Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014

Summary of written submissions furnished by deputations of the trade during the period from March to July 2014

At the meeting of the Bills Committee on the Pharmacy and Poisons (Amendment) Bill 2014 ("the Bill") held on 4 July 2014, Members inquired about the written submissions on the Bill by deputations of the trade. Summary of the written submissions is set out in the **Annex** for Members' reference.

2. According to the written submissions received (including the written submissions from deputations attending the meeting of the Bills Committee held on 20 May 2014), there were 50 organisations/individuals supporting the Bill, 18 organisations opposing to or expressing concerns over the Bill and 241 individuals opposing to the Bill by submitting letters of the same format.

Food and Health Bureau
14 July 2014

Annex

Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014

Summary of written submissions furnished by deputations of the trade during the period from March to July 2014

	Date of submission	Deputations/Individuals	Major concerns expressed in the submissions
1.	February to March 2014	Pharmaceutical Trade Alliance (8 petition letters to the Chairman of the Legislative Council ("LegCo") Panel on Health Services ("HS Panel") and the Secretary for Food and Health) (See Appendix 1 for the sample of the petition letters)	– Expressed concerns about the proposal of providing legal status to the codes of practice ("COPs") for authorised sellers of poisons ("ASPs") and listed sellers of poisons ("LSPs") – Objected to the proposed requirement of placing drug orders in written form (The Government noted the concerns expressed in the letters, yet no written response could be made as no return address was included. For the Government's position on the relevant matters, please refer to LC Paper No. CB(2)1735/13-14(02) in Appendix 1A)
2.	May to June 2014	21 deputations/individuals attending the meeting of the Bills Committee held on 20 May 2014	– The LegCo Secretariat has drafted a summary of the views and concerns expressed by deputations/ individuals at the meeting on 20 May 2014, please refer to LC Paper No. CB(2)1735/13-14(01) in Appendix 2.
3.	23 May 2014	Asia Regulatory Professional Association (addressed to the Chairman of the Bills Committee) (See Appendix 3 for the letter)	– Supported the Bill and the proposal to extend the validity period of clinical trial certificate from two to five years. – Supported the proposed requirement of placing drug orders in written form. – Supported the introduction of COPs/codes of conduct ("COC") through the Bill to improve the standards of the pharmaceutical

	Date of submission	Deputations/Individuals	Major concerns expressed in the submissions
			industry and enhance drug safety.
4.	26 May 2014	School of Pharmacy, Chinese University of Hong Kong (addressed to the Chairman of the Bills Committee) (See Appendix 4 for the letter)	– Supported the Bill and considered that other major issues relating to the pharmaceutical industry, such as the proposal to set up an independent regulatory body for registered pharmacists, should be discussed through other channels.
5.	27 May 2014, 7 July 2014	The Hong Kong Pharmaceutical Manufacturers Association Ltd (addressed to the Chairman of the Bills Committee) (See Appendix 5 for the letter)	– Supported the Bill and agreed to the establishment of authorised persons ("AP") system and the qualification requirements, and proposed to set out the required qualifications clearly – Supported the proposal to empower the Pharmacy and Poisons Board ("PPB") to issue the COPs/COC to regulate the operation of different parties in the trade – Supported the proposal to extend the validity period of clinical trial certificate from two to five years – Supported the requirement that manufacture of pharmaceutical products should only be undertaken by licensed manufacturers – Supported the replacement of the term "Poison" by "Prescription Drug" or "Drug under Supervised Sales" so as to align with international practice – Supported the proposal to raise the requirements of the Good Manufacturing Practice ("GMP") to the standard of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme ("PIC/S") – Supported the inclusion of the requirement of placing drug

	Date of submission	Deputations/Individuals	Major concerns expressed in the submissions
			orders in written form in the code of practice for licensed drug manufacturers and considered that the proposed requirement would not delay the delivery of drugs – Did not agree to the proposal of empowering the courts to order the payment to the Government by the persons convicted any expenses incurred from the drug tests, nor to recover such expenses in the form of civil debt. It also considered that the maximum penalty under the existing law should be raised instead
6.	29 May 2014	Faculty of Medicine, Chinese University of Hong Kong (addressed to the Chairman of the Bills Committee) (See Appendix 6 for the letter)	– Supported the proposal to extend the validity period of clinical trial certificate from two to five years
7.	3 June 2014	Patients' Alliance on Healthcare Reform (addressed to the Chairman of the Bills Committee) (See Appendix 7 (Chinese version only) for the letter)	– Supported the Bill and hoped that the Bills Committee would expedite the vetting of the Bill so as to provide early protection of patients' rights. It opposed to the withdrawal of the Bill and considered that there was more support than opposition to Bill from the trade – Expressed understanding on the consultation carried out by the Government and believed that the Government had balanced the benefits of all parties when drafting the Bill – Supported the setting up of the AP system and the relevant qualification requirements; it also considered that allowing persons who were not registered pharmacists but possessing the relevant professional knowledge

	Date of submission	Deputations/Individuals	Major concerns expressed in the submissions
			to register as APs was in line with international practice – Considered that the issue of COPs/COC was in line with the arrangements for other medical professions – Supported the extension of the validity period of clinical trial certificate from two to five years – Supported the adoption of "negative vetting" procedure for registration of new drugs so as to expedite patients' use of the drugs as early as possible – Supported the requirement of placing drug orders in written form in order to minimise the risks in the supply chain – Supported the separation of prescribing from dispensing of medicines, but opined that this issue should not be linked to the vetting of the Bill – Considered that there should be a standardised COC for the pharmaceutical sector with a view to providing a foundation for the discussion of setting up a "pharmacy council"
8.	4 June 2014	Department of Pharmacology and Pharmacy, University of Hong Kong (addressed to the Chairman of the Bills Committee) (See Appendix 8 for the letter)	– Supported the Bill and the issue of the COPs/COC for drug dealers and registered pharmacists with a view to regulating the operation of different parties in the trade – Supported the extension of the validity period of clinical trial certificate from two to five years and the amendment to the definition of "pharmaceutical product"

	Date of submission	Deputations/Individuals	Major concerns expressed in the submissions
9.	4 June 2014	A joint letter by Department of Pharmacology and Pharmacy, University of Hong Kong, School of Pharmacy, Chinese University of Hong Kong, Hong Kong Association of Pharmaceutical Industry, Hong Kong Pharmaceutical Manufacturers Association, Pharmaceutical Society of Hong Kong, Society of Hospital Pharmacists of Hong Kong and College of Pharmacy Practice (addressed to the Chairman of the Bills Committee) (See Appendix 9 for the letter)	– Supported the Bill, and considered that the Bill enhances the regulation of the pharmaceutical sector and plays an important role in public health protection. – The deputations put forward a proposal to make minor amendments to the Bill at the meeting on 20 May 2014, and also communicated with the Department of Health ("DH") after the meeting. The deputations were of the view that the proposed amendments would not hinder the endorsement of the Bill
10.	4 June 2014	A joint letter by several oncologists (addressed to the Chairman of the Bills Committee) (See Appendix 10 for the letter)	– Supported the Bill and the adoption of the "negative vetting" procedure for registration of new drugs
11.	4 June 2014	Cancer Information (addressed to the Chairman of the Bills Committee) (See Appendix 11 for the letter)	– Supported the Bill and the proposal to streamline the legislative procedures relating to registration of new drugs so as to benefit patients as early as possible
12.	4 June 2014	Hong Kong Association of the Pharmaceutical Industry (addressed to the Chairman of the Bills Committee) (See Appendix 12 for the letter)	– Supported the Bill and the setting up of the AP system and the relevant qualification requirements – Supported the extension of the validity period of clinical trial certificate from two to five years – Supported the adoption of the "negative vetting" procedure for registration of new drugs – Supported the proposed requirement of placing drug orders in written form

	Date of submission	Deputations/Individuals	Major concerns expressed in the submissions
13.	5 June 2014, 9 July 2014	The Hong Kong Association of the Pharmaceutical Industry (addressed to the Chairman of the Bills Committee) (See Appendix 13 for the letter)	– Supported the Bill and the extension of the validity period of clinical trial certificate from two to five years – Supported the adoption of the "negative vetting" procedure for registration of new drugs – Supported the proposed requirement of placing drug orders in written form and considered that written orders could be made by electronic means. Placing written orders would be similarly efficient to placing verbal orders, and would not cause delay in drug delivery – Supported the proposed requirement of employing at least one AP by the licensed drug manufacturer
14.	5 June 2014	A joint letter by 28 APs (addressed to the Chairman of the Bills Committee) (See Appendix 14 for the letter)	– Supported the Bill and agreed to the establishment of AP system and the qualification requirements, and proposed to set out the required qualifications clearly
15.	5 June 2014	DKSH, Zuellig Pharma, LF Asia (addressed to the Chairman of the Bills Committee) (See Appendix 15 for the letter)	– Concerned about the impact of extending the requirement of keeping control sample of finished products (e.g. over-labelling of statement or replacement of product inserts according to the prevailing labelling requirements) to secondary packaging activities (After consideration of the views expressed, the Administration decided to move Committee Stage Amendments to amend the relevant provisions.)

	Date of submission	Deputations/Individuals	Major concerns expressed in the submissions
16.	6 June 2014	Li Ka Shing Faculty of Medicine, University of Hong Kong (addressed to the Chairman of the Bills Committee) (See Appendix 16 for the letter)	– Supported the extension of the validity period of clinical trial certificate from two to five years
17.	9 June 2014	A joint letter by a group of pharmacists (addressed to the Bills Committee) (See Appendix 17 for the letter)	– Considered that the existing definition of ASP should be retained – Considered that APs should be registered pharmacists – Considered that at least 2/3 of members of the PPB should be registered pharmacists, 4/5 of whom should be community pharmacists; and that the PPB should not be empowered to publish or amend COPs/ COC before it changes its composition – Requested the separation of prescribing from dispensing of medicines as early as possible – Raised amendments to various clauses of the Bill
18.	13 June 2014	Hong Kong Rheumatoid Arthritis Association – a self-help organisation of people suffering from rheumatoid arthritis (addressed to the Chairman of the Bills Committee) (See Appendix 18 (Chinese version only) for the letter)	– Supported the streamlining of legislative procedures relating to the registration of new drugs so as to benefit patients as early as possible and called for an early passage of the Bill
19.	16 June 2014	Alliance for Renal Patients Mutual Help Association (addressed to the Chairman of the Bills Committee) (See Appendix 19 (Chinese version only) for the letter)	– Supported the Bill and objected to the withdrawal of the Bill – Supported the adoption of the "negative vetting" procedure for registration of new drugs – Supported the establishment of AP system and the relevant qualification requirements – Supported the extension of the

	Date of submission	Deputations/Individuals	Major concerns expressed in the submissions
			validity period of clinical trial certificate from two to five years – Supported the proposed requirement of placing drug orders in written form
20.	17 June 2014, 27 June 2014, 3 July 2014	Hong Kong Doctors Union (addressed to the Secretary for Food and Health) (See Appendix 20 (Chinese version only) for the letter)	– Requested the withdrawal of the Bill – Disagreed to the proposed requirement of placing drug orders in written form and considered such method as a waste of time since there was already a record system in place upon receipt of drugs (Written reply will be provided by the Administration)
21.	30 June 2014	Dr. Yeung Chiu Fat (addressed to Members of the Legislative Council) (See Appendix 21 (Chinese version only) for the letter)	– Opined that placing order of drugs in written form as mentioned in the Good Dispensing Practice Manual issued by the Hong Kong Medical Association is a suggestive measure rather than a mandatory requirement
22.	2 July 2014	Federation of Medical Societies of Hong Kong (addressed to the Chairman of the Bills Committee) (See Appendix 22 for the letter)	– Supported the Bill and agreed to the proposed requirement of placing drug orders in written form – Supported the establishment of AP system and the relevant qualification requirements; and considered that registered pharmacists should be involved in the drug manufacturing process
23.	2 July 2014, 3 July 2014	Hong Kong Pharmacists Union (addressed to the Chairman of the Bills Committee) (See Appendix 23 (Chinese version only) for the letter)	– Expressed concerns about various parts of the Bill, including: – disagreed to the proposed requirements on the qualifications of APs and considered that the position should be held by registered

	Date of submission	Deputations/Individuals	Major concerns expressed in the submissions
			pharmacists – raised concerns about the qualification and regulation of licensed drug manufacturers in Hong Kong – disagreed to the proposed amendments to the definitions of "ASP" and "pharmaceutical product" – disagreed to the proposal of empowering PPB to issue COPs/COC and considered that the composition of the PPB should be restructured – disagreed with the extension of the validity period of clinical trial certificate from two to five years – put forward suggestions on the replacement of "Poison" with "Prescription Drug" or " Drug under Supervised Sales" – inquired about the consultation process of the Bill
24.	3 July 2014	Hong Kong Pharmacology Society (addressed to the Chairman of the Bills Committee) (See Appendix 24 for the letter)	– Supported the Bill and the proposed requirement of placing drug orders in written form – Supported the establishment of AP system and the relevant qualification requirements, and considered that registered pharmacists should be involved in the drug manufacturing process – Supported the extension of the validity period of clinical trial certificate from two to five years – Suggested that the sale of Part I poisons should be done in the presence of registered pharmacists

	Date of submission	Deputations/Individuals	Major concerns expressed in the submissions
25.	4 July 2014	The Pharmaceutical Distributors Association of Hong Kong (addressed to the Chairman of the Bills Committee) (See Appendix 25 for the letter)	– Generally supported the direction of the Bill, while members of the association could not reach a consensus about the requirement of placing drug orders in written form
26.	11 July 2014	Drug Safety Consortium (addressed to the Chairman of the Bills Committee) (See Appendix 26 (Chinese version only) for the letter)	– Considered that the Bill could not enhance safety of patients and the current format of discussion of the Bill was not fair. Concerns raised by the deputation included: – the proposed amendments to the definitions of ASP and pharmaceutical product – the proposal to empower the PPB to issue COPs/COC – the recovery of costs and expenses incurred from tests of poisons and pharmaceutical products – the qualifications of APs – the replacement of "Poison" with "Prescription Drug" or " Drug under Supervised Sales" – the extension of the validity period of clinical trial certificate from two to five years
27.	May to June 2014	Individuals (Letters addressed to the Chief Executive and Members of the Legislative Council in the same format. According to its record, the Chief Executive's Office received a total of 241 petitions in the same format) (See petition samples at Appendix 27 (Chinese version only))	– Requested the withdrawal of the Bill and requested the Government to carry out consultation on the Bill again (The Government noted the concerns expressed in the letters, yet no written response could be made as no return address was included. For the Government's position on the relevant matters, please refer to LC Paper No. CB(2)1543/13-14(01) in Appendix 27A).

附件 1
Appendix 1

藥業商聯盟 Pharmaceutical Trade Alliance
Tel：8100 4226

如果你支持本請願書的訴求，請簽名並傳真或發電郵的信中所列的議員及政府官員：

致：

立法會衞生事務委員會主席 梁家騮醫生
Email：leungkl01cuhk.org
Fax: 30200205

食物及衞生局局長 高永文醫生
Email： enquiry@fhb.gov.hk
Fax： 25413352

有關：加強規管香港藥劑製品的立法建議

我們反對香港藥物監管制度檢討委員會報告第 32 項建議*：-
「在《藥劑業及毒藥條例》內加入有關發出和修訂《認可毒藥售賣商執業守則》的條文，從而賦予執業守則法律地位，加強監管「獲授權毒藥銷售商」的運作，另為「列載毒藥銷售商」草擬執業守則，「列載毒藥銷售商」的執業守則須與《認可毒藥售賣商執業守則》享有同等的法律地位。」

《認可毒藥售賣商執業守則》及《列載毒藥銷售商執業守則》的真正目的及效能，在於向從事零售藥劑業務的獲授權毒藥銷售商（ASP）及列載毒藥銷售商（LSP），提供有關藥劑業務的指引及指示，以及釐定優良藥劑業務的最低標準。這些執業守則的目的，並非為方便執法者用以監察 ASP 及 LSP 的運作，因為現行法例實際已提供足夠監察。

為了進一步了解建議中提及「在《藥劑業及毒藥條例》內加入有關發出和修訂《認可毒藥售賣商執業守則》的條文，從而賦予執業守則法律地位」對業界的的實際影響，我們要求政府及以書面形式回覆並清楚列明建議修訂的所有詳細法律條文，以供參考及徵求法律意見 。

檢討委員會的建議賦予執業守則法律地位，執業守則與法例上的差異，大有可能導致執法上的混淆。

執法者應遵從確當的程序，提出適當的法例修改，以公平、公開、公正及正規的態度，經由立法會提出適當的修改，而不是依靠修改執業守則以達致修改法例，甚或加入新的法例要求。

因此，我們認為實在毋須賦予執業守則法律地位，因為現行法例實足以履行監察獲授權毒藥銷售商（ASP）及列載毒藥銷售商（LSP） 運作的目的。

其次，除非一個比較目前的廣為業界所用的訂購藥物流程同等或更好的效率的高效能電子訂貨系統可應用於藥品零售商發出和接收藥物訂單，否則我們反對 "要求以書面形式訂藥" 的建議。

日期： *公司名稱：*
姓名及簽署：

20 December 2013

Dr KO Wing-man, BBS, JP
Secretary for Food and Health
Fax: 25413352
Email: enquiry@fhb.gov.hk

Dr Hon LEUNG Ka-lau,
Chairman, & the members of
Panel on Health Services,
Legislative Council
Fax: 3020 0205 / Email: leungkl@leungkl.org
(Dr Leung's office)
Fax: 2537 1851 / Email: pld@legco.gov.hk
(Legislative Council Secretary)

Petition Letter about Legislative proposals to enhance the regulation of pharmaceutical products in Hong Kong

Pharmacists in Hong Kong should have the right as any other individual to have a fair and reasonable environment to work in.

