立法會
Legislative Council

LC Paper No. CB(2)1366/13-14
(These minutes have been seen by the Administration)

Ref : CB2/PL/HS

Panel on Health Services

Minutes of special meeting
held on Tuesday, 10 December 2013, at 10:45 am
in Conference Room 1 of the Legislative Council Complex

Members present	:	Dr Hon LEUNG Ka-lau (Chairman) Prof Hon Joseph LEE Kok-long, SBS, JP, PhD, RN (Deputy Chairman) Hon Vincent FANG Kang, SBS, JP Hon WONG Ting-kwong, SBS, JP Hon CHAN Kin-por, BBS, JP Dr Hon Priscilla LEUNG Mei-fun, SBS, JP Hon Charles Peter MOK Hon CHAN Han-pan Dr Hon KWOK Ka-ki Dr Hon Fernando CHEUNG Chiu-hung Dr Hon Elizabeth QUAT, JP Hon POON Siu-ping, BBS, MH
Member attending	:	Hon CHAN Chi-chuen
Members absent	:	Hon Albert HO Chun-yan Hon CHEUNG Kwok-che Hon Mrs Regina IP LAU Suk-yee, GBS, JP Hon Albert CHAN Wai-yip Hon Alice MAK Mei-kuen, JP Dr Hon Helena WONG Pik-wan Dr Hon CHIANG Lai-wan, JP

Public Officers attending : Item I

Professor Sophia CHAN Siu-chee, JP
Under Secretary for Food and Health

Ms Fiona CHAU
Principal Assistant Secretary for Food and Health (Health) 1

Ms Linda WOO
Assistant Director of Health (Drug)
Department of Health

Attendance by invitation : Hong Kong Doctors Union

Dr YEUNG Chiu-fat
President

Hong Kong Alliance of Patients' Organizations

Mr LAM Chi-yau
Vice Chairman (External Affairs)

School of Pharmacy, The Chinese University of Hong Kong

Professor Vincent H L LEE
Professor and Director

Hong Kong Private Hospitals Association

Dr Peter PANG Chi-wang
Representative

Hong Kong Dental Association

Dr WONG Chi-wai
Vice-President

College of Pharmacy Practice

Dr LEE Shing-cheung
Chairman

The Hong Kong Medical Association

Dr TSE Hung-hing
President

Hong Kong General Chamber of Pharmacy Limited

Mr CHEUNG Tak-wing
Director of General Affairs

Department of Pharmacology and Pharmacy,
The University of Hong Kong

Dr Jenny LAM
Assistant Professor

The Hong Kong Association of the Pharmaceutical Industry

Ms Sabrina CHAN
Executive Director

The Practising Pharmacists Association of Hong Kong

Ms Iris CHANG
President

The Society of Hospital Pharmacists of Hong Kong

Mr William CHUI Chun-ming
President

The Pharmaceutical Society of Hong Kong

Mrs Mary Catherine CHENG
President

Hong Kong Pharmaceutical Manufacturers Association

Mr CHEUNG Yiu-kwong
Vice President

The Pharmaceutical Distributors Association of Hong Kong Limited

Mr William TSUI
Chairman

Individual

Professor Vivian LEE Wing-yan
School of Pharmacy, The Chinese University of Hong Kong

Association of Doctors in Aesthetic Medicine (Hong Kong)

Dr HO Ming-tai
Founding President

Hong Kong Suppliers Association Limited

Mr Albert TANG
Chairman

Association of Medical Practitioners of Societies' Clinics

Dr WONG To-chuen
Vice President

Direct Selling Association of Hong Kong

Mr Paul LEUNG
Advisor - Regulatory Affairs

Pharmaceutical Trade Alliance

Mr LAW Chun-cheong
Chairman

Hong Kong Academy of Pharmacy

Mr CHEUNG Kin-man
Vice President

College of Primary Healthcare Pharmacy

Mr Philip CHAN
Chairman

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

Staff in attendance	**:**	Ms Mina CHAN Senior Council Secretary (2) 5 Ms Michelle LEE Legislative Assistant (2) 5

Action

I. Legislative proposals to enhance the regulation of pharmaceutical products

[LC Paper Nos. CB(2)254/13-14(03), CB(2)414/13-14(01) and (02)]

Members noted the following papers on the subject under discussion -

(a) the Administration's paper entitled "Legislative proposals to enhance the regulation of pharmaceutical products in Hong Kong" (LC Paper No. CB(2)254/13-14(03));

(b) the Administration's paper entitled "The regulation of pharmaceutical products in Hong Kong - supplementary information on written orders of drugs" (LC Paper No. CB(2)414/13-14(01)); and

(c) the background brief entitled "Legislative proposals to enhance the regulation of pharmaceutical products" prepared by the Legislative Council ("LegCo") Secretariat (LC Paper No. CB(2)414/13-14(02)).

