立法會 Legislative Council

LC Paper No. CB(2)1067/14-15

(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 sixth meeting held on Thursday, 17 July 2014, at 10:45 am in Conference Room 2A of the Legislative Council Complex

Members: Prof Hon Joseph LEE Kok-long, SBS, JP, PhD, RN (Chairman)

present Hon LEUNG Yiu-chung

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 LEUNG Kwok-hung Hon Albert CHAN Wai-yip Hon WONG Yuk-man

Hon Claudia MO

Hon Alice MAK Mei-kuen, JP

Dr Hon KWOK Ka-ki

Members : Hon Emily LAU Wai-hing, JP

absent Hon Vincent FANG Kang, SBS, JP

Dr Hon LEUNG Ka-lau Hon CHAN Han-pan, JP

Dr Hon Fernando CHEUNG Chiu-hung

Dr Hon Elizabeth QUAT, JP

Public Officers: <u>Item I</u>

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

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

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)2056/13-14(01) to (03) and CB(3)511/13-14]

<u>The Bills Committee</u> deliberated (index of proceedings attached at **Annex**).

Continuation of clause-by-clause examination of the Bill

2. <u>The Bills Committee</u> continued clause-by-clause examination of the Chinese text of the Bill up to clause 14.

Follow-up actions required of the Administration

Admin

- 3. <u>Members</u> noted that it was the Administration's intention to introduce the following Committee Stage amendments to the Bill -
 - (a) to replace "by a registered pharmacist or in his presence or under his supervision" with "by a registered pharmacist, or in the presence and under the supervision of a registered pharmacist" in section 13(4)(c) of the Pharmacy and Poisons Ordinance (Cap. 138) ("the Ordinance") to align with section 11(1) of the Ordinance; and
 - (b) to replace "Secretary" in the proposed new section 13(7A) and (7B) of the Ordinance with "Board".

Admin

- 4. <u>The Administration</u> was requested to consider the following suggestions on the drafting of the Ordinance and the Bill -
 - (a) to add "and Related Offences" after "Forgery" in section 10(2) of the Ordinance in order to reflect the current heading of Part IX of the Crimes Ordinance (Cap. 200);
 - (b) to make amendment to "forges" in section 10(2) of the Ordinance;
 - (c) to replace "、" with ", " after the expression "更改載於處所註 冊紀錄冊內的" in the Chinese text of the proposed new section 13(7A) of the Ordinance; and
 - (d) to replace "被裁定犯" with "被裁定干犯" in the Chinese text of the proposed new section 15(1)(c) of the Ordinance.
- 5. Noting that the word "conduct" was not defined under the Ordinance and the Bill, some members held the view that the scope of the conduct referred to in the proposed new section 15(1)(e) of the Ordinance should be

restricted to conduct that was relevant to the practice of pharmacy. The Administration was requested to provide a written response to address members' concern in this regard.

II. Any other business

6. <u>Members</u> agreed that the next meeting of the Bills Committee should take place after the summer recess. <u>The Chairman</u> said that he would discuss with the Clerk and the Administration on the date of the next meeting. Members would be informed of the meeting arrangements in due course.

(*Post-meeting note*: The notice of the seventh meeting of the Bills Committee scheduled for 3 November 2014 at 4:30 pm was issued to members on 20 October 2014 vide LC Paper No. CB(2)105/14-15.)

7. There being no other business, the meeting ended at 12:56 pm.

Council Business Division 2
<u>Legislative Council Secretariat</u>
16 March 2015

Proceedings of the sixth meeting of the Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014 held on Thursday, 17 July 2014, at 10:45 am in Conference Room 2A of the Legislative Council Complex

