立法會
Legislative Council

LC Paper No. CB(2)707/14-15
(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 third meeting held on Tuesday, 10 June 2014, at 4:30pm in Conference Room 2 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 CHEUNG Kwok-che Hon Paul TSE Wai-chun, JP Hon Alan LEONG Kah-kit, SC Hon Albert CHAN Wai-yip Hon Claudia MO Hon Alice MAK Mei-kuen, JP Dr Hon KWOK Ka-ki Dr Hon Fernando CHEUNG Chiu-hung
Members absent	:	Hon Vincent FANG Kang, SBS, JP Hon WONG Ting-kwong, SBS, JP Dr Hon LEUNG Ka-lau Hon Mrs Regina IP LAU Suk-yee, GBS, JP Hon LEUNG Kwok-hung Hon WONG Yuk-man Hon CHAN Han-pan Dr Hon Elizabeth QUAT, JP
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, 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) and CB(3)511/13-14]

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

Action

Admin 2. The Administration was requested to provide a summary of the deputations' stance towards the key issues of the Bill.

II. Any other business

3. The Chairman said that subject to the availability of members, the next meeting of the Bills Committee would be held on 17 June 2014 at 10:45 am. Members would be informed of the meeting arrangements in due course.

(*Post-meeting note*: The notice of the fourth meeting of the Bills Committee scheduled for 17 June 2014 at 10:45 am was issued to members on 13 June 2014 vide LC Paper No. CB(2)1807/13-14.)

4. There being no other business, the meeting ended at 6:30 pm.

Council Business Division 2
Legislative Council Secretariat
22 January 2015

Annex

Proceedings of the third meeting of the Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014 held on Tuesday, 10 June 2014, at 4:30pm in Conference Room 2 of the Legislative Council Complex

Time marker	Speaker	Subject(s)/Discussion	Action Required
Agenda item I: Meeting with the Administration			
000123 - 000249	Chairman	Opening remarks	
000250 - 001141	Chairman Admin Mr CHAN Wai-yip	Briefing by the Administration on its response to issues raised by deputations at the meeting on 20 May 2014. [LC Paper No. CB(2)1735/13-14(02)] The Chairman's remarks that the objects of the Bill were to amend the Pharmacy and Poisons Ordinance (Cap. 138) ("the Ordinance"), the Pharmacy and Poisons Regulations (Cap. 138A) ("PPR") and the Poisons List Regulations (Cap. 138B) ("PLR") to implement certain recommendations of the Review Committee on Regulation of Pharmaceutical Products in Hong Kong ("the Review Committee") and update the legislative provisions. The request of some deputations to establish a separate statutory body to take over the existing function of the Pharmacy and Poisons Board ("PPB") for regulating registered pharmacists (i.e. item (a) in the Administration's paper) was not directly relevant to the subject matter of the Bill.	
001142 - 001916	Chairman Dr KWOK Ka-ki Admin	Dr KWOK Ka-ki's view that while he supported the early implementation of the Bill for the sake of patient safety, given the grave concern of the industry, in particular registered pharmacists working in community pharmacies, on the role and composition of PPB, the Administration should, at the least, make a commitment to expeditiously review the regulatory framework for registered pharmacists. Dr KWOK Ka-ki's enquiry about the legal liability of registered pharmacist under the proposed amendment to the definition of authorized seller of poisons ("ASP"), and the implementation of the requirement to place drug orders in written form by phases. The Administration's advice that - (a) three pharmacist associations, including the College of Pharmacy Practice, Pharmaceutical Society of Hong Kong and the Society of Hospital Pharmacists of Hong Kong, had expressed support for the Bill as set out in their joint submission with other parties to the Bills Committee (LC Paper No. CB(2)1743/13-14(04)); (b) the proposed amendment which revised the definition of an ASP to "a registered pharmacist, body corporate	