Views of deputations

2. At the invitation of the Chairman, the following 21 deputations presented their views on the Administration's legislative proposals to enhance the regulation of pharmaceutical products -

(a) Hong Kong Doctors Union;

(b) Hong Kong Alliance of Patients' Organizations;

(c) School of Pharmacy, The Chinese University of Hong Kong;

(d) Hong Kong Dental Association;

(e) College of Pharmacy Practice;

(f) The Hong Kong Medical Association;

Action

(g) Hong Kong General Chamber of Pharmacy Limited;

(h) Department of Pharmacology and Pharmacy, The University of Hong Kong;

(i) The Hong Kong Association of the Pharmaceutical Industry;

(j) The Practising Pharmacists Association of Hong Kong;

(k) The Society of Hospital Pharmacists of Hong Kong;

(l) The Pharmaceutical Society of Hong Kong;

(m) Hong Kong Pharmaceutical Manufacturers Association;

(n) The Pharmaceutical Distributors Association of Hong Kong Limited;

(o) Professor Vivian LEE Wing-yan;

(p) Association of Doctors in Aesthetic Medicine (Hong Kong);

(q) Hong Kong Suppliers Association Limited;

(r) Direct Selling Association of Hong Kong;

(s) Pharmaceutical Trade Alliance;

(t) Hong Kong Academy of Pharmacy; and

(u) College of Primary Healthcare Pharmacy.

3. Members also noted the written submissions from the following organizations -

(a) Consumer Council; and

(b) Hong Kong Retail Management Association.

4. A summary of the views of deputations is in the **Appendix**.

Action

The Administration's responses to the views expressed by deputations

5. Responding to the views expressed by the deputations, Under Secretary for Food and Health ("USFH") and Assistant Director of Health (Drug), Department of Health ("ADH(D), DH") made the following points -

(a) the main objective of the Administration's legislative proposals was to implement most of the recommendations on legislative amendments put forward by the Review Committee on the Regulation of Pharmaceutical Products in Hong Kong ("the Review Committee") in December 2009. Subject to members' views, the plan of the Administration was to introduce the legislative proposals into LegCo in February 2014;

(b) the proposal that all orders for pharmaceutical products should have written records was aimed at building up a complete set of movement records of pharmaceutical products, thus facilitating the tracing of source of pharmaceutical products, minimizing errors in the delivery and receipt of pharmaceutical products and combating illegal sale of pharmaceutical products. The Administration emphasized that the proposal would be implemented through administrative measures rather than legislation, i.e. the Pharmacy and Poisons Board ("PPB") would incorporate the requirement into the relevant Codes of Practice for which the relevant licenced traders would be required to comply with. The proposed modus operandi of the requirement was set out in paragraph 8 of LC Paper No. CB(2)414/13-14(01). On the impact of the requirement on practising doctors, it should be noted that in 2007, the Hong Kong Medical Association ("HKMA") had already recommended in its Good Dispensing Practice Manual that practising doctors should order pharmaceutical products in writing;

(c) it was proposed that the legislative proposal of requiring the presence of a registered pharmacist in the registered premises of an Authorized Seller of Poisons ("ASP") whenever that ASP was open for business, which would be longer than the current statutory requirement of two-thirds of the business hours of an ASP, would be implemented at a later stage having taken into account the current manpower supply of registered pharmacists. At present, there were 592 ASPs and more than 2 000 registered pharmacists in the territory. These registered pharmacists were employed not only by ASPs, but also manufacturers of pharmaceutical products and the private and public healthcare

Action

sectors, etc. It was expected that it would take a few years for the manpower supply of registered pharmacists to become sufficient to meet the manpower demand arising from the above proposal. Meanwhile, the Steering Committee on Strategic Review on Healthcare Manpower Planning and Professional Development would study and formulate recommendations on how to cope with the anticipated manpower demand for the 13 healthcare professions under statutory regulation, including pharmacists;

(d) at present, poisons listed in the First Schedule to the Pharmacy and Poisons Regulations (Cap. 138A) ("PPR") were already required to be stored in locked receptacles, the key for which being retained by the registered pharmacist, at the registered premises of the ASP concerned. The legislative proposal to require all poisons listed in Part I of the Poisons List Regulations (Cap. 138B) ("PLR") (which was proposed to be merged into PPR) also be stored in locked receptacles at the registered premises of the ASP concerned was to ensure that the sale of all poisons listed in Part I of PLR in the registered premises of an ASP would be under the personal control of a registered pharmacist;

(e) the Administration attached great importance to the compliance of pharmaceutical traders with the licensing and statutory requirements. Inspectors of the Department of Health ("DH") would conduct regular and surprise inspections to the licensed premises of the traders. Prosecution would be initiated if there was sufficient evidence indicating a breach of the law; and

(f) as regards the labelling requirement on pharmaceutical products supplied to outpatients by certain institutions such as hospitals and clinics, it was proposed that the instructions for use could be in either English or Chinese, instead of both languages as currently required. The label had to include information on the name of the pharmaceutical product, dosage per unit, and the method and dosage of administration.

Discussion

6. Mr Vincent FANG expressed regret that while the Secretary for Food and Health advised at the meeting of the Panel on 18 November 2013 that the Administration had already gauged the views of relevant stakeholders on the legislative proposals and the proposals had the majority support of the

Action

trade, the deputations had raised a number of concerns about the proposals. He remarked that the Administration should thoroughly consult all trade parties and relevant stakeholders before proceeding with the legislative amendments. USFH assured members that the Administration had conducted extensive consultation with the trade representatives and stakeholders in the process of formulating the legislative proposals.