| Time marker | Speaker | Subject(s)/Discussion | Action required |
|--|------------------------------------|--|-----------------|
| Agenda item I: Meeting with the Administration | | | <u> </u> |
| 000521 - 000625 | Chairman | Opening remarks Arrangement of next meeting | |
| 000626 - 001151 | Chairman Admin | The Administration's briefing on its written responses to issues arising from previous meeting (LC Paper Nos. CB(2)2056/13-14(01) to (03)). | |
| 001152 - 001642 | Chairman Mrs Regina IP Admin | Mrs Regina IP's enquiry about the difficulties faced by local drug traders and private doctors in placing drug orders in written form; and the practice of placing written drug orders in overseas places, such as Singapore and Taiwan. | |
| | | (a) the requirement of placing drug orders in written form aimed to implement the recommendation of the Review Committee on Regulation of Pharmaceutical Products in Hong Kong ("the Review Committee") to develop a complete set of drug movement records, thus facilitating the tracing of the sources of drugs, minimizing errors upon delivery and receipt of drugs. To help the industry to adapt to the requirement, orders placed by electronic means (e.g. emails), fax and mail etc. would be acceptable means of placing drug orders in written form. In addition, the requirement would be implemented by phases in accordance with the risk levels of drugs. Although some drug traders and private doctors might find placing verbal orders more convenient, it should be noted that the requirement could enhance safeguards for public health; and (b) written orders of drugs were required in Singapore and Taiwan where separation of prescribing from dispensing of drugs was implemented. | |
| 001643 - 002139 | Chairman Ms Claudia MO Admin | Ms Claudia MO's view that the principle of self-regulation of the profession should be upheld in mapping out the regulatory framework of registered pharmacists; and her concern over the opposing views expressed by some professional bodies, such as the Hong Kong Pharmacists Union and the Hong Kong Doctors Union, over the empowerment of the Pharmacy and Poisons Board ("PPB") to issue relevant Codes of Practice | |

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| | | ("COPs") for drug traders and Code of Conduct ("COC") for registered pharmacists and the requirement of placing drug orders in written form. | 33,000 |
| | | The Administration's response that it was necessary to empower PPB to promulgate COPs for compliance by the relevant drug traders. As for registered pharmacists, the current situation that three pharmacist associations had their own sets of Code of Ethics for their members to follow was not desirable. The Administration considered that the promulgation of the relevant COPs and COC by PPB would enhance the regulatory control of drugs. | |
| 002140 - 003455 | Chairman Mr LEUNG Yiu-chung Admin | Having regard to the strong opposing views expressed by some professional bodies to the Bill, Mr LEUNG Yiu-chung's suggestion of holding another meeting to receive further views from the stakeholders on the Bill. | |
| | | The Chairman's decision that it was not necessary to hold another meeting to invite further oral representation from the relevant stakeholders on the Bill, as both the Panel on Health Services ("the Panel") and the Bills Committee had gauged the views of deputations at their earlier meetings. It was noted that the relevant stakeholders had also put forward their further views to the Bills Committee for consideration in the form of written submissions. Members might move Committee Stage amendments to the Bill relating to the issues of concern if a consensus could not be reached by the Bills Committee after further deliberation. | |
| | | The Administration's advice that apart from taking note of the views expressed by the deputations attending the respective meetings of the Panel and the Bills Committee, it also consulted the relevant stakeholders on the legislative proposals at various occasions. It would be happy to meet with the Hong Kong Pharmacists Union and any other organizations individually to receive their views on the Bill. | |
| 003456 - 004353 | Chairman Mr Alan LEONG Admin | Mr Alan LEONG's concern over the strong opposing views of the Hong Kong Pharmacists Union, the Hong Kong Doctors Union and other four professional bodies over the legislative proposals on the revised definition of authorized seller of poisons ("ASP") and pharmaceutical product; the qualification requirements of the authorized person ("AP"); the extension of the validity period of clinical trial certificate and medicinal test certificate; and the empowerment of PPB to issue relevant COPs for drug traders and COC for registered pharmacists, as well as the administrative measure of requiring under the relevant COP that drug orders should be placed in written form. Mr Alan LEONG's view that receipts issued by drug | |

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| mai nei | | purpose of building up a complete set of drug transaction records and facilitating the tracing of source of drugs; and his concern about whether placing drug orders in written form would cause delay in delivery of drugs to private doctors, especially when the drugs were urgently required. | requireu |
| | | The Administration's advice that - | |
| | | (a) it should be noted that the Society of Hospital Pharmacists of Hong Kong had submitted a letter to editors of local newspapers expressing its support for, among others, the requirement on written drug orders and the proposal to empower PPB to promulgate COC for registered pharmacists; and | |
| | | (b) major drug suppliers had confirmed that the implementation of placing drug orders in written form would not cause delay to the delivery of drugs. In cases of urgent medical needs, doctors should make a clinical judgment on whether the patient concerned should be delivered to the appropriate hospital for timely treatment. | |
| 004354 - 004925 | Chairman Miss Alice MAK Admin | Miss Alice MAK's expression of support to the requirement of placing written order of drugs, which could enhance the monitoring of the drug supply system and minimize the potential risk in every step of the drug supply chain. | |
| | | On Miss Alice MAK's enquiry on the qualification required for registration as an AP, the Administration's advice that given the diversified and complicated nature of the manufacturing of pharmaceutical products, various scientific considerations were involved in the course of manufacturing of pharmaceutical products. Hence, the qualification requirements for AP also need to be diversified. The proposal to allow other persons with other qualifications, not limited to registered pharmacists, to act as an AP if he/she met the prescribed conditions was in line with international practice, such as the European Union. | |
| 004926 - 005720 | Chairman Mr WONG Ting-kwong Admin | Mr WONG Ting-kwong's expression of support to the Bill; and his view that the opposing views from the trade and some professional groups towards the Bill was due to the reason that the Bill would strengthen the regulatory control over various areas. | |
| | | In response to Mr WONG Ting-kwong's enquiry as to whether drug orders placed by the purchasers through voice mail would be regarded as written orders, the Administration's advice that voice mail would not be considered as an acceptable form of written order having taken into account that the pronunciations of the names | |