According to the current law Chapter 138A Pharmacy and Poisons Regulations, Regulation 19 - Storage of poisons:

R19(2) No person shall store any substance included in the First Schedule in any retail shop or premises used in connection therewith unless the substance is stored-
(a) in a receptacle reserved solely for the storage of poisons, which receptacle shall be locked with an adequate lock the key for which shall be retained by the registered pharmacist; and
(b) in a part of the premises to which customers are not permitted to have access and which is partitioned off or otherwise separated from the remainder of the premises.

If the law is changed to require that the pharmacist should have the ONLY key to the locked receptacles of the pharmacy, then it is not reasonable to expect for the employee pharmacist to ensure that the key given to him/her by the owner of the pharmacy is the one and only key without any duplicate key kept by the owner or any other persons.

Therefore, we object to the Recommendation no.31 in the Legislative proposals to enhance the regulation of pharmaceutical products: *"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."*

Thank you for your kind attention.

Yours truly,

Name:

Sign:

Contact:

LC Paper No. CB(2)1735/13-14(02)

The Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014

Administration's response to issues raised by deputations and individuals

We noted the comments raised by deputations/individuals regarding the Pharmacy and Poisons (Amendment) Bill 2014 ("the Bill") at the meeting on 20 May 2014. Their views can be broadly summarized as follows:

(a) Requested to establish a separate statutory body to take over the existing function of the Pharmacy and Poisons Board ("the Board") for regulating registered pharmacists;

(b) Requested to include more representatives from the industry as members of the Board, so that the Codes of Practice ("COPs")/ Code of Conduct ("COC") issued by the Board for various licensed and listed traders as well as registered pharmacists will be more representative;

(c) Expressed concerns towards the proposal which allows a person, who is not a registered pharmacist, to become an authorized person if he/she holds a qualification awarded on completion of a course recognized by the Board;

(d) Expressed concerns towards the proposed amendments to the definition of "authorized seller of poisons";

(e) Expressed concern towards the proposed amendments to the definition of "pharmaceutical product" and "medicine";

(f) Opposed to the proposal of extending the validity of clinical trial certificates and medicinal test certificates from two years to five years; and

(g) Expressed concerns towards the proposed requirement of placing orders of pharmaceutical products in written form.

2. In the **LC Paper No. CB(2)1543/13-14(01)** issued on 16 May 2014, we have set out in detail the consultation work carried out by the

Administration for enhancing the regulation of the pharmaceutical industry in Hong Kong since March 2009. The said paper has elaborated on the proposals and implementation details for enhancing the regulation of pharmaceutical products in Hong Kong, which were formulated after extensive discussions and studies by organisations and individuals from various sectors over the years, with appropriate adjustments in response to the concerns raised by the trade, stakeholders and the public expressed through various channels. As for the majority of the views expressed by the deputations/individuals at the meeting on 20 May 2014, we have also in earlier time made a detailed written response. In order to facilitate the deliberation of the Bills Committee on the Pharmacy and Poisons (Amendment) Bill 2014 ("the Bills Committee"), the key points of relevant written responses and follow-up work are set out as below.

To establish a separate statutory body for regulating registered pharmacists

[Relevant written response by the Administration:

- *LC Paper No. CB(2)1629/13-14(01) (26 May 2014)]*

3. In view of the proposal raised by some deputations/individuals about establishing a separate statutory body to take over the existing function of the Board in terms of regulating registered pharmacists, we wrote to the Chairman of the Bills Committee on 26 May 2014 (**LC Paper No. CB(2)1629/13-14(01)**) to point out that the request would be followed up by the Pharmacists Sub-group under the Steering Committee on Strategic Review on Healthcare Manpower Planning and Professional Development ("Steering Committee"). The Sub-group will take into account the results of the consultancy study undertaken by the Chinese University of Hong Kong on the long term professional development of healthcare professionals, and discuss the subject before the end of this year.

4. We wish to reiterate that the main purpose of the Bill is to implement some of the recommendations put forth by the Review Committee on the Regulation of Pharmaceutical Products in Hong Kong ("Review Committee") for enhancing the drug safety and safeguarding

public health in Hong Kong. The current Bill will not only enhance the regulation of various aspects in the supply chain of pharmaceutical products, but also facilitate the research and development as well as registration of pharmaceutical products. All these are beneficial to the development of the pharmaceutical industry as a whole as well as the patient groups who can have more choices of pharmaceutical products in good quality. Since the establishment of a separate regulatory body for registered pharmacists is not one of the purposes of the Bill, it therefore should not be a consideration to delay the implementation of the Bill. We consider it more appropriate for the Pharmacists Sub-group under the Steering Committee to follow up with the issue of establishing a separate statutory body to regulate registered pharmacists.

Codes of Practice (COPs) / Code of Conduct (COC)

[Relevant written responses by the Administration:

- *LC Paper No. CB(2)1522/13-14(01) (16 May 2014)*
- *LC Paper No. CB(2)1543/13-14(01)(16 May 2014)*
- *LC Paper No. CB(2)1584/13-14(02)(20 May 2014)]*

5. Deputations/individuals have generally accepted the proposal of the Board to issue COPs/COC for various licensed traders, traders subject to registration requirement and registered pharmacists. However, some deputations/individuals are of the view that the representation of the membership of the Board is inadequate and more trade representatives should be recruited, and that the Board should be empowered to issue COPs/COC only after it has sufficient representatives from the trade. We wish to clarify that in order to fulfill its statutory duties to regulate the pharmaceutical industry, the Board must maintain its independence. At the same time, in order to ensure the effectiveness of its monitoring work in various aspects, the existing eleven members of the Board already include two members holding qualifications in pharmacology, each of whom is teaching at and nominated respectively by the University of Hong Kong and the Chinese University of Hong Kong. Besides, the membership of the Board also includes three registered pharmacists nominated by the industry.

6. As pointed out in Item 14 of the Annex to the **LC Paper No. CB(2)1522/13-14(01)** issued on 16 May 2014, and the **LC Paper No. CB(2)1584/13-14(02)** issued on 20 May 2014, the proposal to empower the Board to issue COPs/COC is similar to section 26 of the Supplementary Medical Professions Ordinance (Cap. 359). As a matter of fact, some existing Ordinances also empower relevant authorities to issue COPs, such as section 3 of the Broadcasting Ordinance (Cap. 562) and section 67 of the Insurance Companies Ordinance (Cap. 41).

7. On the other hand, we have also reiterated on several occasions that the Board has carried out sufficient consultation with the trade when revising/formulating relevant COPs/COC. In **LC Paper No. CB(2)1543/13-14(01)** issued on 16 May 2014, we have listed out in detail the consultation work carried out by the Board and the participation of individual organisations/associations, including the memberships of the working groups on various COPs/COC, and the list of organisations/associations which have participated in relevant consultation meetings, public consultation and briefing sessions. Attending/participating parties included 40 organisations/enterprises from different sectors, all authorized sellers of poisons, all listed sellers of poisons, all licensed wholesalers of poisons and importers/exporters of pharmaceutical products as well as all licensed manufacturers. The above demonstrates that the Board has put in place a well-established mechanism to provide the trade and relevant stakeholders with various channels to participate in formulating, revising and issuing COPs/COC and to express their views on such codes.

<u>Qualification of Authorized Persons (APs)</u>

[Relevant written response by the Administration:

- *LC Paper No. CB(2)1584/13-14(01) (19 May 2014)]*

8. We have clarified in the **LC Paper No. CB(2)1584/13-14(01) i**ssued on 19 May 2014 that the new regulations 30A to 30F added to the Pharmacy and Poisons Regulations (Cap 138A) ("the Regulations") as proposed by the Bill specify that a licensed manufacturer is required to employ at least one AP to ensure and certify that each and every batch of pharmaceutical products manufactured by the manufacturer is in

compliance with the Good Manufacturing Practice (GMP) Guide, registered particulars and requirements of relevant legislation. The proposed regulation 30C provides that all applicants, regardless registered pharmacists or persons holding qualifications awarded on completion of the courses recognised by the Pharmacy and Poisons (Manufacturers Licensing) Committee, must have at least 3 years' experience in manufacturing pharmaceutical products in accordance with the GMP Guide.

9. As shown in the proposed regulation 30C, being a registered pharmacist remains to be the major qualification requirement for APs. Given the diversified and complicated nature of drug manufacturing, various scientific considerations are involved in the course of drug manufacturing. In this regard, the qualification requirements for APs also need to be diversified. As such, besides registered pharmacists, the proposed regulation 30C also allows any person who holds a qualification awarded on completion of a course recognised by the Pharmacy and Poisons (Manufacturers Licensing) Committee to act as an AP, which is also a common international practice. For example, Article 53(2) of the Directive 2001/82/EC of the European Union specifies that any person who possesses qualifications in scientific disciplines (for example experimental physics, organic chemistry, microbiology and toxicology) and relevant qualifications can also act as AP.

10. The Department of Health (DH) and the consultant are now drawing up the relevant requirements for APs, including, inter alia, holding recognised university qualifications and qualifications awarded on completion of recognized courses related to drug manufacturing. It is expected that details of the recognition system will be submitted to the Board for consideration and announced to the public within this year. We would like to reiterate that the proposed AP system as introduced by the Bill is made in accordance with one of the recommendations put forth by the Review Committee to upgrade Hong Kong's GMP standards in manufacturing pharmaceutical products. The Review Committee's recommendations have taken into account the study and recommendations on Hong Kong's GMP made by a consultancy study, which was commissioned by the DH and conducted by overseas GMP experts from Australia in May 2009, in the light of the latest practices

adopted by major drug regulatory authorities in the world. The objective of this proposal is to establish a registration and regulatory system for APs to ensure that they are capable of discharging their duties for strengthening the regulation of pharmaceutical profession and raising the standards of drug manufacturing and quality control of local manufacturers.

11.

Definition of Authorized Sellers of Poisons ("ASP")

[Relevant written responses by the Administration:

- *LC Paper No. CB(2)1522/13-14(01)(16 May 2014)*
- *LC Paper No. CB(2)1584/13-14(02)(20 May 2014)*
- *LC Paper No. CB(2)1629/13-14(01)(26 May 2014)]*

12. As we clarified to Members in our letter to the Chairman of the Bills Committee (**LC Paper No. CB(2)1629/13-14(01)**) issued on 26 May 2014, under the revised definition of ASP as proposed by the Bill, a registered pharmacist who is an employee of an ASP and himself/herself not a holder of an ASP registration would not be liable for breaches of ASP registration conditions committed by the ASP.

13. We wish to reiterate that the amendment to the definition of ASP proposed by the Bill is purely a technical amendment. We have given detailed explanation in Item 1 of the Annex to **LC Paper No. CB(2)1522/13-14(01)** issued on 16 May 2014, and in Paragraphs 1 and 2 in **LC Paper No. CB(2)1584/13-14(02)** issued on 20 May 2014.

Definition of "Pharmaceutical Product" and "Medicine"

[Relevant written responses by the Administration:

- *LC Paper No. CB(2)1522/13-14(01)(16 May 2014)*
- *LC Paper No. CB(2)1584/13-14(02)(20 May 2014)]*

14. As we pointed out in Item 3 of the Annex to **LC Paper No. CB(2)1522/13-14(01)** issued on 16 May 2014 and Paragraph 3 in **LC Paper No. CB(2)1584/13-14(02)** issued on 20 May 2014, the revised definition of "pharmaceutical product" and "medicine" as proposed by the Bill to include "presented as having properties for treating or preventing disease in human beings or animals" is in line with the current

guidance note on registration of pharmaceutical product published by the DH. The guidance note specifies that a product may fall within the definition of pharmaceutical product under the Pharmacy and Poisons Ordinance (Cap. 138) if it contains a drug substance in its composition, or if it carries "medicinal" claims in its label, leaflet, brochure, wrapper, advertisements and other promotional materials. In other words, the revised definition of "pharmaceutical product" and "medicine" as proposed by the Bill only aims to codify the current registration requirement. After the revision, the definition of "pharmaceutical product" and "medicine" will still cover products which have not proven their efficacy but claim to be able for treating or preventing disease, so as to offer protection for consumers.

The validity of clinical trial certificates and medicinal test certificates

[Relevant written response by the Administration:

- *LC Paper No. CB(2)1522/13-14(01)(16 May 2014)]*

15. As we explained in Item 25 of the Annex to **LC Paper No. CB(2)1522/13-14(01)** dated 16 May 2014, in view of the Review Committee's concern that the current two-year validity of the clinical trial certificate and medicinal test certificate is often too short for the completion of a clinical trial / medicinal test, the Bill therefore proposes to extend the validity of clinical trial certificate / medicinal test certificate to not more than five years, so that the applicant does not need to apply for a certificate again if a trial/test lasts more than two years. This proposal will also help enhance the capacity of drug research and development in Hong Kong.

The requirement to place drug orders in written form

[Relevant written responses by the Administration:

- *LC Paper No. CB(2)414/13-14(01) (3 December 2013)*
- *LC Paper No. CB(2)541/13-14(01) (16 December 2013)*
- *LC Paper No. CB(2)1522/13-14(01) (16 May 2014)*
- *LC Paper No. CB(2)1584/13-14(02) (20 May 2014)]*

16. We have explained to the Panel on Health Services of the Legislative Council ("the Panel") and the deputations attending the

special meeting of the Panel, as well as in the **LC Paper No. CB(2)414/13-14(01)** issued on 3 December 2013, Paragraphs 2 to 4 in the **LC Paper No. CB(2)541/13-14(01)** issued on 16 December 2013, Item 35 of the Annex to **LC Paper No. CB(2)1522/13-14(01)** issued on 16 May 2014 and **LC Paper No. CB(2)1584/13-14(02)** issued on 20 May 2014, that according to the recommendation by the Review Committee, the purpose of requiring licensed drug traders to place drug orders in written form is to build up a complete set of drug transaction records, thus facilitating the tracing of source of drugs and minimizing errors in the placing/accepting order, delivery and receipt of drugs so as to offer the best protection for the general public. Besides, placing drug orders in written form can also help combat the illegal sale of drugs. For example, when law enforcement officer finds that a retailer commits in sale of illegal drugs, if the retailer has not retained written records of drug orders, he/she can attempt to evade responsibility by claiming that the illegal drugs have been provided by a supplier without his/her knowledge. Having considered the regulation of the drug supply system and the concerns of the industry, we propose to implement the requirement of placing drug orders in written form by administrative means whereby the Board would incorporate the requirement in the COP for the relevant licenced drug traders. To help the industry adapt to the requirement, the Board will accept drug orders by electronic means (e.g. e-mails), fax and mail, etc.. Such requirement will also be implemented by phases according to the risk levels of drugs.

Conclusion

17. The proposals put forth by the Bill will not only enhance the regulation of various aspects in the supply chain of pharmaceutical products, but also facilitate the research and development as well as registration of pharmaceutical products. All these are beneficial to the development of the pharmaceutical industry as a whole as well as the patient groups who can have more choices of pharmaceutical products in good quality. We noted that various organisations, including –

- the Patients' Alliance on Healthcare Reform, which represents patients and concerns about patients' rights;

- the Hong Kong Association of the Pharmaceutical Industry, which is formed by various enterprises engaged in the research and development of drugs ;
- the Hong Kong Pharmaceutical Manufacturers Association, which represents various pharmaceutical manufacturers;
- the Department of Pharmacology and Pharmacy of the University of Hong Kong;
- the Faculty of Medicine of the Chinese University of Hong Kong; and
- the School of Pharmacy of the Chinese University of Hong Kong

have separately written to the Chairman of the Bills Committee recently to show support to the Bill. We therefore hope that the Bills Committee can support the Bill and endorse our legislative proposals.

Food and Health Bureau
6 June 2014

Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014

Summary of views and concerns expressed by deputations/individual for the meeting on Tuesday, 20 May 2014

Organization/individual	Major views and concerns
(a) Revised definition of "authorized seller of poisons"	
• College of Primary Healthcare Pharmacists • Hong Kong Pharmacists Union • The Pharmaceutical Society of Hong Kong • The Practising Pharmacists Association of Hong Kong	• The deputations were opposed to the proposed amendment under clause 4 of the Bill in respect of the definition of authorized seller of poisons ("ASP"). They considered that the meaning of the amended definition which defined ASP as "a registered pharmacist, body corporate or unincorporated body of persons that is authorized to carry on a business of retail sale of poisons under section 11" was unclear. In particular, The Practising Pharmacists Association of Hong Kong and Hong Kong Pharmacists Union were of the view that the proposed amendment was ambiguous about the respective legal liability of the owners of ASPs and those registered pharmacists who were employees of ASPs. • College of Primary Healthcare Pharmacists and Hong Kong Pharmacists Union suggested that the definition of ASP should remain as "a business authorized to sell poisons under section 11".
(b) Revised definition of "manufacture"	
• School of Pharmacy, The Chinese University of Hong Kong	• The deputation considered it necessary to ensure that the proposed amendment to the definition of "manufacture" under clause 4 of the Bill to cover expressly the packaging and repackaging activities of pharmaceutical products such that these activities should only be carried out by a licensed manufacturer who complied with the Good Manufacturing Practice ("GMP") requirement would not render ASPs not able to carry out, under the supervision of registered pharmacists, those repackaging activities for individual dispensing purpose.

