

立法會
Legislative Council

LC Paper No. CB (2)504/14-15
(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 second meeting
held on Tuesday, 20 May 2014, at 2:30 pm
in Conference Room 1 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 Mrs Regina IP LAU Suk-ye, 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
Dr Hon Fernando CHEUNG Chiu-hung

Members absent : 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

Attendance : College of Primary Healthcare Pharmacists
by invitation

Mr SUNG Ming-tat
External Affairs Director

Alliance of Safe and Quality Use of Medicines

Mr Joseph CHEUNG Ching-po
Public Affairs Director

The Practising Pharmacists Association of Hong Kong

Ms Iris Jacqueline CHANG
President

College of Consultant Pharmacist

Mr Patrick TAM Po-chun
Member

Hong Kong Pharmacists Union

Miss CHEUNG Wan-sze
Council Member

College of Geriatric Pharmacy

Mr KO Hok-yu
Member

Hong Kong Academy of Pharmacy

Mr CHEUNG Kin-man
Head of Professional Affairs

Pharmaceutical Trade Alliance

Mr Philip CHAN Cho-hung
External Communications Director

Department of Pharmacology and Pharmacy,
The University of Hong Kong

Professor WONG Chi-kei
Professor and Head

Hong Kong General Chamber of Pharmacy Limited

Mr CHEUNG Tak-wing
Executive Committee Member

The Hong Kong Association of the Pharmaceutical Industry

Ms Sabrina CHAN
Executive Director

Ms Celine CHENG

School of Pharmacy, The Chinese University of Hong Kong

Dr LEE Chui-ping
Senior Lecturer

Primary Healthcare Quality Alliance

Mr CHUNG Kin-wah
Executive Officer

Drug Safety Consortium

Mr LAW Chun-cheong
Public Relations Manager

Hong Kong Pharmaceutical Manufacturers Association

Mr CHEUNG Yiu-kwong
Vice President

Hong Kong Doctors Union

Dr YEUNG Chiu-fat
President

Asia Regulatory Professional Association

Ms CHIU Pik-kam
Representative

The Society of Hospital Pharmacists of Hong Kong

Ms CHIANG Sau-chu
Member

The Pharmaceutical Society of Hong Kong

Ms Mary Catherine CHENG
President

Hong Kong Alliance of Patients' Organizations

Mr LAM Chi-yau
Vice Chairman (External Affairs)

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 Louisa YU
Clerical Assistant (2) 5

Action

I. Meeting with deputations and 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) to (04), CB(2)1543/13-14(01), CB(2)1560/13-14(01), CB(2)1584/13-14(05) and (07), CB(2)1649/13-14(01) to (03), CB(2)1678/13-14(01), CB(2)1743/13-14(01) to (02), CB(2)1757/13-14(01) to (05), CB(2)1767/13-14(01), (03) to (05), CB(2)1778/13-14(01) and CB(3)511/13-14]

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

2. The Bills Committee received views from 20 organizations and one individual on the Bill. The Bills Committee also noted the written submission provided by the Chemical and Pharmaceutical Industries Council of the Federation of Hong Kong Industries.

Clerk 3. The Clerk was requested to prepare a summary of views and concerns expressed by deputations on the Bill.

Admin 4. The Administration was requested to provide, in writing, a consolidated response to issues raised by deputations at the meeting.

II. Any other business

5. There being no other business, the meeting ended at 4:50 pm.

**Proceedings of the second meeting of
the Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014
held on Tuesday, 20 May 2014, at 2:30pm
in Conference Room 1 of the Legislative Council Complex**