Control of pharmaceutical products

7. Noting the proposal to extend the validity of clinical trial certificate for new pharmaceutical products from two years to not more than five years, Dr KWOK Ka-ki expressed concern that those pharmaceutical products which failed to demonstrate safety and efficacy during the relatively shorter clinical trial period of other jurisdictions could continue to be administered or dispensed in Hong Kong for a prolonged period of time.

8. USFH responded that the proposal was put forward in response to the concern of the trade that the two-year validity period was often too short for the completion of a clinical trial. With the proposed extension, the sponsor of a new pharmaceutical product would not need to apply for a certificate again if a clinical trial lasted more than two years.

Written orders of pharmaceutical products

9. Mr Vincent FANG was of the view that the Administration was trying to circumvent the scrutiny of LegCo on the proposed requirement of placing orders of pharmaceutical products in written form by implementing the requirement through administrative means. Mr CHAN Han-pan expressed concern that not implementing the proposed requirement through statutory means might create loopholes. USFH responded that having considered the regulation of the supply system of pharmaceutical products and the concerns of the industry, the Administration proposed to implement the requirement by administrative means.

10. Mr Charles MOK did not subscribe to the views given by some deputations that the Administration should continue to allow pharmaceutical traders and practising doctors to place orders of pharmaceutical products verbally to facilitate exchange of views between the parties. He saw no reason for not supporting the proposed requirement. Referring to the fatal cases in 2005 which involved a private doctor prescribing inappropriate medications to patients due to the delivery of incorrect pharmaceutical products by the supplier who had erroneously taken the order placed verbally and the doctor's failure to take adequate steps to verify that the products received corresponded to the order, Dr Fernando CHEUNG

Action

considered that the requirement was a positive step forward. He was concerned that there was already a time lag of several years since the putting forth of the recommendations by the Coroner's Court in respect of the death inquest into the above cases in 2007 and the Review Committee in 2009 that orders of pharmaceutical products should be placed in writing.

11. USFH responded that the Administration would recommend the manufacturers and wholesalers of pharmaceutical products to design a standard procurement form for use of their clients so as to facilitate their ordering of pharmaceutical products in writing. To help the industry adapt to the requirement, PPB preliminarily considered that placing orders of pharmaceutical products by electronic means, such as e-mails, could be accepted as written orders. The Chairman asked whether it would be sufficient to have the written order be impressed with the seal or chop of the clinic or company concerned, or it had to be signed by a person authorized for the purpose. ADH(D), DH advised that the former would suffice. Dr Elizabeth QUAT sought clarification as to whether relevant data recorded or preserved on any medium in or by a computer system would be accepted as written orders. USFH replied in the positive.

12. Mr Charles MOK urged the Administration to provide technical or financial support to the trade, in particular those small and medium enterprises, on the use of electronic system to order and manage inventory of pharmaceutical products. He sought views from deputations on their readiness to use such system. Mr William CHUI of the Society of Hospital Pharmacists of Hong Kong advised that the Hospital Authority already had an electronic ordering system for pharmaceutical products put in place. Ms Sabrina CHAN of The Hong Kong Association of the Pharmaceutical Industry advised that members of the Association had been using an electronic data interchange system. The Association was happy to discuss with other traders of pharmaceutical products and practising doctors how to pilot this system for placing orders of pharmaceutical products. Dr Elizabeth QUAT opined that consideration could be given to making available some of the components of the electronic ordering system of the Hospital Authority for use of the trade.

Duration of presence of registered pharmacists in ASPs

13. Having regard to the current manpower supply of registered pharmacists, Mr Vincent FANG did not agree to the Administration's proposal of including the requirement that the registered premises of an ASP had to be under the personal control of a registered pharmacist whenever the registered premises were open for business in this legislative exercise, whereas the implementation of the requirement would take effect at a later

Action

date to be announced in the Gazette. Dr Elizabeth QUAT expressed a similar view, adding that the Administration should carefully consider the impact of the proposed requirement on the small and medium ASPs which had to compete with large enterprises for a limited pool of registered pharmacists. Dr Fernando CHEUNG considered the proposal a step forward in enhancing regulation of pharmaceutical products. This notwithstanding, its effective implementation hinged on an adequate supply of registered pharmacists. USFH stressed that the Administration would give due regard to the manpower supply of registered pharmacists and engage the trade in considering the appropriate timing for the provision, if enacted, to come into operation.

14. Mr Vincent FANG pointed out that many ASPs engaged in the retail sale of a range of other daily goods, such as bottled water and infant milk formula, besides pharmaceutical products. He held a strong view that at times when a registered pharmacist was not present at the part of the premises where poisons were kept for the purpose of retail sale, the rest of the premises should be allowed to remain open for sale of goods not classified as poisons. Mr CHAN Han-pan considered it unreasonable to require the presence of a registered pharmacist in the registered premises of an ASP even at times when that ASP did not intend to sell or dispense any medicines. He called on the Administration to further discuss with the trade in this regard. Dr Elizabeth QUAT expressed a similar view. Mr WONG Ting-kwong pointed out that that the intention of both the present and the proposed requirements was to ensure that the retail sale of poisons would be conducted by a registered pharmacist or in his presence and under his supervision for the sake of public safety. Viewed in this light, there was no reason why the Administration could not refine the arrangement to the effect that only the part of the registered premises of an ASP where poisons were kept for the purpose of retail sale had to be under the personal control of a registered pharmacist whenever that part of the premises was open for business. The Chairman sought clarification as to whether PPB would register an area located within a retail outlet as the registered premises of an ASP for carrying out the retail sale of poisons.