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| | | of certain drugs were quite similar and, hence, the verbal order might be wrongly taken by the drug suppliers. | |
| 005721 - 010442 | Chairman Mr CHEUNG Kwok-che Admin | Mr CHEUNG Kwok-che's enquiry as to the reason why receipts issued by drug suppliers could not serve as a written record for a verbal drug order; and his concern about the enforcement against non-compliance with the requirement of placing drug orders in written form and whether the requirement would cause delay for private doctors to obtain medicine for patients in urgent cases. | |
| | | The Administration's reiteration that the major drug distributors had confirmed that the requirement for a written order as compared to a verbal order would not cause a delay in the delivery of drugs, and private doctors should decide whether it was more desirable to send a patient in urgent conditions to hospital for timely treatment; and its advice that - | |
| | | (a) given that, in most cases, acknowledgement receipts of drug orders were issued after the ordering and delivery of the drugs concerned, they could not serve the purposes of minimizing errors in placing order, delivery and receipt of drugs; and | |
| | | (b) the requirement of placing drug orders in written form was not within the scope of the Bill, as the requirement would only be incorporated into the relevant COPs for licenced drug traders which were not part of the primary and subsidiary legislation. | |
| 010443 - 011323 | Chairman Mr Albert CHAN Admin | Mr Albert CHAN's view that the regulatory power of PPB, which covered pharmaceutical products, drug traders and pharmacists, was too extensive; and his concurrence with the suggestion of holding another meeting, say, after the completion of clause-by-clause examination of the Bill, to receive further views from the relevant stakeholders on the major issues of concern. | |
| | | The Chairman's remarks that while some members and the Administration held different views towards the general merits and principles of some legislative proposals put forward in the Bill, six meetings had already been held to discuss the issues of concern. It was more appropriate for the Bills Committee to continue the clause-by-clause examination of the Bill. The issue of whether to hold another meeting to receive further views from relevant stakeholders on the Bill should be considered at a later stage. | |
| 011324 - 011907 | Chairman Mr WONG Yuk-man | Mr WONG Yuk-man's view that since the policy issues relating to the Bill had been well deliberated at relevant meetings of the Panel, the Bills Committee should focus its efforts in examining the provisions of the Bill. He did not see the need to hold another hearing to receive views from the relevant stakeholders. | |

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| 011908 - 013311 | Chairman Mr Paul TSE Ms Claudia MO Admin | Mr Paul TSE's expression of support to the proposed requirement of placing drug orders in written form as it could prevent errors from spoken communication. Mr Paul TSE and Ms Claudia MO's views that consideration could be given to allowing a written order be placed within a certain period of time, say, 24 hours, after the purchaser had made a verbal order to request the delivery of drugs urgently required for medical treatment. The Administration's advice that - (a) the requirement of placing drug orders in written form was necessary in order to minimize errors in the delivery and receipt of drugs. Should there be any urgent cases whereby placing drug orders in written form was found difficult, PPB would give due consideration to the circumstances in examining the relevant cases of non-compliance; and (b) the Hong Kong Medical Association had already recommended in its Good Dispensing Practice Manual that the ordering of drugs from suppliers should be made in writing. | |
| 013312 - 013903 | Chairman Miss Alice MAK Admin | Miss Alice MAK's view that the operational details of the proposed requirement of placing drug orders in written form could be worked out by the Working Groups on respective COPs set up under PPB, and her enquiry as to whether the Administration would take the opportunity of the current legislative exercise to review the composition of PPB in view of the trade's concern in this regard. The Administration's advice that - (a) PPB had set up different working groups, comprising trade representatives and stakeholders as members, to provide comments on the formulation or revision of the relevant CoPs and CoC; and (b) the main purpose of the Bill was to implement certain recommendations put forth by the Review Committee to enhance the regulation of pharmaceutical products. Given that the role and composition of the Board involved wide policy implications, it was necessary for the Administration to study the issues separately. | |
| 013904 - 014053 | Chairman Mr Paul TSE Mr WONG Yuk-man | Mr Paul TSE and Mr WONG Yuk-man's views that the Administration should address the concerns raised by the professional bodies on the requirement of placing drug orders in written form, albeit that the requirement was not part of the current legislative exercise. | |