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		or unincorporated body of persons that is authorized to carry on a business of retail sale of poisons under section 11" was purely a technical amendment to reflect the usage of the term in the legislation as an entity that carried on a business of retail sale of poisons. It should be noted that under the current provision of the Ordinance, if a natural person wanted to carry on a business as an ASP, such person had to be a registered pharmacist. The proposed revised definition would not impose extra legal liabilities on a registered pharmacist, who was not the holder of certificate of registration of premises of an ASP, working as an employee of an ASP; and (c) to facilitate the industry adapt to the requirement to place drug orders in written form, the requirement would be implemented by phases according to the risk levels of drugs. Initially, the requirement would only apply to drugs in Part I of the Poisons List of PLR, antibiotics and dangerous drugs.	
001917 - 002940	Chairman Ms Claudia MO Admin	Ms Claudia MO's grave concern over the opposing views held by the Hong Kong Pharmacists Union and the Hong Kong Doctors Union ("HKDU") to the Bill and their request for the Administration to withdraw the Bill and to conduct fresh consultation with the industry; and her enquiry on the appropriateness to allow persons not being registered pharmacists to take up the role of authorized person ("AP") for the manufacturers of pharmaceutical products. The Administration's response that - (a) during the process of revising or formulation of the relevant code of conduct ("COC") and codes of practice ("COPs"), the Administration had extensively consult the trade and relevant stakeholders. Over 5 200 copies of letter had been issued for the purpose of gauging views from the trade on the Bill and/or the relevant COC and COPs. A number of consultation meetings, public consultation and briefing sessions had been held, which were attended by more than 700 trade representatives and involved a total of 40 organizations from different sectors. That said, given that the Hong Kong Pharmacists Union was newly established in April 2014, the Administration would be happy to meet with the Union individually to receive its views on the relevant COC and COPs; (b) as regards the requirement for placing drug orders in written form which HKDU had objected to since its being a member of the Review Committee, it should also be noted that the Hong Kong Medical Association ("HKMA") was supportive of this recommendation put forth by the Review Committee in 2009. In addition, the written order practice was	

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		already recommended in the Good Dispensing Practice Manual issued by HKMA. The requirement would be implemented by administrative means whereby PPB would incorporate the requirement in the COPs for the manufacturers, wholesalers and retailers of pharmaceutical products. Apart from HKDU and HKMA, views from Hong Kong Dental Association and Hong Kong Veterinary Association on the COPs for ASPs, Listed Sellers of Poisons and wholesalers and importers/exporters had been invited during the consultation exercises; and (c) allowing registered pharmacists and any other person who held a qualification awarded on completion of the courses recognized by the Pharmacy and Poisons (Manufacturers Licensing) Committee, who had at least three years' experience in manufacturing pharmaceutical products in accordance with the Good Manufacturing Practices Guide ("the GMP Guide"), to act as AP was in line with international practice, such as that adopted by the European Union ("EU").	
002941 - 003754	Chairman Mr Albert CHAN Admin	Mr Albert CHAN's view that while it was important to enhance patient safety, the Administration had to ensure that any regulatory measures put in place in this regard were reasonable and would have the support of the industry, including registered pharmacists and doctors, for smooth implementation; and his concern about the appropriateness to follow the practice of EU in setting the qualification required for registration as an AP having regard to the fact that the whole regulatory regime for pharmaceutical products in Hong Kong was not directly adapted from that of EU. The Administration's advice that - (a) placing drug orders in written form (such as by electronic means, fax and mail) could help facilitating the tracing of source of drugs and minimizing errors in placing or accepting orders, delivery and receipt of drugs so as to offer better protection for the public. To help the industry adapted to the requirement, PPB would implement the requirement by phases according to the risk levels of drugs; and (b) given the diversified and complicated nature of drug manufacturing, various scientific considerations were involved in the course of drug manufacturing. Hence, the qualification requirements for APs also needed to be strengthened, with a view to aligning with international practice, such as that of EU. As such, besides registered pharmacists, the legislative proposal also allowed any persons who held qualifications awarded on completion of recognized courses relevant to drug manufacturing, say, microbiology and toxicology, to act as an AP. All	