Organization/individual	Major views and concerns
(c) Revised definition of "pharmaceutical product" and "medicine"	
• College of Consultant Pharmacist • College of Geriatric Pharmacy • Hong Kong Pharmacists Union • Chemical and Pharmaceutical Industries Council of the Federation of Hong Kong Industries • The Practising Pharmacists Association of Hong Kong • Primary Healthcare Quality Alliance	• The deputations considered that the proposed amendment to the definition of pharmaceutical product and medicine under clause 4 of the Bill was ambiguous and not objective enough. They were concerned about the scope of products that would be regarded as "pharmaceutical product" by virtue of "presented as having properties for treating or preventing disease". There was a view from the Hong Kong Pharmacists Union that the definition of "pharmaceutical product" should remain as it was.
(d) To empower the Pharmacy and Poisons Board to issue codes of conduct and codes of practice for various licensed and listed traders, and registered pharmacists	
• Asia Regulatory Professional Association • Patients' Alliance on Healthcare Reform	• The deputations supported the promulgation of codes of conduct ("COC") and codes of practice ("COP") for providing practical guideline in respect of the Pharmacy and Poisons Ordinance (Cap. 138) ("the Ordinance") for various types of licensed and listed traders, and registered pharmacists. Patients' Alliance on Healthcare Reform considered it appropriate for the Pharmacy and Poisons Board ("PPB"), which had widely consulted the relevant stakeholders on the revision or formulation of relevant COC or COP through the setting up of different working groups and the public consultation exercises, to issue the codes.
• Alliance of Safe and Quality Use of Medicines • College of Primary Healthcare Pharmacists	• The deputations queried the appropriateness of empowering PPB under clause 6 of the Bill to promulgate COC and COP for various licensed and listed traders and registered pharmacists, and from time to time revise the whole or any part of the codes. In their view, the proposal would make the power of PPB too wide.

Organization/individual	Major views and concerns
• Drug Safety Consortium • Hong Kong Academy of Pharmacy • Hong Kong General Chamber of Pharmacy Limited • Hong Kong Pharmacists Union • The Pharmaceutical Society of Hong Kong • The Practising Pharmacists Association of Hong Kong • Primary Healthcare Quality Alliance	• The deputations also expressed grave concern about the composition of PPB, particularly the lack of representation of pharmaceutical traders and registered pharmacists from various pharmaceutical professional bodies in PPB. Some deputations, including Alliance of Safe and Quality Use of Medicines, Hong Kong Academy of Pharmacy, Hong Kong Pharmacists Union and The Practising Pharmacists Association of Hong Kong called for a restructuring of PPB to ensure a balanced representation of members drawn from the trade. Drug Safety Consortium suggested that PPB should be restructured to become three boards each responsible for registration and control of pharmaceutical products; licensing and control of pharmaceutical traders; and registration and discipline of pharmacists. The Pharmaceutical Society of Hong Kong considered that the function of PPB should be confined to registration and control of pharmaceutical products, and licensing and control of pharmaceutical traders. • Given that the Bill was still under scrutiny, Hong Kong General Chamber of Pharmacy Limited expressed concern that PPB had already endorsed a new COP for ASP for taking effect on 2 January 2015. The deputation was particularly concerned about section 1.4 of the new COP which required that the key of the locked receptacles where all Part I poisons, antibiotics, psychotropic substances and dangerous drugs had to be kept by the registered pharmacist. In its view, this requirement did not conform to the existing regulation 19 of the Pharmacy and Poisons Regulations (Cap. 138A) ("the Regulations"). • Primary Healthcare Quality Alliance suggested that COC and COP should be developed from the bottom up, say, by representatives from pharmaceutical trade and pharmaceutical professional bodies respectively for endorsement by PPB.

Organization/individual	Major views and concerns
• Department of Pharmacology and Pharmacy, The University of Hong Kong • Hong Kong Doctors' Union • The Pharmaceutical Society of Hong Kong • School of Pharmacy, The Chinese University of Hong Kong • The Society of Hospital Pharmacists of Hong Kong	• While agreeing the need to develop a COP for registered pharmacists, these deputations considered that the power to register pharmacists, promulgate a code of ethics or conduct and impose disciplinary sanctions against cases of misconduct should be vested with a separate statutory body, say, a pharmacy council, rather than PPB.
• Hong Kong Doctors' Union • Hong Kong Pharmaceutical Manufacturers Association	• The deputations called for a review of the composition of PPB to include more representatives from the industry. There was a view from the Hong Kong Doctors' Union that it was not appropriate for the membership of PPB to continue to include a registered medical practitioner nominated by the Hong Kong Branch of the British Medical Association.
• Patients' Alliance on Healthcare Reform	• The deputation considered that the proposal to establish a separate regulatory body from the current PPB for the registered pharmacists should be considered separately from the current legislative proposal.
(e) Qualification of authorized persons	
• Alliance of Safe and Quality Use of Medicines • College of Consultant Pharmacist • College of Geriatric Pharmacy • College of Primary Healthcare Pharmacists	• On the introduction of an authorized persons system under clause 52 of the Bill, the deputations held a strong view that the requirement for registration as authorized person ("AP") under the proposed new regulation 30C of the Regulations should be confined to being a registered pharmacist in order to ensure the quality of pharmaceutical products. They considered that a person holding a qualification awarded on completion of a course recognized by the

Organization/individual	Major views and concerns
• Hong Kong Academy of Pharmacy • Hong Kong Doctors' Union • Hong Kong Pharmacists Union • Pharmaceutical Trade Alliance • The Practising Pharmacists Association of Hong Kong • Primary Healthcare Quality Alliance	Pharmacy and Poisons (Manufacturers Licensing) Committee and had three years or more relevant experience in manufacturing pharmaceutical products should not be regarded as competent to perform the duties of an AP set out under the proposed new regulation 30A(2). In their views, the proposal to allow these persons to register as APs ran contrary to the spirit of the Bill which was to, among others, enhance regulation of various aspects in the supply chain of pharmaceutical products.
• Chemical and Pharmaceutical Industries Council of the Federation of Hong Kong Industries	• The deputation queried the need to require registered pharmacist, who had undergo proper training, to have at least three years' relevant experience in manufacturing pharmaceutical products in order to be eligible to register as an AP.
• Department of Pharmacology and Pharmacy, The University of Hong Kong • The Hong Kong Association of the Pharmaceutical Industry • Patients' Alliance on Healthcare Reform • Ms Celine CHENG	• The deputations were of the view that apart from registered pharmacists, persons holding recognized qualification and with relevant experience in manufacturing pharmaceutical products in accordance with the GMP Guide were also competent to act as APs.
(f) Extension of the maximum validity period of clinical trial certificate and medicinal test certificate	
• The Hong Kong Association of the Pharmaceutical Industry • Patients' Alliance on Healthcare Reform	• The deputations supported the proposed amendment under clause 59 of the Bill to extend the validity of clinical trial certificate and medicinal test certificate to not more than five years. In their view, the current two-year validity was often too short for the completion of a clinical trial or medicinal test.

Organization/individual	Major views and concerns
• The Practising Pharmacists Association of Hong Kong • Primary Healthcare Quality Alliance	• The deputation considered that the proposed extension of the maximum validity period of any clinical trial certificate or medicinal test certificate from two years to five years was too long. They urged the Administration to review the validity period.
(g) Labelling of pharmaceutical products	
• The Hong Kong Association of the Pharmaceutical Industry	• The deputation supported the proposed amendments under clauses 21, 37 and 67 of the Bill to replace the text "Poison 毒藥", as required to be labeled on pharmaceutical products containing a poison, with "Prescription Drug 處方藥物" (for medicine containing a poison included in the Third Schedule of the Regulations) or "Drug under Supervised Sales 監督售賣藥物" (for medicine containing a poison included in Part I of the Poisons List but not containing a poison included in the Third Schedule of the Regulations).
• College of Consultant Pharmacist	• The deputation agreed to the need to replace the term "Poison 毒藥", as required to be labeled on pharmaceutical products containing a poison, but considered it more appropriate to use "Prescription only medicine 處方藥品" instead of the proposed "Prescription drug 處方藥物", and "Pharmacist only medicine 藥劑師監售藥" instead of the proposed "Drug under Supervised Sales 監督售賣藥物".
(h) Recovery of conviction-related expenses	
• Hong Kong Pharmaceutical Manufacturers Association	• The deputation was opposed to clause 30 of the Bill which provide for the recovery from any person convicted of an offence under the Ordinance of the costs and expenses incurred by the Government in collecting, analyzing or examining any poison, pharmaceutical product or other substance for the criminal proceedings, as such penalty was not required in other criminal cases.

Organization/individual	Major views and concerns
	The Administration should instead consider imposing heavier penalties to increase deterrent effect.
(i) Chinese text of the term "expiry date"	
• Chemical and Pharmaceutical Industries Council of the Federation of Hong Kong Industries	• The deputation suggested to replace "使用期限" with "有效期限" or "失效期限" in the Chinese text of the term "expiry date" under clause 53 of the Bill which, in its view, would be more accurate in the literal meaning of the term and in line with the Chinese text used in other legislation.
(j) Placing drug orders in written form	
• The Hong Kong Association of the Pharmaceutical Industry • Patients' Alliance on Healthcare Reform	• The deputations supported the proposed requirement that all orders for pharmaceutical products to be have written records, as the proposal 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.
• Hong Kong Alliance for Patients' Organizations • Hong Kong Doctors' Union	• The deputations were opposed to the proposed requirement of placing orders of pharmaceutical products in written form, as it might result in possibility of delay in the ordering of pharmaceutical products. In their views, the Administration was trying to circumvent the scrutiny of the Legislative Council on the proposed requirement by implementing it through administrative means. There was a view from The Hong Kong Alliance for Patients' Organizations that the Administration should promote the use of electronic drug ordering system.

Organization/individual	Major views and concerns
(k) Requiring registered pharmacist employed by an ASP be present whenever the ASP is opened for business	
• Department of Pharmacology and Pharmacy, The University of Hong Kong • School of Pharmacy, The Chinese University of Hong Kong	• The deputation requested the Administration to re-consider introducing the proposed requirement in the Bill, 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.
(l) Establishment of pharmacovigilance monitoring platform	
• Department of Pharmacology and Pharmacy, The University of Hong Kong • School of Pharmacy, The Chinese University of Hong Kong • The Society of Hospital Pharmacists of Hong Kong	• The deputations considered that the Bill should provide for mandatory reporting of adverse drug events so as to avoid future incidents of undesirable drug-related outcomes.
(m) Roles of pharmacists	
• Department of Pharmacology and Pharmacy, The University of Hong Kong • School of Pharmacy, The Chinese University of Hong Kong • The Society of Hospital Pharmacists of Hong Kong	• The deputations considered that primary care should be included as part of the duties of pharmacists.

Organization/individual	Submission [LC Paper No.]
Asia Regulatory Professional Association	LC Paper No. CB(2)1522/13-14(03) LC Paper No. CB(2)1649/13-14(02)
Chemical and Pharmaceutical Industries Council of the Federation of Hong Kong Industries	LC Paper No. CB(2)1584/13-14(06)
Department of Pharmacology and Pharmacy, The University of Hong Kong	LC Paper No. CB(2)1584/13-14(05) LC Paper No. CB(2)1743/13-14(01)
Hong Kong Alliance of Patients' Organizations	LC Paper No. CB(2)1649/13-14(03)
The Hong Kong Association of the Pharmaceutical Industry	LC Paper No. CB(2)1743/13-14(01)
Hong Kong Doctors Union	LC Paper No. CB(2)1560/13-14(01)
Hong Kong General Chamber of Pharmacy Limited	LC Paper No. CB(2)1522/13-14(02)
Patients' Alliance on Healthcare Reform	LC Paper No. CB(2)1694/13-14(01)
Hong Kong Pharmaceutical Manufacturers Association	LC Paper No. CB(2)1649/13-14(01)
The Pharmaceutical Society of Hong Kong	LC Paper No. CB(2)1522/13-14(04) LC Paper No. CB(2)1743/13-14(01)
Primary Healthcare Quality Alliance	LC Paper No. CB(2)1584/13-14(07)
The Society of Hospital Pharmacists of Hong Kong	LC Paper No. CB(2)1584/13-14(05) LC Paper No. CB(2)1743/13-14(01)
School of Pharmacy, The Chinese University of Hong Kong	LC Paper No. CB(2)1584/13-14(05) LC Paper No. CB(2)1678/13-14(01) LC Paper No. CB(2)1743/13-14(01)
The Society of Hospital Pharmacists of Hong Kong	LC Paper No. CB(2)1584/13-14(05)
Ms Celine CHENG	LC Paper No. CB(2)1743/13-14(02)

Council Business Division 2
Legislative Council Secretariat
9 June 2014

LC Paper No. CB(2)1649/13-14(02)

23rd May 2014

Prof The Hon Lee Kok Long, Joseph
Chairman, Bills Committee
Pharmacy & Poisons (Amendment) Bill 2014
Legislative Council Complex
1 Legislative Council Road
Central
Hong Kong

Dear Prof Hon Joseph Lee & Members of the Bills Committee,

Re: Pharmacy and Poisons (Amendment) Bill 2014

Asia Regulatory Professional Association (ARPA) is an organization of Healthcare Regulatory Affairs professionals in Asia.

ARPA supports the amendment of the Pharmacy and Poisons (Amendment) Bill 2014 ("the Bill") and has submitted a document to express our views on 12th May 2014.

After the deputation meeting on 20th May 2014, ARPA would like to provide the following information to further support the Bill.

1. Extend the validity of clinical trial certificate from 2 years to 5 years

   At the May 20th deputation meeting, a pharmacist association has expressed concerns on extending the validity of clinical trial certificate as this may pose increased risk of patient safety. This comment is quite misleading. There are international guidelines, for example, Good Clinical Practices (GCP) which provide clear guidance to clinical trial sponsors, investigators and trial subjects regarding their obligations and responsibilities. These guidelines set a very clear governance framework to ensure patients' rights and safety are being carefully looked after whenever they participate in such important and meaningful scientific research activities.

   Besides, in Hong Kong, all certificate holders of clinical trial are required to report any serious and unexpected adverse drug reactions to the Drug Office as well as to submit their study progress report on a yearly basis. If there are any new

safety signals identified from the investigational products, drug companies have to inform and to provide an update of such safety signals to their investigators, ethics committee and the health authority. As such, extending the duration of a clinical trial certificate should not have any direct impact on patient safety. In fact, most developed countries do not impose a valid "shelf-life" on their clinical trial certificates. Once a clinical trial study is granted, its certificate will be valid until the study is completed.

2. Written Orders

Plenty pharmaceutical literatures have documented that a lot of drug errors were resulted due to the problem that some medicines and vaccines have very similar trade names or generic names as well as they may have very similar presentation format.

Untoward incident happened from time to time when wrong medicines were delivered to clinic and subsequently be dispensed to patients because clinic staff has spoken the wrong name and the receiving staff of wholesaler wrongly interpreted the drug name subsequently. On the contrary, written orders are more reliable and more precise. These also allow a permanent record of communications between the two parties. Any profession who puts patient safety first should support the introduction of such good practice in the territory as it can bring additional measures and checking to reduce unnecessary drug errors.

Written orders can also reduce unnecessary drug wastage. In Hong Kong, each day, there are orders that are being wrongly placed to the wholesalers because of poor verbal communications. Medicines and vaccines have very specific storage conditions. Once the medications or vaccines have left the warehouse, they cannot be re-entered into the distribution chain nor be re-used again due to good distribution practice. Wrong orders will be written off and disposed. It is therefore important to capture the name of the medicine or vaccine, its strength and quantity correctly before the delivery. Written orders can allow pharmaceutical wholesaler staff to get ordering information clearly and directly. As a result, the proposal to introduce written orders in the code of practice is a good intention to protect public health and a clear improvement on ordering or distribution practices. It is difficult to understand why professional bodies or individuals do not support the proposal.

3. Code of Practice

ARPA supports any changes in the existing ordinance or regulations that can bring benefits to public and/or improve pharmaceutical products' safety and quality. Introducing Code of Conduct or Code of Practice to manufacturer, wholesaler, retailer and distributor can certainly drive operational excellence and best practices among these key stakeholders in the pharmaceutical industry.

Thank you for your attention.

Yours sincerely,

Chiu Pik Kam
On Behalf of Asia Regulatory Professional Association

School of Pharmacy 藥劑學院
8/F, Lo Kwee-Seong Integrated Biomedical Sciences Building
Area 39, The Chinese University of Hong Kong
香港中文大學第三十九區羅桂祥綜合生物醫學大樓八樓
Tel 電話 : (852) 3943 6860
Fax 傳真 : (852) 2603 5295
Email 電郵: pharmacy@cuhk.edu.hk

May 26, 2014

Professor the Hon. Lee Kok Long, Joseph
Chairman, Bills Committee
Pharmacy and Poisons (Amendment) Bill 2014
Legislative Council Complex
1 Legislative Council Road
Central
Hong Kong

Re: Support of Pharmacy and Poisons Amendment Bill 2014

Dear Professor the Honorable Lee,

On behalf of the Chinese University of Hong Kong School of Pharmacy, I wish to express our support of the Pharmacy and Poisons Amendment Bill 2014 to implement some of the recommendations of the Review Committee to enhance the regulation of pharmaceutical products, as articulated in the 2010 report. We also noted that the Government has taken this opportunity to update some other provisions of the Pharmacy and Poisons Ordinance to bring these provisions in line with the prevailing regulatory framework in Hong Kong which we also support. This is an important step forward in ensuring access of the citizens of Hong Kong to quality and safe medicine that meets international standards. Timely approval of this Amendment is imperative given the proliferation of sources as well as distribution channels of pharmaceutical products today.

We must take a holistic view in the subject of the Amendment, which represents the best thinking and collective wisdom of leaders in the various sectors concerning pharmaceutical products and representatives in the profession and the pharmaceutical trade for the past three years. This is not the time to introduce other issues that may also be important, such as the need for a Pharmacy Council which should be carefully considered and deliberated in separate occasion. For now, it is important to focus on the substance of the Amendment and act in the best interest of the users of pharmaceutical products in Hong Kong.

To reiterate, the Chinese University of Hong Kong School of Pharmacy supports the Pharmacy and Poisons Amendment Bill 2014 with enthusiasm. Legislative approval of this Amendment will be a major milestone in modernizing the regulatory framework of pharmaceutical products in Hong Kong.

Thank you for your consideration. Please do not hesitate to contact me if additional information or clarification is needed.

