

立法會
Legislative Council

LC Paper No. CB (2)721/14-15

(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 fourth meeting
held on Tuesday, 17 June 2014, at 10:45 am
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 CHEUNG Kwok-che
Hon Mrs Regina IP LAU Suk-yee, GBS, JP
Hon Paul TSE Wai-chun, JP
Hon Alan LEONG Kah-kit, SC
Hon Albert CHAN Wai-yip
Hon CHAN Han-pan
Hon Alice MAK Mei-kuen, JP
Dr Hon KWOK Ka-ki
Dr Hon Fernando CHEUNG Chiu-hung
Dr Hon Elizabeth QUAT, JP

Members absent : Hon Vincent FANG Kang, SBS, JP
Dr Hon LEUNG Ka-lau
Hon LEUNG Kwok-hung
Hon WONG Yuk-man
Hon Claudia MO

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
Senior Pharmacist
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

Ms Priscilla LAU
Council Secretary (2) 5

Ms Michelle LEE
Legislative Assistant (2) 5

Action

I. Meeting with the Administration

[File Ref.: FHB/H/23/1 Pt.9, LC Paper Nos. CB(2)1344/13-14(02), CB(2)1522/13-14(01), CB(2)1543/13-14(01), CB(2)1629/13-14(01), CB(2)1735/13-14(01) to (03), CB(2)1810/13-14(01) to (02) and CB(3)511/13-14]

Action

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

Admin

2. The Bills Committee requested the Administration to provide a written response to the issues raised by Mr Vincent FANG in his letter dated 16 June 2014 (LC Paper No. CB(2)1837/13-14(01)) which was tabled at the meeting.

3. The Chairman concluded that while some members and the Administration held different views towards the general merits and principles of some proposed amendments in the Bill, such as the qualification requirements for registration as an authorized person, the empowerment of the Pharmacy and Poisons Board to promulgate codes of practice for relevant licensed drug traders and code of conduct for registered pharmacists, etc., the discussion on other policy aspects of the Bill had been completed. He suggested that the Bills Committee could commence clause-by-clause examination of the Bill and where necessary, revisit the issues of concern when the Bills Committee examined the relevant clauses. Members raised no objection. The Chairman added that members might move Committee Stage amendments relating to these issues if a consensus could not be reached by the Bills Committee after further deliberation.

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Secretariat

4. To facilitate members' scrutiny of the Bill, the Bills Committee requested the Legislative Council Secretariat to prepare a summary of the major issues of concern raised by the Bills Committee and the responses provided by the Administration in this regard, and an information note on the regulations governing the definition, registration and manufacture of medicinal products in the European Union.

Clause-by-clause examination

5. The Bills Committee commenced clause-by-clause examination of the Chinese text of the Bill, and completed scrutiny up to clause 5 of the Bill.

II. Any other business

6. The Chairman said that he would discuss with the Clerk and the Administration on the date of the next meeting and members would be informed of the arrangements accordingly.

(Post meeting note: With the concurrence of the Chairman, the next meeting has been scheduled for Friday, 4 July 2014 at 10:45 am.)

Action

7. There being no other business, the meeting ended at 12:45 pm.

Council Business Division 2
Legislative Council Secretariat
26 January 2015

**Proceedings of the fourth meeting of
the Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014
held on Tuesday, 17 June 2014, at 10:45am
in Conference Room 2B of the Legislative Council Complex**

Time marker	Speaker	Subject(s)/Discussion	Action required
<i>Agenda item I: Meeting with the Administration</i>			
001353 - 001603	Chairman Admin	Opening remarks by the Chairman	
001604 - 002345	Chairman Admin Mr CHEUNG Kwok-che	<p>The Chairman's request for a response from the Administration to the following -</p> <p>(a) concerns raised by Mr Vincent FANG, who was unable to attend the meeting, on the proposed requirement of placing orders of drugs in written form, the empowerment of the Pharmacy and Poisons Board ("PPB") to promulgate relevant codes of practice ("COPs") for licensed drug traders and code of conduct ("COC") for registered pharmacists as set out in his letter dated 16 June 2014 (LC Paper No. CB(2)1837/13-14(01)); and</p> <p>(b) concerns raised by Hong Kong Pharmacists Union, Retina Hong Kong and Drug Safety Consortium on the qualification requirements for authorized person ("AP"), the revised definition of pharmaceutical products and the request for establishing a separate statutory body for regulating registered pharmacists as set out in their press release issued on 16 June 2014 which was copied to the Bills Committee (LC Paper No. CB(2)1837/13-14(06)).</p> <p>The Administration's advice that -</p> <p>(a) the proposed requirement of written orders of drugs aimed to develop a complete set of movement records of drugs, thus facilitating the tracing of the sources of drugs, minimizing errors upon delivery and receipt of drugs and combating illegal sale of drugs. The requirement would be incorporated into the COPs for the relevant licenced drug traders by PPB as one of the licensing requirements for the relevant licensed drug traders;</p> <p>(b) allowing 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 Practices Guide ("the GMP Guide"), to act as an AP was in line with international practice,</p>	