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		applicants for registration as an AP would be required to have at least three years' experience in manufacturing pharmaceutical products in accordance with the GMP Guide.	
003755 - 010012	Chairman Mr LEUNG Yiu-chung Admin	Mr LEUNG Yiu-chung's enquiry about - (a) while the setting of the qualification requirements for APs had made reference with that of EU, whether the standards of local drug manufacturing and quality control of local manufacturers was on par with the standard of EU; (b) in respect of the proposed requirement for placing drug orders in written form, whether the trade needed to keep the records of orders, including orders placed through email, short messaging service ("SMS") and mobile messaging applications (e.g. WhatsApp), for inspection by the authority as and when necessary; (c) whether the consultation exercise carried out by the Administration in the process of drafting the Bill had covered all the legislative amendments, including the proposed amendment to the definition of ASP; and (d) whether the current legislative proposals had covered all or only part of the recommendations put forth by the Review Committee. The Administration's advice that - (a) at present, a total of 24 licensed pharmaceutical manufacturers were in compliance with the Hong Kong GMP Guidelines for Pharmaceutical Products and they would be required to comply with the Guide to GMP for Medicinal Products and its annexes (where applicable) published by the Pharmaceutical Inspection Cooperation Scheme ("PIC/S") by 2015. Under the proposed revised definition of "manufacture", secondary packaging activities (with an exemption for certain activities which did not affect the safety, efficacy and quality of the products) would also be required to be carried out by a licensed manufacturer in compliance with the relevant PIC/S GMP requirements. As such, it was proposed that all applicants, regardless registered pharmacists or persons holding recognized university qualifications, for registration as an AP should have at least three years' experience in manufacturing pharmaceutical products in accordance with the relevant GMP Guide; (b) GMP was a quality assurance approach used by the drug manufacturing worldwide (including Hong Kong) to ensure that products were consistently produced and controlled throughout the manufacturing process;	

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		(c) under the proposed requirement for placing drug orders in written form, traders would be required to keep records of all written orders, regardless of whether they were placed by electronic or non-electronic means; (d) the Administration had carried out extensive consultation on the legislative proposals aimed at enhancing the regulation of pharmaceutical products of Hong Kong. These, however, did not include those legislative amendments which were technical or textual in nature, such as the proposed amended definition of ASP which sought to accurately reflect the meaning of an ASP already adopted by the Ordinance; and (e) a total of 16 among the 75 recommendations put forth by the Review Committee required amendments to the Ordinance and its subsidiary legislation. In response to the concerns raised by some members of the Panel on Health Services and deputations giving views to the Panel on the legislative proposals, the proposal requiring the registered premises of an ASP to be under the personal control of a registered pharmacist whenever the registered premises were open for business (which was longer than the current requirement of not less than two-thirds of the daily business hours of the ASP) had been removed from the current legislative exercise. Other recommendations of the Review Committee that had not been taken forward included, among others, the imposition of licensing control on retailers of non-poisons given its significant impact to the large number of direct sellers of non-poisons.	
010013 - 011015	Chairman Mr CHEUNG Kwok-che Admin	Mr CHEUNG Kwok-che's view that while it was important to ensure that any measures proposed to enhance the regulation of pharmaceutical products should not cause unnecessary impact on the trade, safeguarding the interests of the public should come first; and his enquiry on - (a) in respect of the proposed requirement on placing drug orders in written form which would only be applied to drugs in Part I of the Poisons List of PLR in its initial stage of implementation, the number of drugs involved in this regard; (b) how to ensure that PPB would properly exercise its power and fully consult the trade and relevant stakeholders in formulating and revising the relevant COPs for licensed/registered drug traders and the COC for registered pharmacists; and (c) whether any consensus on the legislative proposals had been reached during the earlier consultation	

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		carried out by the Administration. The Administration's advice that - (a) around 50% of the some 19 000 registered pharmaceutical products in Hong Kong were classified as poisons. It was not uncommon that ASPs, hospitals and medical clinics would order these drugs, which included those for treatment of heart diseases, diabetes mellitus and cancers, for prescribing or dispensing to patients. It should be noted that the proposed requirement for placing drug orders in written form was welcomed by many drug manufacturers and wholesalers as any products returned due to errors in delivery had to be destroyed. Given that many drug suppliers had designed standard procurement forms for use by their clients, written drug orders should not have a significant cost impact on licensed traders and private doctors; (b) PPB had put in place a well-established mechanism to provide the trade and relevant stakeholders with various channels to participate in formulating, revising and issuing the relevant COPs or COC, and to express their views on such Codes. It should be noted that empowering PPB to promulgate these Codes would provide PPB with the flexibility to revise the Codes in response to local circumstances and changes; and (c) the Department of Pharmacology and Pharmacy of The University of Hong Kong, the School of Pharmacy of The Chinese University of Hong Kong, certain patient groups and pharmacist associations had written to the Bills Committee expressing their support for the Bill. The major areas where some trade members held opposing views included, among others, the revised definition of AP, empowerment of PPB to promulgate relevant COPs and COC, and the requirement for placing drug orders in written form.	
011016 - 013043	Chairman Miss Alice MAK Admin	Miss Alice MAK's view that any measure that strived to offer better protection for patients and the public should be supported, albeit the implementation of which might cause some inconvenience to the trade. Miss Alice MAK's concern as to how far the proposed requirement for placing drug orders in written form could prevent the recurrence of drug incidents and facilitate enforcement actions taken against relevant illegal practice of doctors, and whether its implementation would lead to a significant increase in the administration costs of the traders, and hence, the price of the drugs concerned; and her enquiry about the reason why some private doctors remained reluctant to place drug orders in written form.	