Time marker	Speaker	Subject(s)/Discussion	Action Required
<i>Agenda item I: Meeting with deputations and the Administration</i>			
000556 - 001037	Chairman Ms Emily LAU	Opening remarks Ms Emily LAU's request for the Administration to provide a written response on the concerns raised by deputations at the meeting.	Admin
001038 - 001332	College of Primary Healthcare Pharmacists	Presentation of views (LC Paper No. CB(2)1757/13-14(01))	
001333 - 001514	Alliance of Safe and Quality Use of Medicines	Presentation of views (LC Paper No. CB(2)1757/13-14(02))	
001515 - 001823	The Practising Pharmacists Association of Hong Kong	Presentation of views (LC Paper No. CB(2)1757/13-14(03))	
001824 - 002136	College of Consultant Pharmacist	Presentation of views (LC Paper No. CB(2)1778/13-14(01))	
002137 - 002444	Hong Kong Pharmacists Union	Presentation of views (LC Paper No. CB(2)1757/13-14(05))	
002445 - 002746	College of Geriatric Pharmacy	Presentation of views (LC Paper No. CB(2)1757/13-14(04))	
002747 - 002914	Hong Kong Academy of Pharmacy	Presentation of views (LC Paper No. CB(2)1767/13-14(04))	
002915 - 003227	Pharmaceutical Trade Alliance	Presentation of views (LC Paper No. CB(2)1767/13-14(05))	
003228 - 003540	Department of Pharmacology and Pharmacy, The University of Hong Kong	Presentation of views (LC Paper Nos. CB(2)1584/13-14(05) and CB(2)1767/13-14(01))	
003541 - 003854	Hong Kong General Chamber of Pharmacy Limited	Presentation of views (LC Paper No. CB(2)1522/13-14(02))	
003855 - 004132	The Hong Kong Association of the Pharmaceutical Industry	Presentation of views (LC Paper No. CB(2)1743/13-14(01))	
004133 - 004446	Ms Celine CHENG	Presentation of views (LC Paper No. CB(2)1743/13-14(02))	
004447 - 004752	School of Pharmacy, The Chinese University of Hong Kong	Presentation of views (LC Paper Nos. CB(2)1584/13-14(05) and CB(2)1678/13-14(01))	

Time marker	Speaker	Subject(s)/Discussion	Action Required
004753 - 004953	Primary Healthcare Quality Alliance	Presentation of views (LC Paper No. CB(2)1584/13-14(07))	
004954 - 005122	Drug Safety Consortium	Presentation of views (LC Paper No. CB(2)1767/13-14(03))	
005123 - 005401	Hong Kong Pharmaceutical Manufacturers Association	Presentation of views (LC Paper No. CB(2)1649/13-14(01))	
005402 - 005657	Hong Kong Doctors Union	Presentation of views (LC Paper No. CB(2)1560/13-14(01))	
005658 - 005854	Asia Regulatory Professional Association	Presentation of views (LC Paper Nos. CB(2)1522/13-14(03) and CB(2)1649/13-14(02))	
005855 - 010243	The Society of Hospital Pharmacists of Hong Kong	Presentation of views (LC Paper No. CB(2)1584/13-14(05))	
010244 - 010610	The Pharmaceutical Society of Hong Kong	Presentation of views (LC Paper No. CB(2)1522/13-14(04))	
010611 - 010909	Hong Kong Alliance of Patients' Organizations	Presentation of views (LC Paper No. CB(2)1649/13-14(03))	
010910 - 012017	Chairman Admin	<p>The Administration's response to the concerns and issues raised by deputations -</p> <p>(a) under the proposed new regulation 30C of the Pharmacy and Poisons Regulations (Cap. 138A) ("PPR"), being a registered pharmacist remained to be a major qualification requirement for taking up the position of authorized person ("AP") of a licensed manufacturer. That said, given the diversified and complicated nature of drug manufacturing which involved various scientific considerations, the qualification requirements for APs needed to be strengthened. The proposal to allow a person, who held a qualification awarded on completion of a course recognized by the Pharmacy and Poisons (Manufacturers Licensing) Committee and had at least three years' experience in manufacturing of pharmaceutical product in compliance with the Good Manufacturing Practice Guide, to act as AP was in line with international practice, such as that adopted by the European Union;</p> <p>(b) the current situation that three pharmacist associations had their own sets of Code of Ethics for their members to follow; the existing Code of Practice ("COP") for Authorized Seller of Poisons ("ASP") had no legal status for enforcement; and there were no COPs for other licensed drug traders</p>	