Sincerely,

Vincent H.L. Lee, PhD, D.Sc.
Professor and Director
School of Pharmacy
Faculty of Medicine
The Chinese University of Hong Kong

香港製藥商會
Hong Kong Pharmaceutical Manufacturers Association
1/F., GMP Centre, 12 Dai Fu St., Tai Po Industrial Estate, Tai Po, New Territories, Hong Kong
香港新界大埔工業村大富街十二號 GMP 中心一樓
Tel:- (852) 2407 3271 Fax: (852) 2407 5707

27 May 2014

Prof. the Hon. Lee Kok Long, Joseph
Chairman, Bills Committee
Pharmacy and Poisons (Amendment) Bill 2014
Legislative Council Complex
1 Legislative Council Road
Central
Hong Kong

Via Email

Dear Prof Lee,

Ref:- **Pharmacy and Poisons (Amendment) Bill 2014**

On behalf of the Hong Kong Pharmaceutical Manufacturer Association (HKPMA), a body corporate representing a vast majority of the local Pharmaceutical Manufacturers, we write to express our support towards the legislative amendment on the Pharmacy and Poisons Ordinance and related Regulations as proposed by the Hong Kong Special Administrative Region Government (HKSAR). These amendments aim to enhance the existing regulation of pharmaceutical products in Hong Kong, and to ensure the quality and safety of pharmaceutical products in Hong Kong with the ultimate goal of safeguarding the integrity of public health. In addition, there is a need to amend the existing Pharmacy and Poisons Ordinances and Regulations, some of which are not updated and do not fully align with the changed dynamics in the pharmaceutical administration system.

Since the emergence of drug incidents dated back to March 2009, the local pharmaceutical industry has been committed in vigorously upholding the standard of pharmaceutical manufacturing in Hong Kong with an underlying goal of achieving the highly acclaimed PIC/S standard in collaboration with the Department of Health of HKSAR. As one of the key stake-holders in the delivery of healthcare service in Hong Kong, all HKPMA manufacturer members are committed to providing the quality and safe standard of pharmaceutical products and we have no reservation to support the amendment bills in particular of the following :-

1. GMP Upgrade:- the current Hong Kong GMP practice will be upgraded to widely-acclaimed international standard, ie PIC/S. Our manufacturing industry has

香港製藥商會
Hong Kong Pharmaceutical Manufacturers Association
1/F., GMP Centre, 12 Dai Fu St., Tai Po Industrial Estate, Tai Po, New Territories, Hong Kong
香港新界大埔工業村大富街十二號 GMP 中心一樓
Tel:- (852) 2407 3271 Fax: (852) 2407 5707

taken initiatives to pursue the PIC/S roadmap and is working hard to achieve this goal.

2. Clause 52 (PPR, Reg. 30A-F):- imposing a register of AP and revising the qualification required for registration as AP are to align with GMP upgrade to international standard ie. PIC/S. For example, the legal basis for the Qualified Person (similar status as AP) is defined in the DIRECTIVE 2001/83/EC. We suggest that a set of qualification requirements, including but not limited to registered pharmacists, of Authorized Persons (APs) and the course structure that would render qualified status to those personnel to be AP should be defined.
3. Clause 50(3) (PPR, Reg. 29(2)):- Manufacturing of pharmaceutical products must be carried out by licensed manufacturer. Manufacturing of pharmaceutical products other than extemporaneous preparations should be conducted by licensed manufacturer that complies with GMP for quality assurance to safeguard public health.
4. Clause 6 (PPO, Section 4B):- To empower the Board to promulgate corresponding Code of Practices (COPs) in order to provide practical guidance and enhance monitoring for the conduct of the activities of registered pharmacists, different licensed traders and traders subject to registration requirement (including manufacturers, wholesalers and retailers). This aims to ensure that all sectors and professionals from different pharmaceutical sectors operate in a responsible, ethical and professional manner for public health benefits.
5. Clause 21(PPO, Section 27):- To replace the text "Poison 毒藥" by "Prescription Drug 處方藥物" or "Drug under Supervised Sales 監督售賣藥物" depending on the sale restriction so as to avoid confusion that the pharmaceutical products might be harmful and unsuitable for use or consumption. This aims to align with international practices and to provide better understanding on the different levels of control of sales/supply of pharmaceutical products.
6. Control of pharmaceutical products:- the proposal to extend the validity of clinical trial certificate for new pharmaceutical products from two years to not more than five years will allow sufficient time to complete and to minimize interruptions to trials especially for those which provide life-saving treatment to patients.

Whilst supporting the amendment bill, we also have the following suggestion:-

1. Clause 30 (PPO, Section 34A):- regarding to Recovery of conviction-related expenses, we suggest to maintain the fixed "fine" with a higher penalty if required as it is not appropriate to empower the Court to order recovery from the defendant of all expenses incidental to the taking, examination and analyses of any sample of pharmaceutical products incurred by the Administration in respect of which the conviction is based

香 港 製 藥 商 會
Hong Kong Pharmaceutical Manufacturers Association
1/F., GMP Centre, 12 Dai Fu St., Tai Po Industrial Estate, Tai Po, New Territories, Hong Kong
香港新界大埔工業村大富街十二號 GMP 中心一樓
Tel:- (852) 2407 3271 Fax: (852) 2407 5707

and that the convicted trade will bear the "civil debt" which is something not required of in other criminal evictions in the HKSAR.

The pharmaceutical industry in Hong Kong has been committed to serving the public of Hong Kong and as such, the industry should be encouraged to operate in a professional, ethical and well-regulated manner to ensure the appropriate use of medicines and to support the provision of high quality healthcare. This commitment should apply to ALL sectors in the pharmaceutical industry. HKPMA therefore strongly support the above-mentioned amendment bills whilst hoping that the proposed suggestions per above be duly considered and adopted thereof.

Thank you for your attention.

Yours sincerely,

For and on behalf of
Hong Kong Pharmaceutical Manufacturers Association

Celine H.K. Cheng
BPharm, MRPharmS, PhD, MBA
President

香港製藥商會
Hong Kong Pharmaceutical Manufacturers Association
1/F., GMP Centre, 12 Dai Fu St., Tai Po Industrial Estate, Tai Po, New Territories, Hong Kong
香港新界大埔工業村大富街十二號 GMP 中心一樓
Tel:- (852) 2407 3271 Fax: (852) 2407 5707

7 July 2014

Prof. the Hon. Lee Kok Long, Joseph
Chairman, Bills Committee
Pharmacy and Poisons (Amendment) Bill 2014
Legislative Council Complex
1 Legislative Council Road
Central
Hong Kong

Via Email

Dear Prof Lee,

Ref:- **Pharmacy and Poisons (Amendment) Bill 2014 – Written Order**

On behalf of the Hong Kong Pharmaceutical Manufacturer Association (HKPMA), a body corporate representing a vast majority of the local Pharmaceutical Manufacturers, we write to express our support towards incorporating the requirement of Written Order of Drugs into the Code of Practice for licensed manufacturers as proposed by the government of HKSAR. The written order requirement aims to reduce errors throughout the supply chain to ensure the right drugs are delivered to their recipients.

As one of the major stake-holders in the delivery of healthcare service in Hong Kong, we can see the following benefits on imposing of written orders of drugs:-

1. Eliminating errors due to miscommunication of verbally orders;
2. Allowing cross-checking by both parties concerned in placing and receiving orders to ensure the accuracy of the orders;
3. Allowing traceability in the case of any complaints or errors;
4. Improving work efficiency as orders are placed and delivered right on first time.

We would like to stress that from the perspective of local manufacturers, as compared with phone order, placing orders by way of written order will only improve the efficiency in the supply chain by reducing error in delivery and it will not cause any undue delay in the whole logistics and supply chain including the delivery of drugs.

Thank you for your attention.

Yours sincerely,

For and on behalf of
Hong Kong Pharmaceutical Manufacturers Association

Celine Cheng

Celine H.K. Cheng
BPharm, MRPharmS, PhD, MBA
President

Dean's Office 院長室

Shatin, New Territories, Hong Kong
香港新界沙田

Tel 電話 : (852) 2632 1339
Fax 傳真: (852) 2647 1557

Professor Francis K.L. Chan, JP
MBChB(Hons), MD, DSc, FRCP(Lond), FRCP(Edin), FRCP(Irel), FACG, FHKCP, FHKAM(Med)
Dean, Faculty of Medicine
Choh-Ming Li Professor of Medicine & Therapeutics

陳家亮教授 太平紳士
醫學院院長
卓敏內科及藥物治療學講座教授

29th May 2014

Prof Hon Joseph LEE Kok-long
Chairman
Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014
Legislative Council Complex
1 Legislative Council Road
Central, Hong Kong

Dear Prof Lee,

RE: Support Pharmacy and Poisons (Amendment) Bill 2014 on Extension of the Validity of Clinical Trial Certificate/Medicinal Test Certificate

The Faculty of Medicine of The Chinese University of Hong Kong, being highly active in conducting clinical research, supports the Pharmacy and Poisons (Amendment) Bill 2014 on extending the validity of clinical trial certificate/medicinal test certificate from "not more than 2 years" to "not more than 5 years".

For most clinical trials, the current two-year validity of the clinical trial certificate/ medicinal test certificate is often too short for completion of a clinical trial. The proposed amendment will reduce the administration workload as the applicant does not need to apply for a certificate again if a clinical trial lasts for more than two years.

Sincerely

Professor Francis K L Chan
Dean, Faculty of Medicine
Choh-Ming Li Professor of Medicine & Therapeutics

SOCIETY FOR COMMUNITY ORGANIZATION
香港社區組織協會
九龍何文田公主道五十二號三樓 52 Princess Margaret Rd., 3/Fl., Homantin, Hong Kong. Tel: (852) 2713 9165 Fax: (852) 2761 3326 E-mail: soco@pacific.net.hk Website: www.soco.org.hk

立法會
《2014 年藥劑業及毒藥(修訂)條例草案》委員會
主席
李國麟議員, SBS, JP, PhD, RN

李主席：

長期病患者關注醫療改革聯席
對《2014 年藥劑業及毒藥(修訂)條例草案》的意見

長期病患者關注醫療改革聯席（聯席）由十二個病人及關注病人權益組織組成[1]，自 2005 年成立至今，一直關注醫療改革議題，並透過不同的行動，反映病人對於醫療改革的意見。聯席關注立法會現正審議《2014 年藥劑業及毒藥(修訂)條例草案》（條例草案），由於該條例草案涉及病人權益，聯席現致函　閣下表達對條例草案的意見。

2009 年初，本港發生一連五宗的藥物事故，包括：歐化藥業事故：供應含超標毛霉菌的別嘌醇、萬輝藥業事故：藥物有效期與化驗報告不符、琪寶製藥事故：供應醫管局未註冊的甲福明、源輝貿易事故：無牌包裝藥物及竄改有效期、大塚製藥事故：藥物標籤與容量不符。其中歐化藥業事故對病人造成的影響最為嚴重，至少八名病人疑因服食含超標毛霉菌的別嘌醇而死亡，超過四萬名病人需要更換藥物。由此可見，藥物製造、貯存、經銷、零售、監控等過程，都與病人的生命安危息息相關。

為加強對藥物的監管，香港藥物監管制度檢討委員會（檢討委員會）於 2009 年 12 月發表報告，提出合共 75 項建議的改善措施，當中 16 項必須修訂現行的藥劑業及毒藥條例及其附屬法例。聯席完全認同檢討委員會報告中所提出的改善

[1] *長期病患者關注醫療改革聯席成員團體：慧進會（中風及腦損人士自助組織）、心血會有限公司（血癌病人自助組織）、香港哮喘會（哮喘病人自助組織）、香港復康聯盟（殘疾人士自助組織）、香港新聲會（喉癌病人自助組織）、香港強脊會（強直性脊椎炎病人自助組織）、銀屑護關會（銀屑病關節炎病人自助組織）、香港肌健協會（肌肉萎縮症病人自助組織）、香港肝臟移植協康會（肝臟移植病人自助組織）、神經纖維瘤互助小組（神經纖維瘤病人自助組織）、關懷愛滋（愛滋病感染者支援組織）、香港社區組織協會（病人權益協會）*

措施建議，並認為有關政府應盡快落實執行上述建議，才能全面保障病人權益。

對於現時正在審議中的條例草案，聯席認為既然 75 項建議中有 16 項，必須透過修訂現行的藥劑業及毒藥條例及其附屬法例才能落實推行，因此聯席希望閣下主持的法案委員會，在諮詢相關持份者後，盡快完成審議條例草案程序，令法案盡早獲得通過，致令病人權益及早獲得保障，避免重蹈覆轍，減少再次發生嚴重藥物事故禍及病人的機會。

事實上，由 2009 年 12 月檢討委員會作出建議後，政府委託顧問公司進行規管影響評估，評估報告歷時三年才於 2013 年 1 月完成，應該已經深入了解到相關持份者的意見，及全面分析了進行規管的影響。而政府基於評估結果及相關持份者的意見，提出條例草案，也應該已經平衡了各方利益，在保障市民生命健康及病人權益的大前提下，加強對現有藥物監管制度的規管。

聯席參閱業界關注事項和當局的回應（立法會 CB(2)1522/13-14(01)號文件），認為業界對條例草案內相關條文表示支持的多於反對的。同時，經政府解釋及澄清後，曾表示對相關條文表示關注或反對的業界，一般都表示明白及滿意有關澄清。最後，在 2014 年 5 月 20 日的法案委員會會議上，一眾持份者均已發表意見，當中大部份意見早前也曾表達，及已獲當局回應。 閣下主持的法案委員會既然已經聽取各方意見，聯席希望委員會可盡快審議條例草案條文。

對條例草案內個別較有爭議的條文，聯席有以下意見：

條例草案的相關條文	建議修訂	意見
草案第 52 條（《規例》第 30A 至 F 條）	獲授權人制度： 持牌製造商須僱用最少 1 名獲授權人，以確保和證明藥劑製品是按照藥劑製品的《GMP 指引》製造和檢查的。同時也規定管理局須備存獲授權人名冊，增訂條文列明註冊為獲授權人的申請程序和資歷要求，以及其他註冊事宜。	聯席認為製藥過程涉及多個相關專業知識範疇，包括藥劑、醫學、化學、生化工程、微生物學。因此，有資格擔任獲授權人可以是藥劑師，也可以是上述其他相關專業知識領域的人士，並已修畢相關課程及取得有關資格。事實上，聯席認為建議修訂的獲授權人制度（包括可申請成為獲授權人的專業資格）是參照了歐洲聯盟同樣的制度[2]。另外，獲授權人受到註冊制度監管。因此，聯席支持設立獲授權人制度，認為這制度可保障製藥過程符合《GMP 指引》。

[2]詳情可參閱：http://www.qp-association.eu/qualified_person_qp_regulation.html

草案第 6 條（《條例》第 4B 條）	賦權管理局發出《行為守則》／《執業守則》，為各類別的持牌及列載藥商和註冊藥劑師提供指引。	聯席認為透過守則一類的指引文件，可以在有關法例的原則下，較詳細列出對有關人士或機構的行為或執業要求。類似的守則文件常見於規管及指引醫療人員或機構，如《香港註冊醫生專業守則》、《私家醫院、護養院和留產院實務守則》等。 由於這些專業守則並非法例條本，又需要按社會情況適時作出修訂，因此修訂守則根本無須通過立法程序，只要在獲賦權的有關當局在充份諮詢持份者後作出修訂便可。[3] 據政府的回應，藥劑及毒藥管理局（管理局）為制定行為《行為守則》及《執業守則》，已於過去兩年成立由不同持份者組成的工作小組，並透過諮詢會議及公眾諮詢等收集各方意見。聯席認為有關守則已作充份諮詢。 聯席支持由管理局發出《行為守則》及《執業守則》的建議，認為有助規範持牌及列載藥商和註冊藥劑師。
草案第 59 條（《規例》第 36B 條）	把臨床試驗證明書及藥物測試證明書的最長有效期由兩年延長至五年。	聯席支持將臨床試驗／藥物測試證明書的有效期由現時的兩年延長至五年。聯席認為延長有關證明書的有效期可給予試驗及測試項目有更多時間取得充份的研究數據，以確定藥物對疾病治療是否有效。
草案第 23 條（《條例》第 29(1B)條）	毒藥及藥劑製品的註冊法律程序： 訂明就毒藥表或載列於根據《條例》第29(1)條訂立的規例的任何	新研發藥物如能通過臨床試驗及測試，已有充足臨床實證證明該藥物達致認可的安全程度及疾病治療效果，再經把關的食物及衛生局局長批准，及管理局訂立規例作出後，理應可以註冊，引入本

[3]例如香港醫生專業守則內列明：醫務委員會了解醫學倫理須隨着社會理境的轉變而予以更新，因此需要不斷檢討守則內容。在制定守則時，亦會參考一些國際慣例、本地同業意見、法律規定、公眾期望及道德原則（第 4 頁）。醫務委員會最近對守則作出修訂是在 2009 年 1 月。

	物質／物品名單的修訂，經食物及衞生局局長批准後，可由管理局訂立規例作出，並由立法會以先訂立後審議的程序處理。	港讓有需的病人使用。 聯席考慮到近年立法會議員的工作煩重，審議個別議題的時間甚長，如有關的新藥物註冊要等候立法會完成審議後才引入使用，一些有需要使用新研發藥物的病人便會未能盡快使用這些藥物，甚而可能影響病情。 聯席支持立法會以先訂立後審議的程序，處理毒藥及藥劑製品的註冊程序。聯席認為以先訂立後審議的程序，較現時先審議後訂立的程序，更能加快讓有需要的病人盡快可以使用已經通過各專業部門把關的新研發藥物。

另外，聯席就條例草案的其他關注事項有以下意見：

以書面方式訂購藥物	藥劑製品出現問題而需回收的情況時有所聞。如醫療機構（包括醫院、醫療集團、個別醫生診所）在訂購藥物時有書面紀錄，藥商便可按紀錄通知醫療機構停止使用有問題的藥劑製品。另外，按香港醫學會發出的《良好施行配藥手冊(第二版)》列明：「應由主診醫生負責訂購藥物，我們建議以書面方式向藥物供應商訂購，並保留訂購記錄以核對所供應的藥物及以作將來參考之用。」 聯席支持以書方式訂購藥物，認為可以減低藥物供應過程每個環節的潛在風險。
醫藥分家及成立藥劑局	聯席同意推行醫藥分家，透過醫生及藥劑兩個專家互相監察，以更能保障病人權益。現時在公營醫療機構、私家醫院、及大型醫療集團均以醫藥分家的做法為病人提供服務。政府及業界應集中商討如何在配合香港實際的情況下，在個別醫生診所中推行醫藥分家。 至於成立藥劑局，聯席認為政府應與藥劑專業詳細商討有關安排，而現時三個主要藥劑專業團體均有其操守文件，有關專業團體也應先統一對藥劑師專業的操守要求，才能作為討論成立藥劑局的基礎。

	聯席認為，推行醫藥分家及成立藥劑局都並非短期內可以完成，兩項議題的討論亦獨立於對條例草案的審議。因此，聯席認為對條例草案的審議，不應與上述兩項議題掛勾。

對於有意見建議政府應撤回條例草案，聯席表示絕對反對。任何撤回條例草案或拖延條例草案的審議，只會阻慢落實保障病人及市民生命健康的法例。聯席在此懇請　閣下及各法案委員會委員以保障病人及市民的原則為優先考慮，對條例草案進行應有的審議。

長期病患者關注醫療改革聯席　謹上

副本呈：《2014年藥劑業及毒藥(修訂)條例草案》委員會委員

聯絡人：香港社區組織協會幹事彭鴻昌先生
（聯絡地址：九龍何文田公主道52號三樓）
（聯絡電話：27139165）

二零一四年六月三日

The University of Hong Kong
Department of Pharmacology & Pharmacy
香港大學
藥理及藥劑學系

2/F Laboratory Block
21 Sassoon Road
Hong Kong

Telephone: (852) 2819 9441
Fax: (852) 2817 0859
Email: wongick@hku.hk

4th June 2014

Prof. the Hon. LEE Kok Long, Joseph
Chairman, Bills Committee
Pharmacy and Poisons (Amendment) Bill 2014
Legislative Council Complex
1 Legislative Council Road
Central
Hong Kong

Dear Chairman of Bills Committee and Legislative Council members,

Re: Support for Pharmacy and Poisons Amendment Bill 2014.

