥房" (or ASPs, which were commonly known as "pharmacies"); and</p> <p>(d) in respect of the empowerment of the Pharmacy and Poisons Board ("PPB") under the Bill to promulgate Codes of Practice ("COPs") for relevant licensed/registered drug traders, whether the Administration would provide trade members with the draft COPs to ease their concern that PPB might tighten its control over the trade through adopting stringent COPs.</p> <p>The Administration's response that -</p> <p>(a) the main objective of the current legislative proposals was to implement some of the recommendations put</p>	

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		<p>forth by the Review Committee on the Regulation of Pharmaceutical Products in Hong Kong ("the Review Committee") in December 2009, which sought to enhance the safety of pharmaceutical products in Hong Kong and protect public health. A Regulatory Impact Assessment had been conducted to assess the impacts of the recommendations on drug traders and stakeholders. In the legislative process, the Administration had consulted and exchanged views with different trade parties and relevant stakeholders through various channels, and had come to the view that the parties were supportive of the legislative amendments;</p> <p>(b) written drug orders could facilitate the tracing of source of drugs, and minimize errors in the delivery and receipt of drugs. At present, private doctors were recommended to comply with the written order practice recommended in the Good Dispensing Practice Manual issued by the Hong Kong Medical Association;</p> <p>(c) the Administration had decided to leave out the proposal of requiring the presence of registered pharmacists in the registered premises of an ASP whenever that ASP was opened for business in the current legislative exercise. The existing requirement that a registered pharmacist had to be present in an ASP for not less than two-thirds of its daily opening hours would remain unchanged;</p> <p>(d) ASPs and Listed Sellers of Poisons ("LSPs") were authorized to sell drugs of different categories. ASPs required the presence of registered pharmacists for selling the controlled medicines and would display a "R" logo. LSPs, which did not have the service of registered pharmacists, were not allowed to sell controlled medicines. A list of registered ASPs was available at the website of Department of Health ("DH"). This apart, a leaflet explaining the difference between ASPs and LSPs would also be made available at cross boundary check points and tourist centres for distribution to tourists; and</p> <p>(e) DH had been gathering the views of the trade on the revision or formulation of relevant COPs.</p>	
002350 - 003522	Chairman Mr LEUNG Yiu-chung Admin Mr Albert CHAN	<p>Mr LEUNG Yiu-chung's concern that there were views from relevant stakeholders, such as the pharmacist associations, that they were not thoroughly consulted on the legislative proposals, including the proposed amendment to the definition of ASP; and his enquiry about the consultation work to be carried out by the Administration in the coming months.</p> <p>The Administration's reiteration of the objective of the legislative proposals; and its advice that -</p> <p>(a) PPB had set up different working groups, with trade representatives and stakeholders as members, since</p>	

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		<p>January 2012 to provide comments on the revision or formulation of COPs for the relevant licensed/registered drug traders. An overview of the consultation work carried out by the Administration when drafting the legislative proposals was set out in the letter dated 15 January 2014 from the Under Secretary for Food and Health to the Chairman of the Panel on Health Services ("the Panel") (LC Paper No. CB(2)694/13-14(01)); and</p> <p>(b) the Administration had, in response to the concerns expressed by the deputations at the Panel meeting in December 2013, refined the legislative proposals. The Administration hoped to resume the Second Reading debate on the Bill in the 2013-2014 legislative session to enable an early implementation of the recommendations put forth by the Review Committee. The receiving of further public views by the Bills Committee might lengthen the time required for scrutiny and passage of the Bill.</p> <p>The Chairman and Mr LEUNG Yiu-chung's remarks that the time required for scrutiny of the Bill should be determined by the Bills Committee and not the Administration.</p> <p>The Chairman's request for the Administration to provide, in tabular form, information on the concerns raised by the trade and relevant stakeholders on the legislative amendments, the actions taken by the Administration to address their concerns, and the areas which the trade remained concern.</p>	<p>Admin</p>
<p>003523 - 004220</p>	<p>Chairman Ms Emily LAU Admin</p>	<p>Relaying the views of the Hong Kong Pharmacists Union and the Hong Kong General Chamber of Pharmacy Limited which had grave concerns over the legislative proposals, Ms Emily LAU's view that the Bills Committee should receive views from the trade and relevant stakeholders on the Bill; and her concern about the coverage of the consultation work carried out by the Administration and the representation of PPB which would be empowered under the Bill to promulgate COPs for relevant licensed/registered drug traders and Code of Conduct ("COC") for registered pharmacists.</p> <p>The Administration's response that -</p> <p>(a) given that the existing COP for ASPs had no legal status for enforcement, and there were no COPs for LSPs, wholesalers as well as manufacturers respectively, the Review Committee recommended the introduction of COPs for LSPs, wholesalers and manufacturers and the Pharmacy and Poisons Ordinance (Cap. 138) ("the Ordinance") be amended to require these drug traders to follow their respective COPs;</p> <p>(b) views from the Hong Kong General Chamber of Pharmacy Limited were invited during the public consultations on the revised COP for ASPs and the draft COP for LSPs conducted in July to December 2012 and</p>	