Time marker	Speaker	Subject(s)/Discussion	Action Required
		<p>(including listed seller of poisons ("LSP"), wholesalers, importers, exporters and manufacturers) was not desirable. It was therefore proposed that the Pharmacy and Poisons Board ("PPB") should be empowered to issue relevant code of conduct ("COC") and COPs to provide practical guidance for the conduct of the activities of registered pharmacists and licensed/registered drug traders. It was also not uncommon in overseas countries that the relevant authorities were empowered to issue COCs and COPs for the industry. It should be noted that different working groups with trade representatives and stakeholders as members had been set up by PPB to provide comments on the revision or formulation of relevant COC and COPs;</p> <p>(c) the Steering Committee on Strategic Review on Healthcare Manpower Planning and Professional Development ("the Steering Committee") would study, among others, the regulatory framework governing registered pharmacists, including the proposal to establish a separate regulatory body for the profession;</p> <p>(d) the legislative amendment to extend the validity of clinical trial certificate or medicinal test certificate to not more than five years was proposed to address the concern that the current two-year validity period was often too short for the completion of a clinical trial or medicinal test; and</p> <p>(e) the requirement of placing drug orders in written form would help establishing a complete set of movement records of drugs to better protect patient safety in the use of medicine. Placing an order in written form should not be time consuming as orders placed by fax and electronic means would be accepted as written orders. In cases of emergency, a patient should seek immediate treatment at the Accident and Emergency departments of the Hospital Authority.</p>	
012018 - 012524	Chairman Ms Claudia MO Admin	<p>Ms Claudia MO's views that the legislative proposal to empower PPB to promulgate relevant COC and COPs for registered pharmacists and licensed/registered drug traders would make the power of PPB too wide, and a separate statutory body should be established to take over the existing function of PPB for regulating registered pharmacists as proposed by some deputations; and her expression of disappointment that the Secretary for Food and Health or his Under Secretary did not attend the meeting to listen to the views of deputations.</p> <p>In response to Ms Claudia MO's concern as to whether PPB had already formulated some COPs or COC for implementation in January 2015 as pointed out by some</p>	

Time marker	Speaker	Subject(s)/Discussion	Action Required
		<p>deputations, the Administration's advice that the Working Group on the Code of Practice for Authorized Sellers of Poisons ("ASPs") with representatives from ASPs and registered pharmacists had reviewed and revised the existing COP for ASP and come up with a draft new COP. The new COP was endorsed by PPB after consultation with the trade.</p>	
012525 - 013238	<p>Chairman Mr Alan LEONG The Pharmaceutical Society of Hong Kong Admin</p>	<p>Mr Alan LEONG's concern as to whether the existing pharmacist associations had started working on setting up a single pharmacist council to move towards self-regulation of the profession of registered pharmacists.</p> <p>The Pharmaceutical Society of Hong Kong's response that a roadmap for setting up a pharmacist council had been worked out in a pharmacist conference in 2006. The pharmacist associations had met with the then Secretary for Health, Welfare and Food to discuss the proposal. The proposal however had not been followed up for various reasons.</p> <p>In response to the Chairman, the Administration's advice that the purpose of the legislative proposal to empower PPB to promulgate relevant COC and COPs was to enhance the regulation over the conduct of activities of registered pharmacists and licensed/registered drug traders to better protect public health. The proposal did not touch on the regulatory framework governing the registration of pharmacists which was currently being governed by PPB pursuant to the Pharmacy and Poisons Ordinance (Cap. 138). The Steering Committee would study, among others, the long-term development of the profession of registered pharmacists.</p>	
013239 - 013608	<p>Chairman Mr Albert CHAN Admin</p>	<p>Mr Albert CHAN's enquiry as to whether the Administration would withdraw the Bill in the light of the opposing view expressed by the majority of the deputations to the Bill.</p> <p>The Administration's reply in the negative, pointing out that the legislative amendments were proposed to implement most of the recommendations put forth by the Review Committee on Regulation of Pharmaceutical Products in Hong Kong ("the Review Committee") which were conducive to enhancing the regulatory regime for better public health.</p> <p>Mr Albert CHAN's request for the Secretariat to prepare a summary of views of deputations.</p>	<p>Clerk</p>
013609 - 014021	<p>Chairman Dr Fernando CHEUNG Admin</p>	<p>Dr Fernando CHEUNG's concern about the lack of transparency of the operation of, and the inadequate representation of the drug traders and the pharmacist profession in, PPB as pointed out by the deputations; and his view that the Administration should at the very least revise the legislative proposals to address the</p>	