On behalf of the Department of Pharmacology & Pharmacy of the University of Hong Kong, I am writing in strong support for the Pharmacy and Poisons Amendment Bill 2014 (PPAB) which sets out to implement recommendations put forward by the Review Committee on the Regulation of Pharmaceutical Products in Hong Kong in December 2009.

The PPAB has suitably addressed the urgent need for enhancing and updating the regulation of pharmaceutical products in Hong Kong by strengthening the regulation of the pharmaceutical trade, including manufacturers, wholesalers and retailers. The promulgation of the code of practice for the trade as well as pharmacists would also upgrade the standards of the pharmaceutical profession. This will certainly offer better protection to the public. I also fully support other amendments such as modifying the definition of pharmaceutical product, enhancing the regulation of clinical trials, revising the procedures to entering new entities under the Poisons List. These measures are not only in line with international practice, but also streamline the overall regulatory process.

I understand that the Food and Health Bureau is currently conducting a Strategic Review on Healthcare Manpower Planning and Professional Development. I fully trust that the matter regarding the formation of the Pharmacy Council will be managed appropriately in the not too distant future. Hence, there should be no delay in the approval and amendment of the PPAB.

In summary, the Department of Pharmacology & Pharmacy of the University of Hong Kong offers its full support for the PPAB.

Yours sincerely,

Ian Chi Kei Wong
Professor and Head of Department of Pharmacology and Pharmacy
University of Hong Kong

4 June 2014

Prof. the Hon. LEE Kok Long, Joseph
Chairman, Bills Committee
Pharmacy and Poisons (Amendment) Bill 2014
Legislative Council Complex
1 Legislative Council Road
Central Hong Kong

Dear Chairman of Bills Committee and Legislative Council members

Re: Support for the Pharmacy and Poisons Amendment Bill 2014

On behalf of the Department of Pharmacology and Pharmacy of the University of Hong Kong, the School of Pharmacy of the Chinese University of Hong Kong, the Pharmaceutical Society of Hong Kong, the Society of Hospital Pharmacists, the Hong Kong Association of the Pharmaceutical Industry, the College of Pharmacy Practice and Hong Kong Pharmaceutical Manufacturers Association, we wish to express our strong support for the Pharmacy and Poisons Amendment Bill 2014 (PPAB) which sets out to implement recommendations put forward by the Review Committee on the Regulation of Pharmaceutical Products in Hong Kong in December 2009.

The PPAB appropriately strengthens the regulations that govern the pharmaceutical trade including manufacturers, wholesalers and retailers. In our opinion, the PPAB has a definite and important role in safeguarding the health of the general public.

There are a few minor amendments required in the PPAB which we have stated at the consultation on 20 May 2014 and also subsequently communicated to the Drug Office by individual organization. We believe these minor amendments can be sorted out and should not impede the passage of the PPAB.

The pharmacy profession always acts in the best interest of the public by adhering to best practice, which is mandatory to ensure patient drug safety. Therefore, we offer our strongest support for the PPAB.

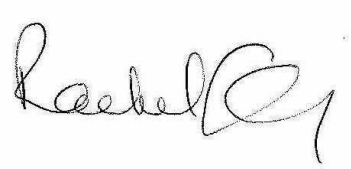
Yours sincerely

Prof Ian C K Wong
Head of Dept of Pharmacology and Pharmacy
The University of Hong Kong

Professor Vincent Lee
Director of School of Pharmacy
The Chinese University of Hong Kong

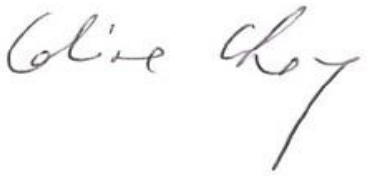
Ms Mary C Cheng
President
Pharmaceutical Society of Hong Kong

Mr William Chui
President
Society of Hospital Pharmacists



Mrs. Rachel Frizberg
President
Hong Kong Association of
the Pharmaceutical Industry

Dr Benjamin Lee
Chairman of Council
College of Pharmacy Practice



Dr Celine Cheng
President
Hong Kong Pharmaceutical Manufacturers Association

香港復康會
The Hong Kong Society for Rehabilitation

Tel +852 2855 9360
Fax +852 2855 1947
香港九龍藍田復康徑7號
香港復康會藍田綜合中心1樓
1/F, HKSR Lam Tin Complex
7 Rehab Path, Lam Tin
Kowloon, Hong Kong
本會為有限公司註冊的慈善團體
A registered charitable organization incorporated with limited liability

本會檔案:SR/167/14

立法會
《2014 年藥劑業及毒藥(修訂)條例草案》委員會
主席
李國麟議員 SBS, JP, PhD, RN

李主席：

香港復康會

對《2014 年藥劑業及毒藥(修訂)條例草案》的意見

香港復康會於 1959 年成立，致力為殘疾人士、長者、慢性病患者及其照顧者提供服務，提升他們的生活質素，並倡議他們在社會、公民、經濟各範疇的平等機會。香港復康會(本會)一直關注醫療和復康的議題，並透過與不同的服務使用者團體一起倡議更有利殘疾人、長者和慢性病患者復康的政策。本會關注立法會現正審議《2014 年藥劑業及毒藥(修訂)條例草案》（簡稱條例草案），由於該條例草案涉及病人的福祉，本會希望能向　閣下表達對條例草案的意見。

2009 年本港發生多宗的藥物事故，其中歐化藥業的事故對病人造成的影響最為嚴重，至少八名病人疑因服食含超標毛霉菌的別嘌醇而死亡，超過四萬名病人需要更換藥物。由此可見，藥物製造、貯存、經銷、零售、監控等過程，都與病人的生命安危密不可分。

為加強對藥物的監管，香港藥物監管制度檢討委員會（檢討委員會）於 2009 年 12 月發表報告，提出合共 75 項改善建議，當中 16 項必須修訂現行的藥劑業及毒藥條例及其附屬法例。本會認同檢討委員會報告中所提出的改善措施建議，並認為有關政策應盡快落實執行，全面保障病人權益，減少再次發生嚴重藥物事故禍及病人的機會。

本會得知，由 2009 年 12 月檢討委員會作出建議後，政府委託顧問公司進行規管影響評估，評估報告歷時三年於 2013 年 1 月完成，相信已經深入了解相關持份者的意見，及全面分析了進行規管的影響，本會希望法案委員會盡快完成審議。

香港復康會
The Hong Kong Society for Rehabilitation

本會對條例草案部份條文及其他關注事項有以下意見：

1. 草案第 52 條（《規例》第 30A 至 F 條）

建議修訂：獲授權人制度 -- 持牌製造商須僱用最少一名獲授權人，以確保和證明藥劑製品是按照藥劑製品的《GMP 指引》製造和檢查的。同時也規定管理局須備存獲授權人名冊，增訂條文列明註冊為獲授權人的申請程序和資歷要求，以及其他註冊事宜。

本會意見：支持設立獲授權人制度，認為這制度可保障製藥過程符合《GMP 指引》。本會進一步認為製藥過程涉及多個相關專業知識範疇，包括藥劑、醫學、化學、生化工程、微生物學等等。因此，有資格擔任獲授權人可以是藥劑師，也可以是上述其他相關專業知識領域的人士，並已修畢相關課程及取得有關資格。特區政府可參考其他經濟相若的國家的做法。這可確保有足夠的專業人士能擔任授權人，令制度能盡快落實。

2. 草案第 59 條（《規例》第 36B 條）

建議修訂：把臨床試驗證明書及藥物測試證明書的最長有效期由兩年延長至五年。

本會意見：支持將臨床試驗／藥物測試證明書的有效期由現時的兩年延長至五年。本會認為延長有關證明書的有效期可給予試驗及測試項目有更多時間取得充份的研究數據，以確定藥物對疾病治療是否有效。

3. 草案第 23 條（《條例》第 29(1B)條）

建議修訂：毒藥及藥劑製品的註冊法律程序 -- 訂明就毒藥表或載列於根《條例》第29(1)條訂立的規例的任何物質／物品名單的修訂，經食物及衞生局局長批准後，可由管理局訂立規例作出，並由立法會以先訂立後審議的程序處理。

本會意見：支持立法會以先訂立後審議的程序，處理毒藥及藥劑製品的註冊程序。新研發藥物如能通過臨床試驗及測試，已有充足臨床實證證明該藥物達致認可的安全程度及疾病治療效果，再經由把關的食物及衞生局局長批准，及管理局訂立規例作出後，理應可以註冊，引入本港讓有需要的病人使用。本會考慮如有關的新藥物註冊要等候立法會完成審議後才引入使用，一些有需要使用新研發藥物的病人便會有可能因等候立法會審議而未能盡快使用，甚而可能影響病情。

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4. 其他關注的事項

以書面方式訂購藥物：本會支持這做法。藥劑製品出現問題而需回收的情況時有所聞。本會認為如醫療機構（包括醫院、醫療集團、個別醫生診所）在訂購藥物時有書面紀錄，倘出現任何事故時，藥商可按據書面紀錄通知醫療機構停止使用有問題的藥劑製品。

另外，按香港醫學會發出的《良好配藥操作手冊(第二版)》列明：「應由主診醫生負責訂購藥物，我們建議以書面方式向藥物供應商訂購，並保留訂購記錄以核對所供應的藥物及以作將來參考之用。」本會深表贊同。

本會在此懇請　閣下及各法案委員會委員以保障病人及市民的生命健康和權益的原則為優先考慮，對條例草案進行應有的審議。

香港復康會主席　張偉良　謹上

二零一四年六月四日

HKAPI
香港科研製藥聯會
The Hong Kong Association of The Pharmaceutical Industry
UNIT A, 20/F., TIMES MEDIA CENTRE, 133 WANCHAI ROAD, WANCHAI, HONG KONG.
TEL: (852) 2528 3061/2 FAX: (852) 2865 6283 WEBSITE: www.hkapi.hk

Position Paper on the Pharmacy and Poisons (Amendment) Bill 2014

Formed in 1968, the Hong Kong Association of the Pharmaceutical Industry(HKAPI), represents 40 international companies engaged in the research and development of pharmaceuticals including the world's top 20 (appendix 1). Our member companies, including regional distributors, provide over 70% of the prescription medicines and distributing over 80% of imported pharmaceutical products in Hong Kong.

The principal consideration of the Association when examining the proposed amendments to the Pharmacy and Poisons Ordinance is, whether these proposed changes can practically enhance the existing supply chain system and further protecting patients safety in Hong Kong.

In addition, Pharmaceutical Industry is the second highly regulated industry in the world as Aviation is number one. There are international practices which were developed for decades, such as **Good Clinical Practice** for clinical trial, **Good Manufacturing Practice** for drug manufacturing, **Good Distribution Practice** for pharmaceutical and medical device distribution. Whether these changes are in line with international practices and whether the industry can comply with the regulations to achieve the objectives of the legislation are also considerations.

HKAPI supports the legislative amendments put forward by the Food and Health Bureau in response to the recommendations made by Review Committee on the Regulation of Pharmaceutical Products in Hong Kong.

Specifically, we have some comments on the following proposed amendments:

Clinical trial certificate

It is proposed that the maximum validity period of any clinical trial certificate to be extended from 2 to 5 years. It takes on average 10 to 12 years for a new drug to be developed, which include three phases of clinical trial. All approved clinical trials in Hong Kong are required to follow **Good Clinical Practice (GCP)** guidelines which define the standards on how clinical trials should be designed and conducted by the

HKAPI
香港科研製藥聯會
UNIT A, 20/F., TIMES MEDIA CENTRE,
133 WANCHAI ROAD, WANCHAI, HONG KONG.
TEL: (852) 2528 3061/2
FAX: (852) 2865 6283
WEBSITE: www.hkapi.hk

investigators. Investigators also need to submit a progress report every year on the clinical research to the health authority. The application for a renewal of the clinical trial certificate will interrupt the trial until a renewal is granted and the administrative approval procedure has to be repeated every two years. Extending the validity of the clinical trial certificate can reduce unnecessary administrative burden without reducing the safety monitoring of clinical trials, and more importantly, can increase Hong Kong's attractiveness and capacity for medical research and clinical trial.

Negative vetting for new drug registration

To improve the efficiency of the drug registration system while maintaining appropriate regulatory control, employing negative vetting procedure could be the first step for Hong Kong to catch up with international regulatory practice in drug registration.

It is proposed by World Health Organization (WHO) to evaluate drug registration by efficacy, safety and quality. The evaluation is a pure scientific evaluation based on clinical papers that in most countries, the drug registration decisions are made under the health authorities without any intervention of administrative authorities, not to mention it has to go through the legislative procedure. Currently in Europe, the US and some advanced Asian countries such as Korea, Japan, Taiwan and Singapore...etc, decision of drug registration is designated to the Health Authorities.[1]

In Hong Kong, the applicants of drug registration need to provide two Certificates of Pharmaceutical Products (CPP) issued by ICH countries[2] when applying for drug registration. The application will then be evaluated by the Registration Committee, Poisons Committee and the Pharmacy and Poisons Board. The scientific evaluation

[1] None of the legislative bodies in Australia, Korea, Singapore, Taiwan, EU, and the States plays a role in the drug approving procedure. The classification and approval of NCE falls entirely under the responsibility of the Health Authority. It is no Legislative procedures during the drug evaluation process.

[2] The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of pharmaceutical product registration. ICH countries refer to countries with their health authorities using the ICH guidelines for pharmaceutical product registration.

HKAPI
香港科研製藥聯會
UNIT A, 20/F., TIMES MEDIA CENTRE,
133 WANCHAI ROAD, WANCHAI, HONG KONG.
TEL: (852) 2528 3061/2
FAX: (852) 2865 6283
WEBSITE: www.hkapi.hk

takes 8-12 months on average. If approved, the whole registration procedure will be completed with the legislative approval procedure in the Legislative Council (LegCo).

We agree with the negative vetting procedure for new drug registration approval as it also avoids delaying in registration caused by ad hoc agenda items at LegCo meetings and increases the efficiency of the new drug registration process as we found that some new drugs, including those for the treatment of cancer, had taken 3 to 9 months to be tabled in LegCo during 2011-2012, and with recent debates in important political agenda, the process can be futher delayed.

Written Order

Drug incident in 2009 proved that things can go wrong if we rely too much on a single procedure and person. **Good Distribution Practice (GDP), which** has been developed for more than two decades, with guidelines under WHO and European Commission, is a quality warranty system that includes requirements for purchase, receiving, storage and export of drugs, by which order verification and delivery verification are important parts of it.

Written order is an important and integral part of the supply chain management of pharmaceutical products under GDP for order verification. The guidelines on GDP of medicinal products published by the European Commission states that '**Written documentation should prevent errors from spoken communication and permits the tracking of relevant operations during the distribution of medicinal products.**' In Hong Kong, the Hong Kong Medical Association recommended in their Good Dispensing Practice Manual that the ordering of drugs from suppliers should be made in writing, the written orders should be kept for verification and all practising doctors should comply with the Good Dispensing Practice Manual.

In general, a written order contains the name of the product, dosage, pack size and quantity. Although the information required for an order is not a lot, wrong orders happen from time to time, and without written order, there would not be any solid reference to verify the order during delivery.

For other products, wrong delivery can be returned. However, it is not the case for

HKAPI
香港科研製藥聯會
UNIT A, 20/F., TIMES MEDIA CENTRE,
133 WANCHAI ROAD, WANCHAI, HONG KONG.
TEL: (852) 2528 3061/2
FAX: (852) 2865 6283
WEBSITE: www.hkapi.hk

pharmaceutical products as there are stringent requirements on the storage of pharmaceuticals, including the control on temperature and humidity and the **First In First Out** procedure[3] has to be followed. For example, vials needed to be refrigerated between 2 to 8 'C. In some cases, the returned pharmaceutical products cannot be re-distributed. Relying on verification at delivery without a written order is not a comprehensive supply chain management. Written order can certainly reduce the miscommunication and errors in drug ordering.