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		<p>July to September 2013 respectively. As regards the Hong Kong Pharmacists Union, it was an organization newly established in April 2014. The Administration welcomed views from all parties on the legislative proposals; and</p> <p>(c) PPB was established under section 3 of the Ordinance to enforce the regulatory measures over pharmaceutical products and drug traders. Its composition included, among others, the Director of Health, the Government Chemist, the Chief Pharmacist of DH, one medical officer in DH, one legally qualified person and representatives from the trade.</p>	
004221 - 005244	Chairman Mr CHAN Han-pan Admin	<p>Mr CHAN Han-pan's question regarding the trade's concern that the Administration was trying to circumvent the scrutiny of the Legislative Council ("LegCo") on the formulation or revision of COPs for drug traders by implementing them through PPB; and the Chairman's enquiry as to whether there were precedents that a statutory body was empowered to devise COPs of similar nature.</p> <p>The Administration's advice that in response to the Review Committee's recommendations, the Administration proposed to empower PPB, which comprised, among others, representatives from pharmaceutical and medical professional bodies and the academia, to promulgate corresponding COPs to provide practical guidance to different licensed/registered traders. Some existing ordinances also empowered relevant authorities to issue COPs. For instance, the Medical Council of Hong Kong was empowered by the Medical Registration Ordinance (Cap. 161) to issue a Code of Professional Conduct for medical practitioners. While it was understandable that some trade members, such as the Hong Kong General Chamber of Pharmacy Limited, might have grave concern over the newly introduced COPs, it should be noted that the legislative proposals would further enhance the safety of pharmaceutical products in Hong Kong and protect public health.</p> <p>In response to the Chairman's enquiry as to whether the Administration could undertake to consult the Panel on the draft COPs and COC, the Administration's advice that it was not in a position to make an undertaking on behalf of PPB.</p>	
005245 - 010201	Chairman Mr WONG Ting-kwong Admin	<p>Mr WONG Ting-kwong's views that -</p> <p>(a) the Administration should meet with representatives of the drug traders and pharmacist bodies who had strong views on the Bill, including the Hong Kong General Chamber of Pharmacy Limited and the Hong Kong Pharmacists Union. Consideration could also be given to including also representatives from the drug traders and labour unions of frontline pharmacists as members of PPB to ensure that their views would be taken into account in the formulation/revision of the relevant COPs and COC;</p>	

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		<p>and</p> <p>(b) any enhancement in the regulation of pharmaceutical products should give due regard to the impact brought about by the proposals on the business environment and the operational feasibility. In his view, drug orders placed through voice mail, fax, and electronic messages sent by short messaging service and mobile phone apps should be accepted as written orders.</p> <p>The Administration's response that -</p> <p>(a) it was willing to meet with the relevant stakeholders to receive their views on the Bill. It should also be noted that PPB had a well-established mechanism in place for consultation with the trade and relevant stakeholders in the drafting, issuing and revision of any COPs and COC. For instance, two representatives from Hong Kong General Chamber of Pharmacy Limited and five representatives from Hong Kong Pharmacists Union were sat on the working group for COP for ASPs and the working group for COC for registered pharmacists respectively. To enhance transparency, all COPs and COC would be made available at the website of PPB for public information once promulgated; and</p> <p>(b) drug orders placed by electronic means (e.g. emails), fax and mail, etc. could be accepted as written orders. Voice mail, however, would not be considered as an acceptable form of written order having taken into account that the pronunciations of the names of certain drugs were quite similar and, hence, the verbal order might be wrongly taken by the drug suppliers.</p>	
010202 - 010343	Admin	<p>Referring to the letter dated 8 April 2014 from Ms Claudia MO (LC Paper No. CB(2)1373/13-14(01)) on the Bill, the Administration's advice that the purpose of the proposal that further amendments to the Schedules to the Pharmacy and Poisons Regulations (Cap. 138A) ("PPR") and the Poisons List to be migrated from the Poisons List Regulations (Cap. 138B) to PPR should be made by means of negative vetting, as opposed to positive vetting as required under the existing provisions, by LegCo was to expedite the imposition of suitable control on pharmaceutical products and poisons.</p>	
010344 - 012331	<p>Chairman Mr CHEUNG Kwok-che Mr LEE Cheuk-yan Admin</p>	<p>Mr CHEUNG Kwok-che and Mr LEE Cheuk-yan's concern about the legal liability of a registered pharmacist who was an employee of an ASP under the proposed amended definition of ASP.</p> <p>The Administration's advice that -</p> <p>(a) the proposed amendment which defined ASP as "a registered pharmacist, body corporate or unincorporated</p>	