[At this juncture, the Chairman informed members of his decision to extend the meeting for 15 minutes beyond its appointed time to allow more time for discussion.]

15. ADH(D), DH explained that under the Pharmacy and Poisons Ordinance (Cap. 138) ("the Ordinance"), ASP was a business authorized to sell pharmaceutical products including those classified as poisons listed either in Part I or Part II of PLR at premises duly registered with PPB for such purpose. When applying for PPB's approval to conduct the retail sale

Action

of these products, applicants had to specify the address of such premises. PPB would consider, among others, whether the premises were suitable to conduct the retail sale of poisons thereon in assessing the applications. It was a statutory requirement that the registered premises of an ASP had to be under the personal control of a registered pharmacist. At present, it would be sufficient compliance with this requirement if a registered pharmacist was present at the registered premises for not less than two-thirds of the daily business hours of an ASP and exercised control and supervision over the persons employed therein.

16. Expressing strong reservation on the proposed requirement on the presence of registered pharmacists in ASPs, Dr Elizabeth QUAT said that while the remaining legislative proposals were conducive to enhancing the regulatory regime for the regulation of pharmaceutical products, she might oppose the whole set of legislative proposals.

Regulation of wholesalers of non-poisons

17. Mr Vincent FANG considered that vitamin preparations should be regarded as food rather than pharmaceutical products such that wholesalers of vitamin preparations would not become subject to the proposed licensing and transaction record keeping requirements.

18. ADH(D), DH explained that the Ordinance provided for a Poison List. Pharmaceutical products containing substances which were not included in the Poison List were commonly referred to as "non-poison pharmaceutical products". Vitamin preparations had all along been regarded as non-poison pharmaceutical products under the Ordinance and had been subject to, among others, registration requirements before they could be sold in Hong Kong. As such, under the current legislative proposals, wholesalers of vitamin preparations would be subject to licensing and inspection controls, and the requirement of transaction record keeping. ADH(D), DH added that due to the significant impact to the large number of direct sellers of non-poison pharmaceutical products, and the significant cost to retailers arising from the wide range and huge volume of products involved, the Administration would not pursue the Review Committee's recommendation that retailers of these products had to subject to licensing control as well.

Monitoring of ASPs

19. Dr KWOK Ka-ki urged DH to step up its efforts in monitoring the sale of prescription medicines without prescription and non-compliance with other licensing and legislative requirements by ASPs. Pointing out that there were cases that ASPs with drug-related offences could successfully restart and operate new ASPs because the owners were not personally convicted of

Action

the offences, he asked whether consideration could be given to making it mandatory that owner or one of the owners of an ASP had to be a registered pharmacist.

20. USFH took note of Dr KWOK's suggestion. ADH(D), DH assured members that if there was evidence proving that the owner of an ASP had committed a drug-related offence, the owner, rather than the registered pharmacist of the ASP concerned, would be held liable for the offence.

Separation of prescribing from dispensing of drugs

21. Holding the view that separation of prescribing from dispensing of medicines could help enhance safety of medication, Dr Fernando CHEUNG sought the Administration's position on the matter. Agreeing that there was a need to separate prescribing from dispensing of medicines in the longer term, Dr Elizabeth QUAT urged the Administration to conduct studies in this regard.

22. USFH advised that the Strategic Review on Healthcare Manpower Planning and Professional Development might look into the matter. At present, patients could ask doctors at private clinics for a prescription to be filled by a registered pharmacist. The matter would require a thorough discussion by the stakeholders concerned and the community as a whole. A consensus should be reached by members of the community before any major change should be made. In response to Dr Fernando CHEUNG's enquiry on the timetable for the completion of the strategic review, USFH advised that the Steering Committee might conclude the strategic review in 2014.

Conclusion

23. In closing, the Chairman requested the Administration to consider refining its legislative proposals in the light of the views and concerns expressed by members and deputations, and revert to the Panel accordingly.

24. There being no other business, the meeting ended at 12:50 pm.

Council Business Division 2
Legislative Council Secretariat
24 April 2014

Panel on Health Services

Summary of views and concerns expressed by deputations for the special meeting on Tuesday, 10 December 2013