We understand that this requirement may require changing ordering practices. However, this is worth implementing in view of its enhancement to patient safety by order validation, and reduction of wastage caused by wrong orders, as drugs are valuable resources for patients. Members of our Association who distribute more than 80% of drugs in Hong Kong are dedicated to enhance our workflow to cope with this requirement.

Authorized Person (AP)

In accordance with the WHO guidelines and European Commission's requirements, the release of pharmaceutical products should be the responsibility of the AP as a part of **Good Manufacturing Practice**. To qualify as an AP, the person needs to have the knowledge of pharmacy, pharmacology, microbiology, etc and have relevant training and working experience in quality assurance and drug manufacturing process. (Please refer to Appendix 2 for the Personnel Requirements provided in the WHO guidelines on quality assurance of pharmaceuticals) In many countries, the eligibility of an AP needs to be certified by professional bodies. It is reasonable to require each licensed manufacturer to employ at least one AP.

Conclusion

The Association supports the proposed legislative amendments which aim to enhance regulatory monitoring that span across the whole supply chain including the regulations for manufacturers, wholesalers, retailer of pharmaceutical products and

[3] First In First Out: An inventory control system where products are retrieved according to the date of entry into the warehouse, products stored first will be sent out first. When there is discrepancy between the manufacturing date and the storage entry date, products should be retrieved according to the manufacturing date.

HKAPI
香港科研製藥聯會
UNIT A, 20/F., TIMES MEDIA CENTRE,
133 WANCHAI ROAD, WANCHAI, HONG KONG.
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FAX: (852) 2865 6283
WEBSITE: www.hkapi.hk

pharmacists. We believe that the amendments can bring these provisions in line with international regulatory practice which is necessary to safeguard public health.

The Association is disappointed with the delay in passing the above legislative proposals. Despite the fact that the drug incidents happened six years ago, the necessary legislative amendments still have not been made and there is still no timetable for the implementation of some of the recommended changes in regulations and policies.

We reckon that now is a good opportunity to amend the Pharmacy and Poisons Ordinance and Regulations in order to improve the overall standard of supply chain management for pharmaceutical products in Hong Kong and further enhance drug safety for patients in Hong Kong.

HKAPI
香港科研製藥聯會

UNIT A, 20/F., TIMES MEDIA CENTRE,
133 WANCHAI ROAD, WANCHAI, HONG KONG.
TEL: (852) 2528 3061/2
FAX: (852) 2865 6283
WEBSITE: www.hkapi.hk

Appendix 1

THE HONG KONG ASSOCIATION OF THE PHARMACEUTICAL INDUSTRY

FULL MEMBERS (40)

A. MENARINI HONG KONG LIMITED
ABBVIE LIMITED
ALCON HONG KONG LIMITED
ALLERGAN HONG KONG LIMITED
ASTELLAS PHARMA HONG KONG COMPANY LIMITED
ASTRAZENECA HONG KONG LIMITED
B. BRAUN MEDICAL (H.K.) LTD
BAUSCH & LOMB (HK) LTD
BAXTER HEALTHCARE LTD
BAYER HEALTHCARE LTD
BOEHRINGER INGELHEIM (HK) LTD
BRISTOL-MYERS SQUIBB PHARMA (HK) LIMITED
CELGENE LIMITED
CSL BEHRING ASIA PACIFIC LIMITED
DAIICHI SANKYO HONG KONG LIMITED
EISAI (HK) CO LTD
ELI LILLY ASIA INC
FERRING PHARMACEUTICALS LTD
FRESENIUS-KABI H.K. LIMITED
GALDERMA HONG KONG LIMITED
GILEAD SCIENCES HONG KONG LIMITED
GLAXOSMITHKLINE LTD
IPSEN PHARMA (HONG KONG)
JANSSEN, A DIVISION OF JOHNSON & JOHNSON (HK) LTD
KYOWA HAKKO KIRIN (HONG KONG) CO LTD
LUNDBECK EXPORT A/S
MEDINOVA AG
MERCK PHARMACEUTICAL (HK) LIMITED
MERCK SHARP & DOHME (ASIA) LTD
MUNDIPHARMA (HONG KONG) LIMITED
NOVARTIS PHARMACEUTICALS (HK) LTD
NOVO NORDISK HONG KONG LTD
OTSUKA PHARMACEUTICAL (H.K.) LTD
PFIZER CORPORATION HONG KONG LIMITED
RECKITT BENCKISER HONG KONG LTD
ROCHE HONG KONG LIMITED
SANOFI-AVENTIS HONG KONG LIMITED
SERVIER HONG KONG LTD
TAKEDA PHARMACEUTICALS (HONG KONG) LIMITED
UCB PHARMA (HONG KONG) LTD

AFFILIATE MEMBER (1)

AMGEN (ASIA) LIMITED

Appendix 2

Quality assurance of pharmaceuticals

A compendium of guidelines
and related materials

Volume 2, 2nd updated edition

Good manufacturing practices
and inspection

World Health Organization

of each other. In large organizations, it may be necessary to delegate some of the functions; however, the responsibility cannot be delegated.

9.7 Key personnel responsible for supervising the manufacture and quality control of pharmaceutical products should possess the qualifications of a scientific education and practical experience required by national legislation. Their education should include the study of an appropriate combination of:

(a) chemistry (analytical or organic) or biochemistry;
(b) chemical engineering;
(c) microbiology;
(d) pharmaceutical sciences and technology;
(e) pharmacology and toxicology;
(f) physiology;
(g) other related sciences.

They should also have adequate practical experience in the manufacture and quality assurance of pharmaceutical products. In order to gain such experience, a preparatory period may be required, during which they should exercise their duties under professional guidance. The scientific education and practical experience of experts should be such as to enable them to exercise independent professional judgement, based on the application of scientific principles and understanding to the practical problems encountered in the manufacture and quality control of pharmaceutical products.

9.8 The heads of the production and quality control generally have some shared, or jointly exercised, responsibilities relating to quality. These may include, depending on national regulations:

(a) authorization of written procedures and other documents, including amendments;
(b) monitoring and control of the manufacturing environment;
(c) plant hygiene;
(d) process validation and calibration of analytical apparatus;
(e) training, including the application and principles of quality assurance;
(f) approval and monitoring of suppliers of materials;
(g) approval and monitoring of contract manufacturers;
(h) designation and monitoring of storage conditions for materials and products;
(i) performance and evaluation of in-process controls;
(j) retention of records;
(k) monitoring of compliance with GMP requirements;
(l) inspection, investigation and taking of samples in order to monitor factors that may affect product quality.

9.9 The head of the production generally has the following responsibilities:

HKAPI
香港科研製藥聯會
The Hong Kong Association of The Pharmaceutical Industry
UNIT A, 20/F., TIMES MEDIA CENTRE, 133 WANCHAI ROAD, WANCHAI, HONG KONG.
TEL: (852) 2528 3061/2 FAX: (852) 2865 6283 WEBSITE: www.hkapi.hk

9 July 2014

Prof. the Hon. Lee Kok Long, Joseph
Chairman, Bills Committee
Pharmacy and Poisons (Amendment) Bill 2014
Legislative Council Complex
1 Legislative Council Road
Central
Hong Kong

Dear Prof Lee,

Pharmacy and Poisons (Amendment) Bill 2014 – Written Order

The Hong Kong Association of the Pharmaceutical Industry (HKAPI), represents 40 international companies engaged in the R&D of pharmaceuticals as well as regional distributors that provide over 70% of the prescription medicines and distribute over 80% of imported pharmaceutical products in Hong Kong, supports the proposed amendment to the Code of Practice for Wholesale Poisons Licence holders where purchasers of pharmaceuticals need to provide a written order.

Patient and drug safety is always a prime concern of the pharmaceutical industry, we strongly believe that the implementation of this requirement will minimize errors arisen as a result of miscommunication when placing order verbally, enable the track and trace of pharmaceuticals and thus enhancing patient safety. This practice of providing a written order is also in line with the Good Distribution Practice developed under the WHO and European Commission and it has been incorporated in the Good Dispensing Practice Manual of the Hong Kong Medical Association since 2007.

In view of the benefits written order can bring to patients, members of the HKAPI who distribute more than 80% of drugs in Hong Kong are dedicated to enhance the workflow to cope with this requirement. With the wide availability of electronic means in placing written orders, they can be handled as efficiently as verbal orders

HKAPI
香港科研製藥聯會
UNIT A, 20/F., TIMES MEDIA CENTRE,
133 WANCHAI ROAD, WANCHAI, HONG KONG.
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FAX: (852) 2865 6283
WEBSITE: www.hkapi.hk

and we do not foresee any problems that will cause undue delay in drug delivery. Instead, we believe it is a measure to enhance the efficiency of the ordering system and reduce the wastage caused by wrong orders as drugs are valuable resources for patient safety.

Yours sincerely,

Sabrina Chan
Executive Director

5 June 2014

Prof. the Hon. Lee Kok Long, Joseph
Chairman, Bills Committee
Pharmacy and Poisons (Amendment) Bill 2014
Legislative Council Complex
1 Legislative Council Road
Central
Hong Kong

Dear Prof Lee and Legislative Council members,

Ref:- **Support of Pharmacy and Poisons (Amendment) Bill 2014**

On behalf of a group of Authorized Persons (APs) (pls see list below), we would like to express our strong support towards the legislative amendment on the Pharmacy and Poisons Ordinance and related Regulations as proposed by the HKSAR to enhance the existing regulation of pharmaceutical products in Hong Kong, and to ensure the quality and safety of pharmaceutical products in Hong Kong with the ultimate goal of safeguarding the integrity of public health.

We support the amendment bills in particular of the followings:-

1. Clause 52 (PPR, Reg. 30A-F):- imposing a register of Authorized Persons (AP) and revising the qualification required for registration as AP are to align with GMP upgrade to international standard ie. PIC/S. It is important that the status of AP is recognized. The legal basis for the Qualified Person (similar status as AP) is defined in the DIRECTIVE 2001/83/EC. To avoid misunderstanding, we suggest that a set of qualification requirements of Authorized Persons (APs), including but not limited to registered pharmacists, and the outline of the approved course rendering their qualified status to be AP shall be clearly defined in the guidance notes for AP.
2. Clause 6 (PPO, Section 4B):- To empower the Board to promulgate corresponding Code of Practices (COPs) in order to provide practical guidance and enhance monitoring for the conduct of the activities of registered pharmacists, APs, different licensed traders and traders subject to registration requirement (including manufacturers, wholesalers and retailers) to ensure that all sectors and professionals from different pharmaceutical sectors operate in a responsible, ethical and professional manner for public health benefits.

As one of the key health care professional in Hong Kong, we are committed to providing the best and continuous improving quality pharmaceutical care service to the public and we therefore further emphasize our support to the above bills.

Yours sincerely,
For and on behalf of
A group of Qualified Authorized Persons

Celine H.K. Cheng
BPharm, MRPharmS, PhD, MBA, Reg Pharmacist, AP

cc All APs below:-

CHAN Pui John
CHAN Tai Fu
CHENG Chi Hoi Simon
CHEUNG Yiu Kwong
CHOW Pui Chuen Paul
CHUI Tak Chuen Terry
FOK Siu Kee
HO Pui Shan Lorita
KO Sze Ka Cindy
LAM Norman
LAU Wing Yiu Catherine
LEE King Yaw Joshua
LEE Hon Kwong William
LEE Ming Chi
LEUNG Herman
LI Kit Ching Joanna
LUNG Chi Ho Markus
MUI Chun Fai Duncan
NG Wing Tak Brian
POON Oi Chu Louisa
SHIU Kwok Sang Nelson
WONG Cheong Moon Simon
WONG Chi Ming
WOO Pui Hong Christopher
YIP Yuen Wah
YIU Hing Yuen Peter
YOUNG Wai Cheong

香港中區立法會道 1 號
立法會綜合大樓
《2014 年藥劑業及毒藥(修訂)條例草案》委員會
李國麟主席

李主席:

腎友聯
對《2014 年藥劑業及毒藥(修訂)條例草案》意見書

背景

腎友聯（下稱「本會」）於 1996 年 4 月成立，是由全港 9 個腎病病人自助組織所組成。宗旨為加強腎友會間的溝通及聯繫，團結力量向政府反映腎病患者的需要，發揮自助互助精神，並為病人爭取合理權益，現時的團體會員包括:

1. 腎之友（瑪麗醫院）
2. 腎康會（威爾斯親王醫院）
3. 腎友互助協會（瑪嘉烈醫院）
4. 屯門醫院腎誼會（屯門醫院）
5. 東華腎友互助會（東華醫院）
6. 康寧腎友會（基督教聯合醫院）
7. 伊利沙伯醫院腎友互助會（伊利沙伯醫院）
8. 東區腎友自助會（東區尤德夫人那打素醫院）
9. 紅豆會有限公司（雅麗氏何妙齡那打素醫院）

前言

有關《2014 年藥劑業及毒藥(修訂)條例草案》（下稱「條例草案」），本會原則上是贊成有關條例草案的修訂，並希望委員會可繼續審議有關的法案，以保障香港的藥物安全及維護病人的權益。

據瞭解，本條例草案的修訂，是鑑於 2009 年香港曾發生的多宗藥物事故，香港藥物監管制度檢討委員會（下稱「檢討委員會」）於 2009 年 3 月成立，全面檢討現行規管藥劑製品的機制，並提出 75 項的改善建議。本會認為政府應全面落實執行檢討委員會的建議，以保障香港市民的健康、以及避免藥物事故的再次發生。

腎・友・聯
Alliance for Renal Patients Mutual Help Association
九龍橫頭磡邨宏禮樓地下
G/F Wang Lai House Wang Tau Hom Estate Kowloon
Tel: 8100 0821
Fax: 2336 9794
Email: arpmha@arpmha.org.hk
Website: http://www.arpmha.org.hk

意見

1. 草案第 23 條（《規例》第 29(1B)條）

建議修訂：毒藥及藥劑製品的註冊法律程序，訂明就毒藥表或載列於根據《條例》第 29(1)條訂立的規例的任何物質/物品名單的修訂，經食物及衛生局局長批准後，可由管理局訂立規例作出，並由立法會以先訂立後審議的程序處理。

本會意見：有關毒藥及藥劑製品的註冊法律程序，本會支持以先訂立後審議的程序處理，因為有關的藥品已有足夠的臨床實證證明，並經過食物及衛生局局長批准。此修訂將可加快新藥劑製品的引入及註冊程序，讓有需要的病人盡早可以使用已通過臨床試驗及測試的新藥物，避免病人因等候立法會的審議，延遲用藥而影響病情。

2. 草案第 52 條（《規例》第 30A 至 F 條）

建議修訂：獲授權人制度，持牌製造商須僱用最少一名獲授權人，以確保和證明藥劑製品是按照藥劑製品的《GMP 指引》製造和檢查的。同時也規定管理局須備存獲授權人名冊，增訂條文列明註冊為獲授權人的申請程序和資歷要求，以及其他註冊事宜。

本會意見：有關獲授權人制度的修訂，除註冊藥劑師適合擔任獲授權人外，本會贊成可由其他專業範疇，包括修畢醫學、化學、微生物學及生化工程相關課程及取得專業資格的人士擔任。本會認為藥劑製品的製造過程，牽涉多個不同的專業範疇，現時的建議修訂，將可進一步提升香港藥劑製品在製造和檢查上的安全。

3. 草案第 59 條（《規例》第 30B 條）

建議修訂：把臨床試驗證明書及藥物測試證明書的最長有效期由兩年延長至五年。

本會意見：現時新藥劑製品的研發過程非常繁複，本會認為將臨床試驗證明書及藥物測試證明書的最長有效期由兩年延長至不超過五年，將可給予藥品製造商足夠的時間，去進行多項的臨床試驗，以搜集足夠的數據，用以確定該藥品的安全及對疾病治療的成效。

4. 其他意見

本會對書面訂藥的安排表示支持，並認為此項建議將可降低藥劑製品在供應過程中出現的潛在風險。如當供應藥物出現問題，需要進行個別追蹤或全面回收的時候，有齊全的書面記錄作參考，必定可以加快整個藥物回收的程序，減少對病人的影響。另外，書面訂藥制度亦可以減少因訂錯藥或送錯藥而引致的藥物事故。對保障病人及藥物安全，起了防衛的作用。

腎・友・聯
Alliance for Renal Patients Mutual Help Association
九龍橫頭磡邨宏禮樓地下
G/F Wang Lai House Wang Tau Hom Estate Kowloon
Tel: 8100 0821
Fax: 2336 9794
Email: arpmha@arpmha.org.hk
Website: http://www.arpmha.org.hk

總結

作為腎病病人組織，本會非常贊成加強規管香港藥劑製品，讓市民及病人可以安心用藥。雖然病人是最終的用家，但實際上，大部份的病人都不清楚藥物在製造、銷售及監管過程中出現的潛在風險，他們只會遵從醫生及註冊藥劑師的指示服用藥物。所以，本會認為政府及有關當局是有責任加強對藥劑製品的監管，為市民做好把關的工作，確保所有在香港供應的藥劑製品均是安全的。

我們明白，政府當局在進行立法規管的時候，必定會引起業界或各持分者的反對，但是否有反對的聲音，就表示條例草案不適合推行呢？甚至要撤回條例草案重新諮詢呢？其實，自 2009 年起，政府當局已就條例草案進行了廣泛及深度的諮詢，並廣邀業界及各持分者提供專業的意見，如現階段才要求推倒重來，撤回有關的條例草案，本會表示絕對的反對，此舉不但違背了病人的期望，亦扼殺了業界各持分者多年來的努力。

本會希望　閣下及法案委員會各成員，可按照程序對條例草案進行審議，以保障香港市民的健康及權益！

腎友聯主席
劉國輝謹上

聯絡人：腎友聯社區關係經理陳佩嵐小姐
聯絡電話：81000821

2014 年 6 月 16 日

腎・友・聯
Alliance for Renal Patients Mutual Help Association
九龍橫頭磡邨宏禮樓地下
G/F Wang Lai House Wang Tau Hom Estate Kowloon
Tel: 8100 0821
Fax: 2336 9794
Email: arpmha@arpmha.org.hk
Website: http://www.arpmha.org.hk

HONG KONG DOCTORS UNION
香港西醫工會

Room 901, Hang Shing Bldg., 363-373 Nathan Road, Kowloon.
Email: hkdu@hkdu.org Home page: http://www.hkdu.org
Tel. No.: 2388 2728 Fax: 2385 5275

Our ref.: HKDU/098/2014(R)

17th June, 2014

By hand

Dear Legislative Council Members,

Re: Expose the Lies of Government Officials

Hong Kong Doctors Union (HKDU) is the unique trade union with doctor members in both public and private services. Registered with the Trade Union Registry to look after the interests and rights of doctors in their employer employee relationship, HKDU is committed to upgrade the standard of medical doctors to cater for the health of the Hong Kong community.