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| 014222 - 014301 | Chairman Admin | Continuation of clause-by-clause examination of the Bill | required |
| 014302 - 014359 | Chairman Admin | Examination of clause 7 | |
| 014400 - 014437 | Chairman Admin | Examination of clause 8 | |
| 014438 - 014557 | Chairman Admin Mr Paul TSE | Examination of clause 9 In response to Mr Paul TSE's enquiry on the difference between the terms "prescribed form" and "specified form", the Administration's advice that the former referred to the form stipulated in the Schedule to the Pharmacy and Poisons Regulations (Cap. 138A) which was proposed to be deleted in this legislative exercise. | |
| 014558 - 014811 | Chairman Admin ALA6 Mr Paul TSE | Examination of clause 10 ALA6's suggestions in respect of section 10(2) of the Pharmacy and Poisons Ordinance (Cap. 138) ("the Ordinance") that - (a) "and Related Offences" should be added after "Forgery" in the section in order to reflect the current heading of Part IX of the Crimes Ordinance (Cap. 200); and (b) "forges" in the section might have to be amended. In response to Mr Paul TSE's enquiry on the penalty for non-compliance with the proposed revised section 10 of the Ordinance, the Administration's advice that pursuant to section 34 of the Ordinance, any person who was guilty of an offence under this proposed revised section would be liable on conviction to a fine at level 6 (i.e. \$100,000) and to imprisonment for two years. | Admin |
| 014812 - 014844 | Chairman Admin | Examination of clause 11 | |
| 014845 - 014947 | Chairman Admin | Examination of clause 12 | |
| 014948 - 015520 | Chairman Admin ALA6 Mr WONG Yuk-man | Examination of clause 13 The Administration's undertaking to, in response to ALA6's enquiry, make textual amendments to - (a) section 13(4)(c) of the Ordinance by replacing "by a registered pharmacist or in his presence or under his supervision" with "by a registered pharmacist, or in the presence and under the supervision of a registered | Admin |

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| | | Ordinance; and (b) the proposed new section 13(7A) and (7B) of the Ordinance by replacing "Secretary" with "Board". Mr WONG Yuk-man's suggestion for the Administration's consideration of using "," instead of "、" after the expression "更改載於處所註冊紀錄冊內的" in the Chinese text of the proposed new section 13(7A) of the Ordinance. | Admin |
| 015521 - 021239 | Chairman Admin Mr WONG Yuk-man Mr Paul TSE Miss Alice MAK ALA6 | Examination of clause 14 Mr WONG Yuk-man's suggestion for the Administration's consideration of using "被裁定干犯" instead of "被裁定犯" in the Chinese text of the proposed new section 15(1)(c) of the Ordinance. | Admin |
| | | Noting that the word "conduct" was not defined under the Ordinance and the Bill, Mr Paul TSE, Mr WONG Yuk-man and Miss Alice MAK's view that the scope of the conduct referred to in the proposed new section 15(1)(e) of the Ordinance should be restricted to conduct that was relevant to the practice of pharmacy. | |
| | | The Administration's advice that the proposed new section 15(1)(e) of the Ordinance only preserved the existing power of PPB to appoint a Disciplinary Committee as provided for in the current section 15(1) of the Ordinance such that PPB might appoint a Disciplinary Committee to inquire into the conduct of a registered pharmacist, an employee of a registered pharmacist, an ASP or an employee, officer or partner of an ASP if it appeared necessary or desirable to PPB to inquire into the conduct of any of these persons. | |
| | | At the request of the Chairman, the Administration's undertaking to provide a written response to address members' concern in this regard. | Admin |
| Agenda ite | m II: Any other business | | <u> </u> |
| 021240 - 021246 | Chairman | Closing remarks | |

Council Business Division 2 <u>Legislative Council Secretariat</u> 16 March 2015