A. Legislative proposals to enhance the regulation of pharmaceutical products in Hong Kong

Organization/individual	Major views and concerns
(a) General provisions	
(i) To empower the Pharmacy and Poisons Board ("PPB") to promulgate corresponding codes of practice for licensed traders and registered pharmacists; and to impose licensing conditions, revoke or suspend licence, suspend such directions, or issue warning letter to the relevant licence or registration holders upon non-compliance with the codes or licensing conditions or on conviction of the relevant offences *[Recommendations 11, 21 and 32 of the Review Committee on the Regulation of Pharmaceutical Products in Hong Kong ("the Review Committee") refer*]*	
● Consumer Council	● The deputation supported the proposal, and considered that the PPB should assess if the applicant and/or the directors of the company had been convicted of any drug offence in considering a licence application.
● Hong Kong Academy of Pharmacy ● Hong Kong General Chamber of Pharmacy Limited ● Pharmaceutical Trade Alliance ● The Practising Pharmacists Association of Hong Kong	● The deputations were opposed to the proposal of monitoring the authorized sellers of poisons ("ASP") and listed sellers of poisons ("LSPs") through the codes of practice promulgated by PPB. The reason put forward by the Hong Kong Academy of Pharmacy and Pharmaceutical Trade Alliance was that PPB could at any time make amendments to the codes of practice without going through a legislative process with the Legislative Council.
● The Society of Hospital Pharmacists of Hong Kong	● The deputation considered it inappropriate for PPB to introduce a code of practice for registered pharmacists. The Administration should instead facilitate the setting up of a pharmacy council to oversee the registration, conduct and discipline of registered pharmacists, including the promulgation of a code of ethics or conduct.

Organization/individual	Major views and concerns
(b) Regulation of manufacturers	
(i) To empower the PPB to maintain an authorized person ("AP") register and remove any AP from the register should the AP be found incompetent to perform the AP role *[Recommendation 6 of the Review Committee refers*]*	
● College of Pharmacy Practice ● The Society of Hospital Pharmacists of Hong Kong	● The deputations supported the maintaining of an AP register for all drug manufacturers, and considered that the qualification requirements for AP should include being a registered pharmacist specialized in areas such as pharmaceutics, quality assurance and medication safety.
● Consumer Council	● The deputation was of the view that in case the AP of a licensed manufacturer was found incompetent to perform the AP role and was removed from the AP register, the manufacturer concerned could only be allowed to perform the manufacturing of pharmaceutical products when a new AP was appointed.
● School of Pharmacy, The Chinese University of Hong Kong	● The deputation suggested the Administration to formulate different levels of qualifications for AP based on factors such as product complexity and risk.
(ii) To require both primary and secondary packaging be carried out by a licensed manufacturer which complies with the Good Manufacturing Practice ("GMP") requirements *[Recommendation 20 of the Review Committee refers*]*	
● Consumer Council	● The deputation supported the revision to the definition of "manufacture" to explicitly include both primary and secondary packaging, such that these activities should only be carried out by a licensed manufacture who complied with the GMP requirements. It also supported the proposed exemption of certain secondary packaging activities which did not affect the safety, efficacy and quality of the products from licensing control.

Organization/individual	Major views and concerns
(iii) To require manufacturers to label the container of each pharmaceutical product with batch number and expiry dates, to ensure the finished products would conform to the registered particulars of the registered pharmaceutical products and to complete the relevant manufacturing records at the time when the manufacturing process was being carried out [Recommendations 53 and 57 of the Review Committee refer]*	
● Consumer Council	● The deputation supported the proposal, and considered that the Administration should specify the required duration of keeping records relating to the manufacture, testing and sale or supply of pharmaceutical products by the manufacturers. This duration should correspond to the expiry dates of these products.
(c) Regulation of importers, exporters and wholesalers	
(i) To require all wholesalers of non-poisons to be subject to inspection and licensing control [Recommendation 18 of the Review Committee refers]* *(ii) To require all wholesalers to keep transactions records of all pharmaceutical products, including Part II poisons and non-poisons in the same manner as for Part I poisons [Recommendation 19 of the Review Committee refers*]*	
● Consumer Council ● Department of Pharmacology and Pharmacy, The University of Hong Kong	● The deputations supported the proposals to tighten up the regulatory control over wholesalers of non-poison pharmaceutical products.
● Direct Selling Association of Hong Kong ● Hong Kong Suppliers Association Limited	● The deputations were opposed to the imposition of the proposed inspection and licensing control over the wholesalers of non-poison pharmaceutical products. The Direct Selling Association of Hong Kong considered that vitamin preparations and minerals dietary supplements without any disease treatment indications should be regarded as food. The Hong Kong Suppliers Association Limited was of the view that hair dye products should be regarded as cosmetic products. In their views, wholesalers of these products should not be subject to the proposed regulatory control.

Organization/individual	Major views and concerns
(d) Regulation of retailers	
(i) To require the presence of a registered pharmacist whenever an ASP is open for business [Recommendation 30 of the Review Committee refers]*	
● College of Pharmacy Practice ● Consumer Council ● Department of Pharmacology and Pharmacy, The University of Hong Kong ● The Hong Kong Association of the Pharmaceutical Industry ● The Hong Kong Medical Association ● School of Pharmacy, The Chinese University of Hong Kong ● The Society of Hospital Pharmacists of Hong Kong ● Professor Vivian LEE Wing-yan	● The deputations supported the proposed requirement, so as to ensure that ASPs would be under the personal control of registered pharmacists for the provision of safe and professional pharmaceutical service to the general public. ● Some of these deputations, including the College of Pharmacy Practice, the Department of Pharmacology and Pharmacy of The University of Hong Kong and The Society of Hospital Pharmacists of Hong Kong, urged the Administration to map out a concrete implementation timetable having taken into account the fact that there should be enough registered pharmacists (i.e. including both local pharmacy graduates and pharmacists who were trained abroad and returned to practise in Hong Kong) to cope with the manpower demand arising from the proposal in three to five years' time. According to some deputations, the implementation of the proposal would require around 200 to 300 extra registered pharmacists. ● There was a view from The Hong Kong Medical Association that registered pharmacists of ASPs should be required to identify themselves to consumers. There was also a view from the Consumer Council that it was necessary to require that the premises of ASPs could ensure the privacy of consumers in seeking advice from registered pharmacists. The Administration should also advise consumers on how to verify the identities of the registered pharmacists. ● Some deputations, including the College of Pharmacy Practice and The Society of Hospital Pharmacists of Hong Kong, urged the Administration to enhance the role and responsibilities of community pharmacists. There was a further view from The Hong Kong Medical Association that the Administration should