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		The Administration's advice that - (a) the proposal to require retailers of pharmaceutical products and doctors to place drug orders in written form, as recommended by the Review Committee in 2009, would help to build up a complete set of record in the drug supply chain and minimize errors in the placing or accepting orders as well as delivery and receipt of drugs which were necessary to protect the safety of patients. In addition, the proposed written order could facilitate the enforcement actions against illegal possession of dangerous drugs, as it served to establish if a large quantity of dangerous drugs were ordered by the doctors themselves for treatment of patients, or by someone else without their knowledge; (b) any increase in administration costs that might arise from the implementation of the proposed requirement would be minimal. To facilitate the industry adapted to the requirement, it was proposed that placing drug orders by electronic means could be accepted as written orders. In addition, the requirement would be implemented by phases; and (c) it should be noted that while HKDU was opposed to the proposed requirement, HKMA was in support of the proposal. Drug manufacturers, wholesalers and retailers also raised no strong opposition to the introduction of the requirement. As far as registered pharmacists were concerned, the Pharmaceutical Society of Hong Kong, Society of Hospital Pharmacists and College of Pharmacy Practice, with more than 700 members in total, had expressed their strong support for the Bill which sought to implement the recommendations of the Review Committee.	
013044 - 014319	Chairman Mr LEUNG Yiu-chung Mr CHEUNG Kwok-che Admin	Given that deputations attending the Bills Committee's meeting on 20 May 2014 had raised a number of concerns over the amendments required in the Bill and it was not likely that the Bills Committee could complete the scrutiny of the Bill for resumption of the Second Reading debate on the Bill at the last Council meeting of the current session, Mr LEUNG Yiu-chung's view that the Administration should further discuss with the trade and relevant stakeholders during the summer recess with a view to reaching some common grounds as far as practicable. Mr CHEUNG Kwok-che's concurrence of the view of Mr LEUNG Yiu-chung, adding that the Administration should not rush for the enactment of the Bill as important issues might be overlooked in the hasty process of scrutiny. The Administration's reiteration of the extensive consultation work it had carried out in the process of drafting the Bill, and its advice that it would endeavor to work towards the	

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		target of resuming the Second Reading debate on the Bill at the last Council meeting in the current legislative session on 9 July 2014, as some patient groups had called for the early enactment of the Bill. It should also be noted that the greatest concern expressed by the deputations was on the present regulatory framework for registered pharmacists. Their request for establishing a separate statutory body for registered pharmacists would be followed up by the Pharmacists Sub-group under the Steering Committee on Strategic Review on Healthcare Manpower Planning and Professional Development.	
014320 - 015852	Chairman Mr LEUNG Yiu-chung Mr CHEUNG Kwok-che Admin	The Chairman's remarks that while the Bills Committee had no obligation to ensure that the Administration's target to resume the Second Reading debate on the Bill at the Council meeting of 9 July 2014 could be achieved, he did not see any need for the Bills Committee to withhold the holding of meetings in the current session to continue to scrutinize the Bill. The Chairman's request for the Administration to provide a summary of the deputations' stance towards the key issues of the Bill. Discussion on the discussion arrangement at the future Bills Committee meetings.	**Admin**
Agenda item II: Any other business			
015853 - 020013	Chairman	Date of next meeting	

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22 January 2015