HKDU puts interests and welfare of patients first when considering legislations concerning health and medical issues. The recent Pharmacy and Poisons (Amendment) Bill 2014 contains some acceptable recommendations, but those on written orders and lowering the requirement of authorized person for drug manufacturing endanger patients and are unacceptable.

HKDU obtains the opinions of members before we put in our suggestions on their behalf and the requirement to use written order as the only method of ordering drugs has been strongly opposed by a majority of members and their patients. HKDU feels committed to explain how this requirement affects patients' health causing unnecessary delay in obtaining drugs. The Government repeatedly claims that the Hong Kong Medical Association (HKMA) supports written order is not absolutely true, as it reflects only the opinion of some HKMA council members lacking support from a survey on her members.

Those who blindly support compulsory written method for ordering drugs cannot show any evidence that using this method is superior to the conventional and efficient oral method. Instead the written method causes delay in obtaining the correct medicine for the patients, exactly opposite to the benefit they claim.

What is more irritating is the statement made by Ms. Janice Tse, Deputy Secretary for Food & Health (Health) on the Bills Committee Meeting held at Legco Building on 20.5.2014, who does not know how the medical world function, that patients can go to the Hospital Authority if there is delay caused by written orders. Is this the attitude of Food & Health Bureau to flood the overburdened public medical system? Ms. Tse is totally irresponsible.

Further Ms. Tse claims, as reported in the news media on 10.6.2014 (Annex 1), there is doctor overstocking ORAL Ketamine (K仔 - 氯胺酮), **a forbidden drug, who when challenged claim he did not order them. This show how ignorant Ms. Tse is. ORAL Ketamine (K仔 - 氯胺酮) is not manufactured by any legal drug firm in the world. She is inventing this story to tarnish the image of the medical profession and insults doctors turning them into forbidden drug dealers.**

Cont.../P. 2

HONG KONG
DOCTORS UNION
香港西醫工會
Room 901, Hang Shing Bldg., 363-373 Nathan Road, Kowloon.
Email: hkdu@hkdu.org Home page: http://www.hkdu.org
Tel. No.: 2388 2728 Fax: 2385 5275

Our ref.: HKDU/098/2014(R)

Since Ms. Janice Tse is making up stories, lacking credibility and not possessing the basic trust and honesty government officials should possess, we ask her to step down from her office for the sake of patients and citizens of Hong Kong.

In relation to the recent proposed Pharmacy and Poisons Amendment Bill 2014, we would like to support the proposal made by Legislative Council members to retract the bill so that an effective and thorough consultation process with all stakeholders involved can be conducted.

Yours truly,

Dr. Ho Ock Ling Thomas
Hon. Secretary
Hong Kong Doctors Union

Encl.

明報新聞網
news.mingpao.com

ANNEX 1

西醫藥劑師反修藥劑例

2014年6月10日 星期二

【明報專訊】2009年多名公立醫院病人服用發霉痛風藥後死亡，政府為改善問題，提出《2014年藥劑業及毒藥條例（修訂）草案》，但新增要求如藥物採購須以「書面方式訂購藥物」、藥劑師擔任藥房持牌人等卻惹爭議。香港藥劑師工會及香港西醫工會反對修訂，要求政府撤回草案再諮詢。但長期病患者關注醫療改革聯席、港大藥理及藥劑學系均認為草案以保障病人利益為前提，支持修例。

發霉痛風藥「別嘌醇」當年引致病人死亡後，政府推出75項改善措施，當中16項須修訂現行條例才可落實，立法會法案委員會正審議有關修訂草案。

買藥擬須書面紀錄

修訂草案提出訂購藥物者包括醫生及藥劑師，須以「書面方式購買藥物」，香港藥劑師工會及香港西醫工會表示，修訂會延誤藥房和醫生診所尋找藥物供應鏈及藥物採購的效率。他們又反對修訂「藥房持牌人定義」，認為若由藥劑師擔任藥房持牌人，會加重藥劑師的法律責任，並指政府諮詢未夠全面，要求撤回草案再諮詢。

食物及衞生局副局長陳肇始接受本報訪問表示，現時向藥廠訂藥不用書面紀錄，「打個電話便行，衞生署到診所巡查，發現診所持有處方藥物超出數量，醫生否認是他落單，但藥廠堅稱憑單送貨」。食衞局副秘書長（衞生）謝小華補充，有醫生訂購大量K仔（氯胺酮），但因無書面紀錄難以追查，故政府建議改例將漏洞堵塞。

盼堵毒品流出漏洞

陳肇始說，藥房持牌人目前定義是一種業務（Business）而非法人，律政署認為已過時，建議藥房持牌人必須列明是藥劑師或註冊公司。謝小華說，藥劑師若在藥房只是僱員而不是持牌人，毋須承擔法律責任，而修改也屬技術修訂，與現時情況並無分別。

病人組織學者撐修例

長期病患者關注醫療改革聯席代表彭鴻昌，支持「書面方式購買藥物」，也支持政府修訂藥物製造商除僱用藥劑師外，也可授權具相關知識如生化工程的人監督製藥生產。

港大醫學院藥理及藥劑學系主任黃志基認同草案是以維護及保障病人利益為前提，故支持先通過修訂草案。至於藥劑業界要求成立藥劑局（Pharmacy Council）為管理藥劑師的機構，可遲一步討論，毋須與修訂草案綑綁式通過。

HONG KONG DOCTORS UNION
香港西醫工會
Room 901, Hang Shing Bldg., 363-373 Nathan Road, Kowloon.
Email: hkdu@hkdu.org Home page: http://www.hkdu.org
Tel. No.: 2388 2728 Fax: 2385 5275

Our Ref.: HKDU/104/2014

27th June 2014

By fax & mail

Dr. Ko Wing Man
Secretary for Food & Health
Food and Health Bureau
18/F., East Wing, Central Government Offices
2 Tim Mei Avenue
Tamar, Hong Kong

Dear Dr. Ko,

Re: Hong Kong Doctors Union (HKDU) Ask Ms. Janice Tse to step down from her office

HKDU has discussed the government's attitude on written orders for drug purchase and the changes to the pharmacists and doctors in the recent Pharmacy and Poison (Amendment) Bill 2014. We are particularly annoyed with the behavior and statements made by Ms. Janice Tse, the Deputy Secretary for Food and Health (Health)1 who persistently confabulates stories concerning doctors storing high volume of oral Ketamine using the lack of written orders in pinning them down.

Ms. Tse supported another claim that some doctors overstock prescription drugs and again the lack of written orders allow these doctors to escape investigation. Further Ms. Tse claimed written orders cause no delay in doctors getting the correct drugs and even if this happen patients can turn to Accident & Emergency departments for help.

We feel gravely insulted by her stories tarnishing the image of doctors depicting us as drug peddlers. As oral Ketamine is not manufactured legally anywhere in the world, we challenge Ms. Tse to supply evidence and since she cannot, she is inventing this story. Again overstocking of drugs is difficult to define and not illegal. Why should such doctors need to hide behind verbal orders to escape responsibility? Another invented story! Ms. Tse brushed aside the dangerous delay of patients not able to get timely drugs and frankly suggested to send patients to flood the overburdened public health care system. This shows how irresponsible she is.

As a senior government official, Ms. Tse demonstrated lack of honesty, integrity and responsibility expected of someone in her position. As such she is a burden to the community, a threat to the health care system and is unworthy of carrying on her high position in the government. HKDU strongly ask her to step down from her office.

Yours sincerely,

Dr. Ho Ock Ling
Hon. Secretary
Hong Kong Doctors Union

Cont.../P. 2

HONG KONG DOCTORS UNION
香 港 西 醫 工 會
Room 901, Hang Shing Bldg., 363-373 Nathan Road, Kowloon.
Email: hkdu@hkdu.org Home page: http://www.hkdu.org
Tel. No.: **2388 2728** Fax: **2385 5275**

Our Ref.: HKDU/105/2014

3rd July 2014

By fax and email

Dear Legislative Council Members,

Re: Pharmacy & Poisons (Amendment) Bill 2014

Hong Kong Doctors Union (HKDU) is the unique trade union with doctor members in both public and private services. Registered with the Trade Union Registry to look after the interests and rights of doctors in their employer employee relationship, HKDU is committed to upgrade the standard of medical doctors to cater for the health of the Hong Kong community.

HKDU wish to make several clarifications regarding what were said by government officials and some Legislative Council members in the captioned Bills Committee meeting held on 17.6.2014 at 10:45 a.m. at Legislative Council Complex.

i) When a doctor, on receipt of medicine delivered by the supplier, refuses to accept it, the courier is expected to contact his firm and the sales agent to clarify if possible. If the doctor still refuses the drugs, the courier normally will take the goods back and to later sort things out before bringing back the correct medicine if applicable. It is a fallacy to claim the unaccepted drugs need to be destroyed. These unaccepted drugs can be redistributed to other purchasers.

ii) In the case of Dr. Lee Sai Lai, it is not because written order was not enforced that cause the mishap but because the nurse changed the container of the drugs. In fact, we usually forbid any clinic nurse to change the container of the drugs. As such, with or without written order the mistake would still happen.

iii) When considering the drug delivery time involved in the case of verbal order versus such time used in written order: Time is wasted with writing out and signing an order. Time is wasted when the fax is not received for various reasons. Time is wasted when the receiving supplier's end is not manned by staff to closely monitor fax. Time is wasted due to errors in writing the order. Delay happens when there is need to clarify the correct dosage or form of the drug because of difficulty to decipher what is written. Delay happens in getting back to the doctor to confirm the overall accuracy of the order. Delay when the doctor needs to ring up afterwards to find out if the fax order is received.

In these modern days, fax alone is not fast or safe enough because it is one sided and any adjustment needs feedback and feedback by telephone is still the most efficient.

Furthermore, HKDU and pharmacists are angry with the high handedness which the government has been using in dealing with these issues and even more annoyed with Ms. Janice Tse, Deputy Secretary for Food and Health (Health)1, who has been willfully slandering the medical profession with invented stories of illegal drug peddling and who, when questioned about the delay induced by written orders, retorted irresponsibly that patients can use the Accident & Emergency Departments. The medical and pharmaceutical profession demonstrated our fury and frustration by taking part in the July 1st demonstration and called for the resignation of Ms. Tse and retraction of this bill. (Photos of our activity enclosed) Please note the excuse of demanding written form of ordering that this provides a complete set of record is not acceptable because we have already a written record of orders on receiving the ordered drugs which is always a source to trace what was ordered and to justify payment.

Cont…/P. 2

HONG KONG DOCTORS UNION
香 港 西 醫 工 會
Room 901, Hang Shing Bldg., 363-373 Nathan Road, Kowloon.
Email: hkdu@hkdu.org Home page: http://www.hkdu.org
Tel. No.: **2388 2728** Fax: **2385 5275**

Our Ref.: HKDU/105/2014

Yours truly,

Dr. Ho Ock Ling Thomas
Hon. Secretary
Hong Kong Doctors Union

cc: Ms. Iris Chang, President, The Practising Pharmacists Association of Hong Kong
Mr. Kevin Cheung, Chairman, Hong Kong Pharmacists Union

Outgoing 15


謝小華
(食衞局副秘書長)
大話精
下台
反對強制書面訂藥
有欠公允
政府高官懵閉閉
非法合法混一體
HONG KONG
DOCTORS UNION
香港西醫工會
HONG KONG PHARMACISTS UNION
香港藥劑師工會


謝小華
(食衞局副秘書長)
大話精
下台
反對強制書面訂藥
有欠公允
HONG KONG PHARMACISTS UNION
香港藥劑師工會
政府高官懵閉閉
非法合法混一體
未能分辨好閉醫
如不稱職請落嚟
HONG KONG
DOCTORS UNION
香港西醫工會

Dr. Yeung Chiu Fat Henry
楊超發醫務所
Specialist in Paediatrics
M.B.,B.S.(H.K.) D.C.H.(London) D.C.H.(Glasgow)
F.R.C.P. (Edinburgh) F.R.C.P.(Ireland) F.R.C.P.(Glasgow) F.H.K.C.(Paed) F.H.K.A.M.(Paediatrics)
Shop 7 Hong Kwai House Cheung Hong Estate
Tsing Yi
Tel: 2495-6268 Fax: 2433-0221

30th June 2014

Dear LegCo members,

Ref.: Pharmacy & Poison (Amendment) Bill 2014
Hong Kong Medical Association Good Dispensing Practice Manual

I would like to make a clarification about the position of the Hong Kong Medical Association on the need to mandatory requirement of drugs to be ordered in writing as referred by the Government officials on the captioned bill.

In 2005 and 2007, when I was the chairman of the Task Force on drafting the Good Dispensing Practice Manual of the Hong Kong Medical Association, it was purposely mentioned that ordering drugs in writing is " **recommended** " (Please see page 8 of Enclosure 1 and page 6 of Enclosure 2) but is not mandatory for the following reasons:

1. Drugs that are urgently required may be ordered by telephone and the receipt of the order is verified by signing of 2 documents, namely, the "order receipt form" and the " poison form";

2. Because the drugs can be effectively traced to where they are delivered with the above mentioned 2 documents, there is no need to depend on the written order for tracking and tracing where the drugs had been sold to by the drug suppliers;

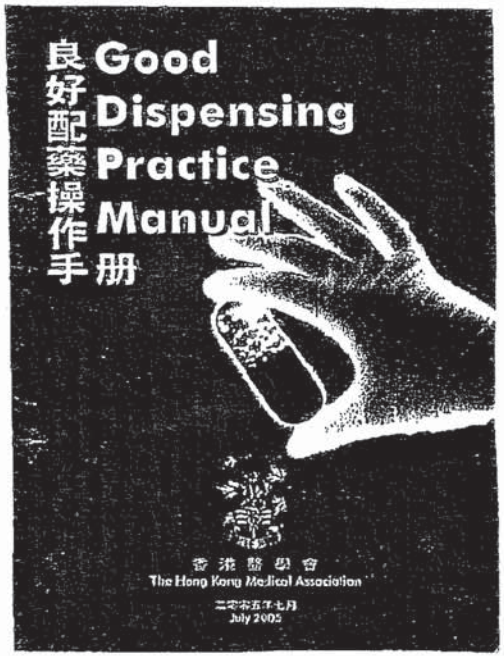
3. In all developed countries in the world including USA, UK, Australia, Canada, and others, there is no mandatory requirement for drugs to be ordered in writing.

As the fact is that the Good Dispensing Practice Manual adopted by the Hong Kong Medical Association and promulgated by the Medical Council of Hong Kong does not mandatorily require drug to be ordered in writing, it should not be a mandatory requirement by the Government.

Yours sincerely,

Dr. Yeung Chiu Fat Henry
Former Chairman of the Task Force on drafting the Good Dispensing Practice Manual of the Hong Kong Medical Association

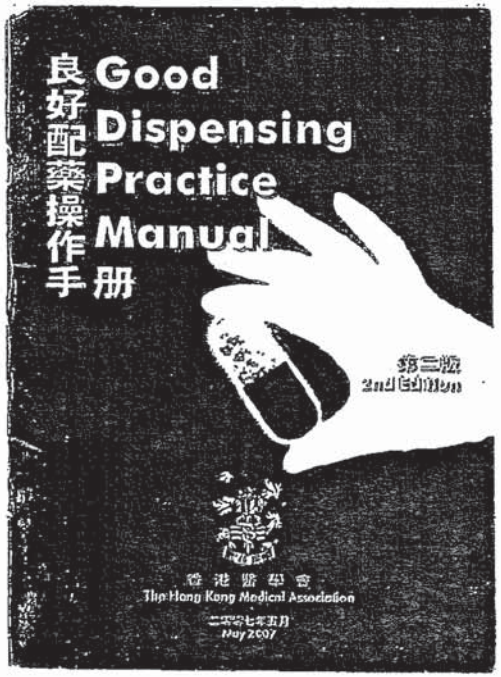
Encl.



4 STORES PROCUREMENT AND STOCK MANAGEMENT

Stores procurement

The Doctors in-charge are responsible for the requisition of pharmaceutical stores. Orders for drugs are recommended to be made in writing via post or fax by the doctor. All drugs should be checked and receipts signed by the doctor upon delivery of the drugs. (A sample order form is attached on P. 26 for reference)



5 STORES PROCUREMENT AND STOCK MANAGEMENT

Stores procurement

The Doctors in-charge are responsible for the requisition of pharmaceutical stores. It is recommended that the ordering of drugs from suppliers be made in writing, the written order to be kept for checking by the doctor against the drugs delivered and for future reference. (A sample order form is attached on P.16 for reference.)