Organization/individual	Major views and concerns
	mandatorily require partial ownership of ASPs by registered pharmacists to enhance the professional accountability of registered pharmacists over the sale of prescription drugs in the premises of ASPs.
● Hong Kong Academy of Pharmacy ● Hong Kong Alliance for Patients' Organizations ● Hong Kong General Chamber of Pharmacy Limited ● Hong Kong Retail Management Association ● The Pharmaceutical Society of Hong Kong ● Pharmaceutical Trade Alliance ● The Practising Pharmacists Association of Hong Kong	● The deputations were opposed to the proposed requirement. Some of these deputations, including Hong Kong Alliance for Patients' Organizations, Hong Kong General Chamber of Pharmacy Limited and Hong Kong Retail Management Association, were of the view that this proposal should only be considered when there was adequate manpower supply of registered pharmacists. Some other deputations, including The Pharmaceutical Society of Hong Kong, the Pharmaceutical Trade Alliance and The Practising Pharmacists Association of Hong Kong, considered that the Administration should not take forward the requirement unless it introduced the separation of prescribing from dispensing of drugs to generate higher volume of dispensary business for ASPs. ● Some deputations, including the Hong Kong Academy of Pharmacy and The Practising Pharmacists Association of Hong Kong, were of the view that at times when a registered pharmacist was not present at the part of the premises of an ASP where poisons were kept for the purpose of retail sale, the rest of the premises should be allowed to remain open for the retail sale of other daily goods and the provision of other paramedical services such as that of dietitian. ● There was a view from the Pharmaceutical Society of Hong Kong that ASP should only be required to notify consumers that dispensing of prescription medicines would not take place when no registered pharmacist was on duty in its premises.

Organization/individual	Major views and concerns
(ii) To require all Part I Poisons be stored in locked receptacle in the premises of an ASP and that only the pharmacist should hold the key to the locked receptacle *[Recommendation 31 of the Review Committee refers*]*	
● Hong Kong Retail Management Association	● The deputation supported the proposed requirement so as to enhance protection to consumers.
● College of Primary Healthcare Pharmacy ● Hong Kong Academy of Pharmacy ● Hong Kong General Chamber of Pharmacy Limited ● The Pharmaceutical Society of Hong Kong ● The Practising Pharmacists Association of Hong Kong	● The deputations were opposed to the proposed requirement. The reason put forward by the College of Primary Healthcare Pharmacy, the Hong Kong Academy of Pharmacy and The Pharmaceutical Society of Hong Kong was that that it was impractical for most registered pharmacists, who were employees of ASPs, to ensure that the key they held was the only key to the locked receptacle in the premises of the ASPs concerned. ● There was a view from The Practising Pharmacists Association of Hong Kong that registered pharmacists employed by ASPs did not have the legal rights over the tenancy of the ASP premises and the ownership of the locked receptacles and of the property locked inside the receptacles. Hence, these registered pharmacists should not be required to perform due diligence to ensure that they held the only key to the receptacles concerned.
(iii) To give PPB the authority to revoke the licence of an ASP at any time after that ASP has been convicted of serious drug offence *[Recommendation 33 of the Review Committee refers*]*	
● Consumer Council ● Department of Pharmacology and Pharmacy, The University of Hong Kong ● The Pharmaceutical Society of Hong Kong	● The deputations supported this legislative proposal, so as to protect the safety of consumers. ● There was a view from the Department of Pharmacology and Pharmacy of The University of Hong Kong and The Pharmaceutical Society of Hong Kong that any cases of conviction should go through a Disciplinary Committee of PPB.

Organization/individual	Major views and concerns
● Hong Kong General Chamber of Pharmacy Limited	● The deputation opposed to this legislative proposal.
(e) Pre-market control of drugs	
(i) To allow licensed wholesalers who had contracted out the manufacturing to other licensed GMP manufacturers to apply for registration of pharmaceutical products	
● The Hong Kong Pharmaceutical Manufacturers Association	● The deputation considered that only those licensed wholesalers who had contracted out the manufacturing activities to local, rather than overseas, GMP manufacturers could be allowed to register the pharmaceutical products so produced with PPB.
(ii) To replace the term "Poison 毒藥", as required to be labelled on pharmaceutical products classified as poisons, with other terms *[Recommendation 14 of the Review Committee refers*]*	
● Consumer Council	● The deputation considered that the Administration should step up publicity and public education to enhance public awareness on the proposed replacement of the word "Poison 毒藥" by "Prescription drug 處方藥物" or "Drug under supervised sale 監督售賣藥物", and the respective restrictions on their sale.
● The Hong Kong Pharmaceutical Manufacturers Association	● The deputation agreed to the need to replace the term "Poison". However, it would be more appropriate to introduce a provision to empower PPB to specify the term to be labeled on pharmaceutical products classified as poisons, rather than stipulating the term in the legislation, in order to obviate the need to amend the Ordinance from time to time to reflect the latest development in this regard.