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		<p>such as that adopted by the European Union ("EU");</p> <p>(c) at present, all licensed manufacturers engaged in the manufacturing of western drugs were in compliance with the Hong Kong GMP Guidelines for Pharmaceutical Products. The Department of Health had conducted 89 and 119 inspections to licensed drug manufacturers in 2012 and 2013 respectively;</p> <p>(d) the amendment to the definition of pharmaceutical products would make it more closely aligned with the definition of medicinal product adopted by the European Commission and similar definitions adopted by some overseas countries; and</p> <p>(e) the current legislative proposals did not touch on the regulatory framework for registered pharmacists. The issue would be studied by the Pharmacists Sub-group under the Steering Committee on the Strategic Review on Healthcare Manpower Planning and Professional Development ("the Steering Committee") before the end of 2014.</p>	
002346 - 003010	Chairman Mr CHEUNG Kwok-che Admin	<p>Mr CHEUNG Kwok-che's view that the Administration should commit to establish a separate regulatory body for regulating registered pharmacists in the longer term.</p> <p>The Administration's reiteration that the Pharmacists Sub-group under the Steering Committee would study the issue. In the meantime, PPB would remain as the regulatory body governing the registration and discipline of pharmacists by virtue of the Pharmacy and Poisons Ordinance (Cap. 138) ("the Ordinance") and its subsidiary legislation.</p> <p>The Chairman's remarks that the objects of the Bill were to amend the Ordinance and its subsidiary legislation to implement certain recommendations of the Review Committee on Regulation of Pharmaceutical Products in Hong Kong ("the Review Committee") and update the legislative provisions.</p>	
003011 - 003657	Chairman Mr Albert CHAN	<p>Discussions on the arrangements for scrutiny of the Bill.</p> <p>Mr Albert CHAN's request for the Legislative Council Secretariat to prepare a summary of the major issues of concern raised by the Bills Committee and the responses provided by the Administration, and an information note on the regulations governing the definition, registration and manufacture of medicinal products in EU.</p>	Clerk
003658 - 010245	Chairman Mr CHEUNG Kwok-che Admin	Mr CHEUNG Kwok-che's concern about and the Administration's further response to issues raised in the letter from Mr Vincent FANG concerning the proposed requirement of written order of drugs -	

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		<p>(a) different working groups with trade representatives and stakeholders as members were formed to provide comments on the revision or formulation of COC for registered pharmacists and COPs for relevant drug traders. The revised COP for ASPs was endorsed by PPB at its meeting; and</p> <p>(b) the proposed requirement of placing drug orders in written form, which would be incorporated into the COPs for relevant drug traders, would enable the relevant suppliers and corresponding parties to check the orders upon delivery and receipt of drugs, thereby preventing drug incidents. It would also enable the Administration to trace the source of the problem from the written records of drug orders and take corresponding measures to safeguard public health in the event of drug incidents.</p> <p>Mr CHEUNG Kwok-che's concern about the difficulties in ensuring compliance by private doctors who were not bound by the relevant COPs promulgated by PPB for the drug traders concerned (including manufacturers, wholesalers and retailers) and did not wish to place drug orders in written form for various reasons.</p> <p>The Administration's advice that under the proposed requirement, relevant drug traders had to obtain an order in writing issued by the purchaser before the completion of a sale of the drugs covered by the requirement, and arrange the delivery of the drugs accordingly. Compliance with the relevant COPs was one of the licensing conditions for issuing the licences for the drug traders concerned. Breach of the relevant COPs might lead to revocation or suspension of the licenses for a period which PPB thought fit. While it was understandable that private doctors, being the stakeholders who would be affected by the proposed requirement, had different views towards the requirement, it should be noted the purpose of which was to offer better protection for public health.</p>	
010246 - 010950	Chairman Miss Alice MAK Admin	<p>Miss Alice MAK's questions on whether any guidelines were available for doctors on how drug orders should be placed, as well as the concerns raised by the Hong Kong Doctors Union in its submission dated 17 June 2014 (LC Paper No. 1837/13-14(03)) as to whether there was any evidence supporting that the proposed requirement of written orders of drugs was better than the conventional verbal orders, and whether the requirement would cause a delay in drug delivery by the suppliers.</p> <p>The Administration's advice that the proposed requirement of written orders of drugs was supported by the Hong Kong Medical Association ("HKMA"). The written order practice, i.e. the ordering of drugs from suppliers should be made in writing and the written orders should be kept for</p>	