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		<p>body of persons that is authorized to carry on a business of retail sale of poisons under section 11" was purely a technical amendment. The legal liability of a registered pharmacist who was an employee of an ASP remained unchanged; and</p> <p>(b) the person who would be liable to prosecution in case of non-compliance with the relevant provisions in the Ordinance would depend on the evidence available and the circumstances of each case. It was the common law principle that the burden of proof rested with the prosecution.</p> <p>On Mr CHEUNG Kwok-che's enquiry about the existing regulation over the conduct of registered pharmacists, and how to improve the representation of community pharmacists working in ASPs in the working group for COC for registered pharmacists, the Administration's advice that -</p> <p>(a) the working group for COC for registered pharmacists comprised five representatives from each of the four pharmacists associations, i.e. the Hong Kong Pharmacists Union, the Pharmaceutical Society of Hong Kong, the Practising Pharmacists Association of Hong Kong and the Society of Hospital Pharmacists of Hong Kong. It would provide after the meeting the membership of all the working groups set up by PPB on the revision or formulation of relevant COPs or COC for reference by the Bills Committee; and</p> <p>(b) at present, three individual sets of Codes of Ethics were promulgated by the Pharmaceutical Society of Hong Kong, the Practising Pharmacists Association of Hong Kong and the Society of Hospital Pharmacists of Hong Kong respectively to govern the professional conduct of their members.</p> <p>At the Chairman's request, the Administration's undertaking to revert to the Bills Committee the outcomes of discussions after meeting with the Hong Kong Pharmacists Union and the Hong Kong General Chamber of Pharmacy Limited.</p>	<p>Admin</p> <p>Admin</p>
012332 - 013743	Chairman Dr Fernando CHEUNG Admin	<p>Dr Fernando CHEUNG's view that the standard of practice and professional conduct of registered pharmacists should be left to self-regulation by the profession. Given that only three out of the 13 members of PPB were registered pharmacists nominated by the relevant professional association, a separate statutory body should be established to take over the existing function of PPB for regulating registered pharmacists.</p> <p>The Administration's advice that -</p> <p>(a) the composition of PPB had ensured a balanced representation of the pharmaceutical trade and the profession of pharmacists, as it was responsible for</p>	

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		<p>enforcing the regulatory measures over pharmaceutical products, drug traders and pharmacists;</p> <p>(b) the Government had set up a Steering Committee on Strategic Review on Healthcare Manpower Planning and Professional Development ("the Steering Committee") to formulate recommendations on, among others, the long-term professional development of the 13 healthcare professions subject to statutory regulation, including pharmacists. The suggestion for establishing a separate regulatory body for registered pharmacists would be relayed to the Steering Committee for consideration; and</p> <p>(c) the proposal to empower PPB to promulgate a COC for registered pharmacists was a step forward from the current practice of having three sets of codes of ethics in maintaining the standard of practice and conduct of registered pharmacists.</p> <p>Dr Fernando CHEUNG's request for the Administration to provide a roadmap towards the establishment of a separate regulatory body for registered pharmacists; and the Chairman's remarks that the current legislative proposals did not touch on the regulatory framework governing registered pharmacists. Where necessary, the issue could be referred to the Panel for follow-up.</p>	
013744 - 014251	Chairman Dr Elizabeth QUAT Admin	<p>Dr Elizabeth QUAT's enquiry on the steps to be taken by the Administration to ease the pharmacist profession's concern regarding the proposal to provide PPB, which in its view, did not have adequate representation of the profession, with wide power to promulgate a COC for registered pharmacists.</p> <p>The Administration's reiteration of the recommendations put forth by the Review Committee on the need to introduce COPs for the licensed/registered drug traders and a COC for registered pharmacists, and the mechanism put in place by PPB for consultation with the trade and relevant stakeholders in the drafting, issuing and revision of the COPs and COC.</p>	
014252 - 015454	Chairman Mr Paul TSE Admin	<p>Mr Paul TSE's enquiry about whether the empowerment of PPB under the Bill to promulgate various COPs for the licensed/registered drug traders was to regularize the existing practices; and the Administration's stance on self-regulation of the healthcare profession given the international trend of moving from the premise of self-regulation of the profession to protect its own interests to one of co-regulation in partnership with the Government.</p> <p>The Administration's advice that -</p> <p>(a) at present, retailers, manufacturers, importers, exporters and wholesalers of pharmaceutical products were subject to different sets of licensing or registration control of PPB. The drafting and revision of the relevant COPs by</p>	

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		<p>the working groups set up under PPB would take into account existing practices, as well as views from trade representatives and stakeholders. Views from members of the public on the draft COPs would also be gauged through public consultation; and</p> <p>(b) the proposal to empower PPB to promulgate a COC in order to provide guidance and enhance monitoring for the conduct of registered pharmacists was a step forward from the current practice of having three individual sets of codes of ethics issued by the pharmacist associations. In the meantime, the Steering Committee was studying, among others, the long-term professional development of the pharmacist profession.</p>	
015455 - 015833	Chairman Mr Paul TSE	Meeting to receive public views on the Bill Closing remarks by the Chairman	

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28 November 2014