Organization/individual	Major views and concerns
(f) Recovery of convicted-related expenses	
(i) To amend the Pharmacy and Poisons Ordinance to include provision for the Court to order the convicted person to pay the analytical costs incurred by the Government to increase the deterrent effect *[Recommendation 74 of the Review Committee refers*]*	
● Hong Kong General Chamber of Pharmacy Limited	● The deputation was opposed to this legislative proposal.

B. Recommendations of the Review Committee that the Administration not intended to take forward

Organization/individual	Major views and concerns
(a) Regulation of wholesalers	
(i) The Administration proposed not to take forward the Review Committee's recommendation that wholesalers should keep samples of each batch of drugs handled to facilitate investigation when needed [Recommendation 19 of the Review Committee refers]*	
● Department of Pharmacology and Pharmacy, The University of Hong Kong	● The deputation shared the Administration's view that as long as the traders could provide samples within a specified period upon request, it was not necessary for wholesalers to keep samples of each batch of drugs handled.
(b) Regulation of retailers	
(i) The Administration proposed not to take forward the Review Committee's recommendation that all retailers of non-poisons should be subject to licensing and inspection control [Recommendation 29 of the Review Committee refers]*	
● College of Pharmacy Practice ● Department of Pharmacology and Pharmacy, The University of Hong Kong ● The Pharmaceutical Society of Hong Kong	● The deputations did not subscribe to the Administration's view, and considered that retailers of all registered pharmaceutical products, including non-poisons, should be subject to inspection and licensing control.

C. Recommendations of the Review Committee not requiring legislative amendments and other issues

Organization/individual	Major views and concerns
(a) Regulation of manufacturers	
(i) To upgrade Hong Kong's current GMP licensing standards by a phased approach to the standard devised by the Pharmaceutical Inspection Cooperation Scheme, i.e. the PIC/S standard *[Recommendation 1 of the Review Committee refers*]*	
● The Hong Kong Pharmaceutical Manufacturers Association	● Taking into account the rapid advancement in medicine technology, the deputation considered that the PIC/S standard should be a licensing but not a statutory requirement.
(b) Regulation of retailers	
(i) To strengthen the monitoring of ASPs and LSPs by means of more frequent and more detailed inspections *[Recommendation 35 of the Review Committee refers*]*	
● Hong Kong Dental Association	● The Administration should conduct more frequent inspections to ASPs and LSPs and step up its enforcement actions against cases of non-compliance.
● The Hong Kong Medical Association	● The deputation considered that the penalty level for the sale of prescription drugs without a prescription should be raised to achieve sufficient deterrent effect. More frequent test purchases and inspections should be conducted.
(c) Orders of pharmaceutical products by ASPs, LSPs and private doctors	
(i) To require that all orders for pharmaceutical products to have written records *[Recommendation 37 of the Review Committee refers*]*	
● Association of Doctors in Aesthetic Medicine (Hong Kong) ● Hong Kong Academy of Pharmacy ● Hong Kong Alliance for Patients' Organizations	● The deputations objected to the proposed requirement which, in their view, might result in possibility of delay in the ordering of pharmaceutical products and an increase in administrative costs which might be passed on to consumers. Some of these deputations, including the Association of Doctors in Aesthetic Medicine (Hong Kong), the Hong Kong Alliance for Patients' Organizations and

Organization/individual	Major views and concerns
● Hong Kong Doctors Union ● The Pharmaceutical Distributors Association of Hong Kong Limited ● Pharmaceutical Trade Alliance ● The Practising Pharmacists Association of Hong Kong	the Hong Kong Doctors Union, did not see the reason why the written order requirement could curb the illegal trading of pharmaceutical products. ● There was a view from the Hong Kong Doctors Union that requiring practising doctors to sign the delivery notes within a specified period, say 48 hours, upon the delivery of the pharmaceutical products would be sufficient to ensure the accuracy of delivery and receipt of the products. The Practising Pharmacists Association of Hong Kong considered that the Administration should impose requirement on the qualification of the person placing the orders and receiving the products. ● The Practising Pharmacists Association of Hong Kong pointed out that Regulations 5(3) and 5(4) of the Pharmacy and Poisons Regulations (Cap. 138A) had provided that seller of poisons had to obtain an order in writing signed by the purchaser before the completion of the sale unless in urgent situations whereby the order in writing could be provided within the next 48 hours. The Hong Kong Academy of Pharmacy remarked that many developed countries, such as Australia, the United Kingdom and the United States, did not require mandatory written orders for pharmaceutical products. ● The Hong Kong Alliance for Patients' Organizations urged the Administration to promote the use of electronic ordering system which provided instant information on stock level and delivery timetable, and would be more cost effective. There was a view from the Association of Doctors in Aesthetic Medicine (Hong Kong) that the Administration's efforts should focus on introducing measures to prevent erroneous dispensing of medicines by practising doctors to patients.