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		<p>verification upon delivery of the drugs and for future reference, was already recommended in its Good Dispensing Practice Manual. The proposed requirement was also supported by the Hong Kong Association of the Pharmaceutical Industry which represented a number of distributors of pharmaceutical products in Hong Kong, as any products returned due to errors in delivery had to be destroyed. In addition, many of the drug suppliers had designed standard procurement forms for use by their clients in order to save their efforts. The Administration did not see any reason why there would be a delay in drug delivery due to the implementation of the requirement.</p> <p>In response to Miss Alice MAK's enquiry as to whether the maintaining of a complete set of drug movement records would facilitate patients' claims for compensation in case of drug incidents, the Administration's advice that the proposed requirement would effectively reduce the risk of miscommunication between suppliers and purchasers, and facilitate the tracing of the source of the problem.</p>	
010951 - 012627	Chairman Mr WONG Ting-kwong Admin	<p>Mr WONG Ting-kwong's remarks that to his understanding, the proposed requirement of written orders of drugs was welcomed by drug suppliers, as any products returned due to errors in delivery had to be destroyed; and his enquiry about whether drug suppliers should regard an electronic drug order message sent by a sales representative, who received a verbal order from a purchaser (e.g. practising doctors), through short messaging service ("SMS") and mobile messaging applications (e.g. WhatsApp) as the purchaser's written order.</p> <p>The Administration's advice that drug order sent by the sales representatives on behalf of their clients in electronic mode would not be regarded as written orders of purchasers, unless the purchasers had sent a written message to the sales representatives beforehand to confirm the orders.</p> <p>In reply to the Chairman, the Administration's advice that three briefing sessions on the COP for Licensed Manufacturers and Authorized Persons, which covered, among others, the requirement on placing drug orders in written form, had been organized in September 2013, January 2014 and March 2014 respectively, with an attendance of 206 representatives from the trade and relevant stakeholders. Upon the enactment of the Bill, further briefing sessions on the COP and the amended Ordinance would be organized for the trade.</p>	
012628 - 014647	Chairman Mr LEUNG Yiu-chung Admin	<p>Mr LEUNG Yiu-chung's concern over the opposing views of the Hong Kong General Chamber of Pharmacy on the proposed requirement of written orders of drugs in written form. The Chamber considered that a well-established drug transaction record system was already in place. The proposed requirement would merely result in an increase in operation cost and, hence, the price of the drugs concerned.</p>	

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		<p>While it was proposed that the requirement would only apply to poisons listed in Part I of the Poisons List Regulations (Cap. 138B) ("Part I Poisons") in the initial stage of its implementation, these drugs accounted for around 50% of the pharmaceutical products in Hong Kong and were widely ordered by ASPs. The Administration's remarks that the trade was in support of the COP for ASPs also did not reflect the full picture because a number of representatives of the trade had raised opposing views to the COP at the consultation meetings held in 2012.</p> <p>The Administration's advice that -</p> <p>(a) at present, ASPs could only supply the poisons listed in the First Schedule to the Pharmacy and Poisons Regulations (Cap. 138A) by way of wholesale dealing if a written order signed by the purchaser, which included the particulars such as the name, address, the trade or business or profession of the purchaser, and the name and quantity of the product to be purchased, was obtained before the completion of the sale. It was proposed that in future, the supply of all Part I Poisons would also be subject to the same requirement. In addition, the acquisition of Part I Poisons by ASPs from dug manufacturers, wholesalers or other retailers had to be by way of a written order; and</p> <p>(b) while it was true that the Administration had not taken on board all the different views expressed by the trade, it should be noted that the Administration had struck a balance among the interests of the trade, various stakeholders and the public in drafting the Bill and the relevant COPs, with a view to strengthening the regulation of pharmaceutical trade without causing unnecessary impacts on the trade.</p>	
014648 - 014921	Chairman Miss Alice MAK	Miss Alice MAK's view that the Bills Committee should commence the clause-by-clause examination of the Bill.	
014922 - 015105	Chairman Admin	The Chairman's request for the Administration to provide a written response to the issues raised by Mr Vincent FANG in his letter dated 16 June 2014.	Admin
015106 - 015156	Chairman	Commencement of clause-by-clause examination of the Bill	
015157 - 015349	Chairman Admin	<u>Examination of the long title and clauses 1 to 3</u>	
015350 - 015807	Chairman Admin	<u>Examination of clause 4</u> The Chairman's remarks that the Bills Committee would revisit the issue relating to the issuance of COC and COPs by PPB at its future meetings.	

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015808 - 015906	Chairman Admin	<u>Examination of clause 5</u>	
015907 - 020038	Chairman Admin	<u>Examination of clause 6</u> The Bills Committee agreed to continue the examination of clause 6 at the next meeting.	
<i>Agenda item II: Any other business</i>			
020039 - 020055	Chairman	Date of next meeting to be scheduled	

Council Business Division 2
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26 January 2015