Time marker	Speaker	Subject(s)/Discussion	Action Required
		<p>above concern of deputations even if the establishment of a separate regulatory body for registered pharmacists could not be made available overnight.</p> <p>The Administration's response that a Regulatory Impact Assessment had been conducted to assess the impacts of the proposed legislative amendments on drug traders and stakeholders. Issues pertaining to the present regulatory framework for registered pharmacists and in that connection the role and composition of PPB should not be a consideration to delay the present legislative proposals which primarily aimed at enhancing the regulation of pharmaceutical products for patient safety.</p>	
014022 - 014645	Chairman Mr Vincent FANG Admin	<p>Mr Vincent FANG's concern about the lack of representation of operators of community pharmacies in the composition of PPB, and the discrepancy in meaning between the expression of "shall be" in regulation 19(2)(a) of PPR and the expression of "must be" in section 1.4 of the new COP for ASPs on the requirement relating to the keeping of the keys of the locked receptacles where the controlled medicine was stored by the registered pharmacist; and his enquiry about -</p> <p>(a) the reason why PPB could endorse a new COP for ASPs to replace the existing one with effect from 2 January 2015 when the Bill, including those provisions related to the empowerment of PPB to promulgate the relevant COP, was still under scrutiny; and</p> <p>(b) how the amendments proposed under the Bill could avoid the recurrence of incidents concerning incorrect dispensing of drugs by private clinics.</p> <p>The Administration's response that -</p> <p>(a) compliance with the new COP for ASPs endorsed by PPB to replace the existing one with effect from 2 January 2015 was merely a licensing condition but not a legal requirement prior to the enactment of the Bill; and</p> <p>(b) the Bill proposed to empower PPB to promulgate relevant COPs for the drug traders concerned. Such COPs would cover various requirements that would help prevent drug incidents, such as relevant drug traders were required to keep or accept drug orders in written form, and ASPs and LSPs were required to keep relevant supporting documents, such as sales invoices related to every purchase of all pharmaceutical products. This would enable the Administration to trace the source of the problem from the written records to safeguard public health in the event of drug incidents.</p>	

Time marker	Speaker	Subject(s)/Discussion	Action Required
014646 - 014656	Chairman	The Chairman's decision to extend the meeting for 15 minutes beyond its appointed time to allow more time for discussion.	
014657 - 015055	Chairman Dr LEUNG Ka-lau Admin The Practising Pharmacists Association of Hong Kong	<p>Dr LEUNG Ka-lau's enquiry on how the requirement of placing orders of drugs in written form could enhance patient safety and combat illegal sale of drugs; and his view that the signing and keeping of the drug suppliers' delivery notes by the medical clinics could better serve the purpose.</p> <p>The Administration's response that misunderstanding might easily arise when the orders for the drugs were placed verbally as the pronunciation of the names of many drugs was similar. The requirement for placing drug orders in written form would help enhance the monitoring of the drug supply system and minimize the potential risk in every step of the drug supply chain, and hence, enhance patient safety.</p> <p>The advice of the Practising Pharmacists Association of Hong Kong that requiring the registered pharmacists of retailers of drugs or medical practitioners of private clinics to acknowledge the receipt of the drugs ordered, regardless whether or not the verbal orders were placed by them, could serve the same purpose.</p>	
015056 - 020223	Chairman Mr LEUNG Yiu-chung Hong Kong General Chamber of Pharmacy Limited Asia Regulatory Professional Association The Society of Hospital Pharmacists of Hong Kong Hong Kong Doctors Union Department of Pharmacology and Pharmacy, The University of Hong Kong The Hong Kong Association of the Pharmaceutical Industry College of Primary Healthcare Pharmacists	<p>Mr LEUNG Yiu-chung's concern about the effectiveness of the consultation carried out by the Administration in drafting the Bill given the conflicting stances of the Administration and the deputations. The Administration advised that the trade and stakeholders were supportive of the legislative amendments, whereas the deputations advised that their views on the legislative amendments, such as those relating to the proposed amendment to the definition of ASP and the empowerment of PPB to promulgate relevant COC and COPs, had not been taken heed of by the Administration.</p> <p>The Hong Kong General Chamber of Pharmacy Limited's response that the Administration had failed to take on board most of the views expressed by the Chamber on the draft COP for ASPs.</p> <p>The Asia Regulatory Professional Association's advice that the trade and relevant stakeholders were involved in the Working Group on Codes of Practice for Holders of Wholesale Poisons Licence and Holders of Certificate of Registration as an Importer and Exporter of Pharmaceutical Products set up by PPB, and consensus was reached on each provision of the COP concerned in the course of discussion.</p> <p>The Society of Hospital Pharmacists of Hong Kong's advice that members of PPB and its Working Group on Codes of Practice for Pharmacists had not been advised</p>	