Organization/individual	Major views and concerns
● College of Pharmacy Practice ● Department of Pharmacology and Pharmacy, The University of Hong Kong ● The Hong Kong Association of the Pharmaceutical Industry ● Hong Kong Dental Association ● The Hong Kong Medical Association ● The Pharmaceutical Society of Hong Kong ● School of Pharmacy, The Chinese University of Hong Kong ● The Society of Hospital Pharmacists of Hong Kong ● Professor Vivian LEE Wing-yan	● The deputations supported the proposed requirement which could help to maintain a complete set of movement records of pharmaceutical products and minimize errors in delivery of pharmaceutical products for the sake of patient safety. ● The Hong Kong Dental Association in principle supported the Administration's proposal to implement the requirement through administrative measures. There was however another view from The Society of Hospital Pharmacists of Hong Kong that the Administration should implement the requirement through statutory means. ● There was a view from the Hong Kong Dental Association all orders placed and stored by electronic means, including those through online and mobile phone platform (e.g. Facebook, SMS and WhatsApp), should be accepted as written orders. The Society of Hospital Pharmacists of Hong Kong urged the Administration to encourage the placing of orders by electronic means in the longer term.
(d) Risk Communication	
(i) To require that more information on drugs and patient-oriented advice be provided along with drugs dispensed to patients at hospitals or clinics *[Recommendation 72 of the Review Committee refers*]*	
● Hong Kong Dental Association	● While not objecting to the proposed requirement, the deputation considered that the Administration should give due regard to the possible behavioural change in patients' use of medicines; and engage the professional bodies, such as The Medical Council of Hong Kong and Hong Kong Dental Association, in drawing up the relevant guidelines.

Organization/individual	Major views and concerns
(e) Other issues	
● Hong Kong General Chamber of Pharmacy Limited ● The Pharmaceutical Society of Hong Kong ● Professor Vivian LEE Wing-yan	● The deputations urged the Administration to expeditiously implement the separation of prescribing from dispensing of medicines. The Hong Kong General Chamber of Pharmacy Limited and The Pharmaceutical Society of Hong Kong considered that that the Administration should conduct a public consultation exercise to gauge the view of the public on the subject.
● School of Pharmacy, The Chinese University of Hong Kong	● The deputation called on the Administration to increase the first-year intake of students for Bachelor of Pharmacy. In addition, the curriculum should cover the manufacturing and regulation of pharmaceutical products.
● The Society of Hospital Pharmacists of Hong Kong	● The deputation urged the Administration to set up a Centre for Drug and Medical Device Safety to be headed by a registered pharmacist in order to enhance medication and medical device safety. ● Pointing out that the number of LSPs was currently more than six times of that of ASPs but the retail sale of poisons listed in Part II of the Poisons List Regulations (Cap. 138B) by LSPs was not required to be supervised by registered pharmacists, the deputation called on the Administration to cease the issuance of LSP license to protect public health.

* *The number of the recommendations put forward by the Review Committee as appeared in its report issued in December 2009.*

Organization/individual	Submission [LC Paper No.]
Association of Doctors in Aesthetic Medicine (Hong Kong)	LC Paper No. CB(2)478/13-14(02)
College of Pharmacy Practice	LC Paper No. CB(2)499/13-14(03)
Consumer Council	LC Paper No. CB(2)458/13-14(01)
Department of Pharmacology and Pharmacy, The University of Hong Kong	LC Paper No. CB(2)414/13-14(06)
Direct Selling Association of Hong Kong	LC Paper No. CB(2)478/13-14(04)
Hong Kong Academy of Pharmacy	LC Paper No. CB(2)499/13-14(01)
Hong Kong Alliance for Patients' Organizations	LC Paper No. CB(2)467/13-14(01)
The Hong Kong Association of the Pharmaceutical Industry	LC Paper No. CB(2)499/13-14(02)
Hong Kong General Chamber of Pharmacy Limited	LC Paper No. CB(2)414/13-14(05)
Hong Kong Doctors Union	LC Paper No. CB(2)414/13-14(03)
The Hong Kong Medical Association	LC Paper No. CB(2)467/13-14(02)
The Hong Kong Pharmaceutical Manufacturers Association	LC Paper No. CB(2)414/13-14(08)
Hong Kong Retail Management Association	LC Paper No. CB(2)467/13-14(05)
Hong Kong Suppliers Association Limited	LC Paper No. CB(2)478/13-14(03)
The Pharmaceutical Distributors Association of Hong Kong Limited	LC Paper No. CB(2)414/13-14(09)

Organization/individual	**Submission [LC Paper No.]**
The Pharmaceutical Society of Hong Kong	LC Paper No. CB(2)414/13-14(07)
The Practising Pharmacists Association of Hong Kong	LC Paper No. CB(2)467/13-14(03)
School of Pharmacy, The Chinese University of Hong Kong	LC Paper No. CB(2)414/13-14(04)
The Society of Hospital Pharmacists of Hong Kong	LC Paper No. CB(2)467/13-14(04)

Council Business Division 2
Legislative Council Secretariat
24 April 2014