Time marker	Speaker	Subject(s)/Discussion	Action Required
		<p>of the legislative proposal to empower PPB to promulgate a COC for registered pharmacists; and its view that a separate regulatory body should be set up for governing the professional practice and conduct of registered pharmacists.</p> <p>The Hong Kong Doctors Union's advice that the Administration had all along failed to take heed of the Union's opposing views on the requirement of placing orders of drugs in written form.</p> <p>The Department of Pharmacology and Pharmacy of The University of Hong Kong's views that while it was necessary to develop a COC for registered pharmacists, the Administration should formulate a roadmap for the establishment of a separate regulatory body for governing, among others, the conduct of registered pharmacists; and the requirement for the relevant licensed traders of pharmaceutical products to place orders of drugs in written form could facilitate the tracing of the sources of the products and provide better protection for the public and patients.</p> <p>The Hong Kong Association of the Pharmaceutical Industry's expression of agreement with the view given by the Asia Regulatory Professional Association that consensus was reached on each provision of the COP concerned in the course of discussion of the Working Group on Codes of Practice for Holders of Wholesale Poisons Licence and Holders of Certificate of Registration. The Administration had also gathered views from the trade on the revision or formulation of relevant COPs through a number of briefing sessions.</p> <p>The College of Primary Healthcare Pharmacists' concern that PPB would be empowered under the Bill to promulgate relevant COPs and COC, and revise the whole or any part of these Codes from time to time.</p>	
020224 - 020539	Chairman Ms Emily LAU Admin	<p>Ms Emily LAU's concern about how the Administration would address the various grave concerns expressed by the deputations on the Bill.</p> <p>The Administration's response that the legislative amendments were proposed to implement most of the recommendations put forth by the Review Committee. Given that issues pertaining to the present regulatory framework for registered pharmacists and in that connection the role and composition of PPB involved wide policy implications, the Administration would study the issues separately where necessary. It should also be noted that trade representatives and relevant stakeholders could provide their comments on the drafting and revision of relevant COPs and COC at the meetings of the working groups set up by PPB for the purpose.</p>	

Time marker	Speaker	Subject(s)/Discussion	Action Required
020540 - 020957	Chairman Mr Paul TSE Admin	<p>On the suggestion of setting up a separate regulatory body for registered pharmacists, Mr Paul TSE's view that it was important to take into account the international trend of moving from the premise of self-regulation of the profession to one of co-regulation in partnership with lay persons.</p> <p>Mr Paul TSE's enquiry as to whether the Administration could rely on the existing practice to govern the conduct of activities of licensed drug traders, such as placing orders of drugs in written form; and the Administration's advice that while a COP for ASPs was available, compliance with which was merely a licensing condition but not a legal requirement. There were currently no COPs for other licensed drug traders (including LSPs, wholesalers, importers, exporters and manufacturers). Hence, there was a need to empower PPB to promulgate corresponding COPs for various drug traders.</p>	
020958 - 021419	Chairman Dr KWOK Ka-ki Admin	<p>The Chairman's decision to extend the meeting to 5:00 pm to allow more time for discussion.</p> <p>Dr KWOK Ka-ki's views that -</p> <ul style="list-style-type: none"> (a) the Administration should not withdraw the Bill for the sake of enhancing the regulation of pharmaceutical products in Hong Kong for better protection to the public; (b) the Administration should step up its enforcement actions against ASPs on non-compliance with the relevant legislation; and (c) there was a need for the Administration to review the composition of PPB to enhance its representation, say, inviting representatives from registered pharmacists working in community pharmacies to sit in PPB. <p>The Administration's reiteration that issues pertaining to whether a separate regulatory body should be established for registered pharmacists and in that connection the role of PPB would be studied by the Steering Committee.</p>	
021420 - 021649	Chairman Miss Alice MAK Admin	<p>Miss Alice MAK's view that there was a need to pursue the legislative proposals which aimed to implement the recommendations put forth by the Review Committee in 2009 for enhancing the regulation of pharmaceutical products in Hong Kong; and her concern about the effectiveness of the consultation efforts made by the Administration in drafting the Bill and the relevant COPs and COC.</p> <p>The Administration's advice that while it had not taken on board all the views expressed by the representatives</p>	

Time marker	Speaker	Subject(s)/Discussion	Action Required
		of the trade and relevant stakeholders gathered during the various consultation exercises for various reasons, it had extensively consulted the trade members and relevant stakeholders when drafting the legislative proposals, details of its consultation work were set out in LC Paper No. CB(2)1543/13-14(01).	
021650 - 022050	Chairman Dr LEUNG Ka-lau Admin	<p>Dr LEUNG Ka-lau's view that the requirement of placing orders of drugs in written form could not prevent drug suppliers from taking the orders erroneously. A better way to facilitate tracing of the source of drugs and protect patient safety was to require the parties receiving the drugs to keep the duly signed copies of the drug suppliers' delivery notes and doctors to counter check the accuracy of the prescriptions given to patients.</p> <p>The Administration's advice that while it was mindful of the inconvenience caused to drug traders and private doctors in some cases due to the requirement of placing orders of drugs in written form, it should be noted that the benefit to patients would far out-weight the inconvenience caused.</p>	
<i>Agenda item II: Any other business</i>			
022051 - 022314	Chairman	Closing remarks	