July 2, 2014

Prof. HON Joseph LEE Kok-long, SBS, JP, PhD, RN
Chairman, Bills Committee
Pharmacy and Poisons (Amendment) Bill 2014
Legislative Council Complex
1 Legislative Council Road
Central
Hong Kong

Dear Prof. LEE,

Pharmacy and Poisons Amendment Bill 2014

The Federation of Medical Societies of Hong Kong (FMSHK) was established in 1965. The FMSHK is a non-profit making organization and is the umbrella organization of 134 medical, dental, nursing and allied health professional societies of Hong Kong representing more than 50,000 individual professionals. We endeavor to provide leadership and mechanism whereby the activities of her member societies can be co-ordinated to promote professional interests, achieve fraternity and to advance our common ideals.

The major consideration of the Federation when examining the Pharmacy & Poisons Bill Amendments put forward by the Food and Health Bureau, in response to the recommendations made by the Review Committee on the Regulation of Pharmaceutical Products in Hong Kong, is whether the amendments could safeguard the health of patients and safety in medication use.

In principle, we are in favour of the direction of the Bill amendment with two remarks.

1. With regards to the written orders of pharmaceutical products proposed in the code of practice for drug wholesalers, we support documentary evidence during procurement of pharmaceutical products to ensure accurate drugs and their precise strengths be delivered to the right place. However, to effectively implement this initiative, workable procedures which are patient-friendly, convenient and time-saving for all parties concerned should be defined.

4/F, Duke of Windsor Social Service Building, 15 Hennessy Road, Wanchai, Hong Kong • Tel: (852) 2527 8898 • Fax: (852) 2865 0345
Homepage: www.fmshk.org • E-mail: info@fmshk.org

2. We are also of the view that the “Authorized Person” of drug manufacturers must have the appropriate training and experience to oversee the drug manufacturing process. While this person may or may not be a registered pharmacist, to ensure the quality of the drug manufactured, a registered pharmacist should still be involved.'

Thank you very much for your kind consideration. If additional information is needed, please do not hesitate to contact me.

Your sincerely,

Dr. Raymond See-kit LO
President
The Federation of Medical Societies of Hong Kong

4/F, Duke of Windsor Social Service Building, 15 Hennessy Road, Wanchai, Hong Kong・Tel: (852) 2527 8898・ Fax: (852) 2865 0345
Homepage: www.fmshk.org ・ E-mail: info@fmshk.org

HONG KONG PHARMACISTS UNION
香 港 藥 劑 師 工 會
4/F, Duke of Windsor Social Service Building, 15 Hennessy Road, Wanchai, Hong Kong.
Tel: 8100 4226 E-mail: hkpharmacistsunion@gmail.com

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供各委員傳閱

Pharmacy and Poisons (Amendment) Bill 2014 Committee, LEGCO
F 2185 7845 E bc_54_13@legco.gov.hk

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致《2014 年藥劑業及毒藥(修訂)條例草案》委員會 李國麟主席：

投訴：有不準確的信息提供法案委員會委員作審議法案參考

由於從過去幾次的法案委員會會議中發現食物及衛生局有向委員會議員提供不準確的信息，我們現要求主席於委員會繼續審議法案程序前，向食衛局提出正式要求澄清此等不準確的信息。 此外，我們懇請主席要求食物及衛生局在會議繼續審議法案及委員會有所表決前作出答覆及回應。

就六月十七日本委員會會議上，有關官員未有回應議員提問之重點，當中更部分資料與事實不乎。現詳列如下作澄清，並促請局方於七月四日會議中及在表決前繼續回應相關疑問：

（一）有關獲授權人

謝小華：「嗰個獲授權人，其實我哋在這個草案委員會同書面已經答過秘書處同各位委員好多次，我想我唔再重複嗰個獲授權人，我哋用嘅資格係同歐盟一致。但我唸藥劑師工會，佢哋仍然好似唔係好明。」
謝小華：「而家政府話所有製造商都係 GMP 要求，已經答咗。」

局方不斷強調要跟歐盟接軌，但是局方現正申請的歐盟標準 PIC/S，而這標準香港的藥廠並未達到歐盟的認可。今天 2014 年香港藥廠的 GMP 規格只能合乎 1995 年的 GMP 規定，就連中國的 C-GMP 也不如，絕對不能跟歐盟的 PIC／S 標準看齊。歐盟所建立的藥廠，每個主要部門都聘任了多名藥劑師監察整個生產過程，藥物測試等等工作，確保了藥物安全，然後由 AP 簽發銷售。因為歐盟的藥廠已經有多名藥劑師在不同崗位上把關，藥物出錯的機會相對減低。所以，歐盟的藥廠（如英國容許部份已有 Royal Society of

4/F, Duke of Windsor Social Service Building, 15 Hennessy Road, Wanchai, Hong Kong.
Tel: 8100 4226 E-mail: hkpharmacistsunion@gmail.com

Chemistry, Society of Biology 學會資格的人仕申請為 Qualify Person，即是香港的 AP）。
似乎仍然唔係好明歐盟標準與香港 GMP 的分別是謝小華女士，而非藥劑師工會及業界團體。

然而香港的藥廠規模比較小型，多數藥廠只聘任一位藥劑師做 AP，監督生產，做最後藥物把關的工作。如跟據局方要求開放給非專業人擔任 AP，藥廠有可能不用聘任藥劑師，對藥物安全亦開始響起了警號。

現請局方清晰回應以下議員曾經提出而局方未有正面回答的問題：

1. **為什麼只跟歐盟標準的中的AP不要求藥劑師，而不是要求其他PIC／S的規定局方如何釐定什麼標準能保障市民用藥安全？**
2. **為什麼不要求所有本地持牌製藥商於各方面需達歐盟PIC/S標準？**
3. **藥廠AP由非藥劑師擔任，能否提高藥物出的安全性？**
4. **香港一些藥廠的GMP水平遠遠低於國際水平，我們應否先提高藥廠水平，才放寬對AP的要求？**
5. **除了政府聲稱要「跟歐盟接軌」之外，有沒有其他原因決定修改此例呢？**

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（二）有關本地持牌製藥商規格及監管問題

謝小華：「過去三年本地製造商有幾多次例行同特擊檢查，我請吳小姐（Linda Woo）答，我哋係有數據嘅。」

Linda Woo：「在 2012 年持牌製造商有 89 次、2013 年有 119 次。依兩年 2012-13 年藥房有 2408 次、藥行有 15172 次、批發商有 2166 次、進出口商有 338 次。」

吳小姐於上次會議中只讀出衛生署例行檢查的次數，並無交代具體內容，發現及結果。為進一步讓議員了解行業實況，現請局方清晰回應以下議員曾經提出而局方未有正面回答的問題：

1. **食衛局報告在過去3年對本地製造商有多少及突擊巡查？**
2. **巡查中發現製造商能否符合GMP的要求？**
3. **有否對本地藥劑製品進行測試？ 有否發現有多少不符合規定？**

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4/F, Duke of Windsor Social Service Building, 15 Hennessy Road, Wanchai, Hong Kong.
Tel: 8100 4226 E-mail: hkpharmacistsunion@gmail.com

（三）藥劑製品定義

謝小華：「至於藥劑製品定義，我哋法律專員同我哋聯絡過，話個解釋係歐盟定義，但係我哋香港係有小小字眼上面改咗，但係完全嗰內容係差唔多，大同小異。列如：佢哋用心 medicinal drug，我哋用來 pharmaceutical product and medicine 咁樣。嗰定義同國際上都大致相同啦。」

我們不同意，法案提出的新定義內容跟現行法例定義有根本的分別，不是以上所謂的小小字眼更改。檢討委員會在報告中從來沒有建議更改*藥劑製品*的定義。我們更不同意食物及衞生局悄悄地改變了在修訂條例內*藥劑製品*的定義。局方沒有與業界磋商，而是私自更改*藥劑製品*的定義。局方悄悄地在修訂條例內改變了*藥劑製品*的定義，而沒有與業界磋商。

現行法例中*藥劑製品*的定義是十分明確的。目前，醫療人員判斷一個產品是否是一種*藥劑製品*是明確和客觀的。一般是基於產品的的成分，以及有關產品的說明。在一般情況下，當產品的成分中有藥性成分，或在其標籤、傳單、宣傳冊子、包裝、廣告或其它宣傳物品上載有“醫療”用途時，該產品會被列為符合藥劑製品的定義。例如，如附錄1所示，有兩個食品及根據現行法律，他們並不需要註冊為藥劑製品。然而，根據修訂後*藥劑製品*的定義，便不清楚這些產品是否需要註冊？現有*藥劑製品*的定義是明確及客觀的。

然而，草案中建議*藥劑製品*的新定義則十分模糊的。修改後的定義採用了一種主觀和不明確的字眼*被表述為*。*被表述為*定義是什麼？誰去界定什麼是*被表述為*？是否有一個國際準則，以幫助前線醫療人員判斷什麼是*藥劑製品*？另外，「看似藥劑製品」這個定義帶有很多的主觀色彩，這將給藥劑製品的監管帶來很大的困難。如何公正、理智、客觀地評價一個產品是否藥劑製品，將全靠政府官員的眼力。同一產品「看似」或「不看似」藥劑製品，所有的監管人員都要有同樣的判定，這個難度是相當大的。若做不到這一點，人們會認為監管人員不秉公事，而把責任推到政府官員身上。 使用這種含糊的字眼（*被表述為*）對製藥行業是一種倒退而這個定義也不是什麼國際慣例。

此外，使用這種含糊的字眼不是一個國際慣例。國際國家，包括中國，美國，加拿大，新西蘭等都不使用這含糊的措辭（*被表述為*）。儘管一些歐盟國家使用*被表述為*字眼，然而，他們的*藥劑製品*註冊要求與香港的不同。首先，根據歐盟的相關法例，「藥劑製品」和「健康食品」都可以申請註冊。歐盟允許多種維生素，草藥提取物例如銀杏等的健康食品申請註冊。其次，這些非醫療產品（健康食品）可以通過簡化登記制度登記，縮短登記時間。而香港沒有對於「健康食品」註冊的相關法例，若按照新的法例執行，便是將「健康食品」硬拉入「藥劑製品」的範疇，與「藥劑製品」進行同樣的監管，這

4/F, Duke of Windsor Social Service Building, 15 Hennessy Road, Wanchai, Hong Kong.
Tel: 8100 4226 E-mail: hkpharmacistsunion@gmail.com

將給註冊、管理、銷售及購買的過程帶來極大的不便。局方這是太大意了，只抄*藥劑製品*的定義，而不考慮在香港的情況。

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（四）監管藥劑師獨立法定機構

至於監管藥劑師獨立法定機構，我哋都承諾咗今年年底一定會開會傾。但係依件事同草案內容冇關係，專業藥劑師日後自己規管過程點樣，其實一路都有討論，不過我哋亦都明白業界嘅關注，所以我哋會在未來幾個月內會安排再同佢哋討論。亦都有其他藥劑師團體寫信黎，佢明白我哋都願意去傾，咁上次的信都寫咗比主席同各位委員，佢哋覺得都係將兩件事分開。咁我唸我就依三點已經回應咗。

我們建議除非藥劑及毒藥管理局的成員組成進行重組，能夠充分代表今天業界及市民不同持份者的聲音及意見之前，任由藥劑及毒藥管理局可以集發牌，制訂守則及執法所有功能於一身，並不恰當。
仿效先進國家的藥物規管制度沒有不妥，但如果取表不取裏，恐怕只是金肉其外，新制度並沒有以病人利益為依歸，反而處處桎梏了前線醫藥同業守護病人權益，為藥物把關守尾門。香港的法例，莫以方便執法者執法為本，應以大眾利益市民健康為依，為了病人，為了市民，不要捨本逐末。

就政府回應有關及另設監管註冊藥劑師的獨立法定機構，因應部分代表團體/個別人士提出另設獨立法定團體接管現時由管理局負責監管註冊藥劑師的功能的建議，表示上述建議將會由醫護人力規劃及專業發展策略檢討督導委員會（ “ 督導委員會” ） 轄下的藥劑師小組跟進。該小組會參考香港中文大學就醫護人員長遠專業發展進行的顧問研究結果， 並在今年年底前討論上述事宜。

但可惜，代表業界大部份前線從業員的藥劑師工會曾多次去信要求加入該督導委員會參與意見卻被食衛局拒絕。 工會嚴重抗議食衛局的態度及決定，一再拒絕聽取業界意見。

根據草案提出的修訂建議有以下疑問，希望局方澄清：

1. ***為何草案並無按 2009 年檢討委員會的建議及最後一次會議的承諾***
2. ***在同意給予藥劑及毒藥管理局有關行業業務守則的新法定權力前，先重組藥劑及毒藥管理局於今天已經過時的的架構？***

HONG KONG PHARMACISTS UNION
香 港 藥 劑 師 工 會
4/F, Duke of Windsor Social Service Building, 15 Hennessy Road, Wanchai, Hong Kong.
Tel: 8100 4226 E-mail: hkpharmacistsunion@gmail.com

3. ***作為官方機構，缺乏主流業界代表聲音，為何藥劑業及毒藥管理局能夠就行業業務守則，同時集制訂， 不定時修訂及執法所有權力於一身？***
4. ***是否會有一個公平公開的機制存在，監察藥劑業及毒藥管理局所有運作及決定？***
5. ***由政府主導的藥劑及毒藥管理局，如何能平衡製定守則及執法時的利益衝突？***
6. ***政府是否企圖透過行政手段，控制業界運作？為何不能參照業界建議，引用行內既有由業界制訂的業務守則，交由藥劑及毒藥管理局執行？***

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（五）有關與業界團體溝通（包括藥劑師工會）

謝小華：「我哋都 offer 過同藥劑師開會，但佢哋話唔得閒。我哋由 4 月約到 6 月，佢哋都話唔得閒。」

香港藥劑師工會澄清，工會並非"唔得閒"，而且已多次書面回覆局方及歡迎會面的邀請。事實上衛生署於較早前向業界舉行多次簡介會，工會代表亦有出席，唯衛生署藥劑師代表未能解釋有關法案中的法律觀點。因應工會法律顧問的意見，工會要求官方法律顧問或代表出席會議，以釐清法案中的法律用字及解答其他法律要求的疑問。由於局方未能就此要求作回應，故會面未能安排。

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希望主席重視以上投訴 ，因為國際藥劑業界都非常不滿於議會中容許非正確及不全面的資料給立法會議員在審議此種要的法案時作參考，危害公眾健康。

香港藥劑師工會 會長
張建民
二零一四年七月二日

HONG KONG PHARMACISTS UNION
香 港 藥 劑 師 工 會
4/F, Duke of Windsor Social Service Building, 15 Hennessy Road, Wanchai, Hong Kong.
Tel: 8100 4226 E-mail: hkpharmacistsunion@gmail.com

供各委員傳閱 Pharmacy and Poisons (Amendment) Bill 2014 Committee, LEGCO
F 2185 7845 E bc_54_13@legco.gov.hk

《2014 年藥劑業及毒藥(修 訂)條例草案》
業界對草案所有顧慮
我們要求政府澄清及回應

Pg	項目			草案內容
2	1		監管影響評估 RIA Report	監管影響評估 Regulatory Impact Assessment (RIA) 從業員對草案咨詢過程疑惑 We urge government to disclose the RIA report
5	1	第 2 部	第 4 條. 修訂第 2 條 (釋義)	(1) 第 2(1) 條，**獲授權毒藥銷售商的定義**
7	2	第 2 部	第 4 條. 修訂第 2 條 (釋義)	(3) 第 2(1) 條，**藥劑製品及藥物的定義**
10	3	第 2 部	第 4 條. 修訂第 2 條 (釋義)	(6) 第 2(1) 條 “ **《行為守則》 (code of conduct)** 指根據第 4B 條發出的、不時根據該條修訂的《行為守則》； **《執業守則》 (code of practice)** 指根據第 4B 條發出的、不時根據該條修訂的《執業守則》；
	3	第 2 部	第 5 條. 修訂第 3 條 (藥劑業及毒藥管理局)	6. 加入第 4B 條 “4B. 《行為守則》及《執業守則》 在第 15(1A) 條之前—— 加入 a) 管理局接到投訴，而投訴是關於某註冊藥劑師或某註冊藥劑師的僱員的行為操守，或管理局覺得，某註冊藥劑師已違反適用於該藥劑師的《行為守則》；
12	4	第 2 部	第 13 條. 修訂第 13 條(處所的註冊)	(6) 在第 13(7)之後 加入 “(7A) 任何獲授權毒藥銷售商可向秘書申請批准，更改載於處所註冊紀錄冊內的、關

4/F, Duke of Windsor Social Service Building, 15 Hennessy Road, Wanchai, Hong Kong.
Tel: 8100 4226 E-mail: hkpharmacistsunion@gmail.com

				於就該銷售商註冊的任何處所的記項。 (7B)如秘書處批准有關更改，有關獲授權毒藥銷售商須為該項更改，繳付訂明費用。
	3	第 2 部	第 14 條. 修訂第 15 條(紀律委員會的委出)	在第 15(1A) 條之前—— 加入 a) 管理局接到投訴，而投訴是關於某註冊藥劑師或某註冊藥劑師的僱員的行為操守，或管理局覺得，某註冊藥劑師已違反適用於該藥劑師的《行為守則》；
	3	第 2 部	第 15 條. 修訂第 16 條(紀律委員會的權力)	
	5	第 2 部	第 30 條. 加入第 34A 條	“34A. 追討收集或化驗毒藥或藥劑製品等的費用及開支
14	6	第 3 部	第 52 條. 加入第 30A 至 30F 條	30C. 申請註冊為獲授權人 (ii) 持有在修畢委員會認可的課程後頒授的資格；
20	7	第 3 部	第 67 條. 修訂附表 5 (為本條例第 27(c)條的施行而根據本規例第 15 條訂明的說明)	(4) 附表 5—— 加入 “12. 須加上標籤標明“Prescription Drug 處方藥物”的字句—— 含有附表 3 所列毒藥的藥物 13. 須加上標籤標明“Drug under Supervised Sales 監督售賣藥物”的字句
21	8		第 59 條 36B	Clinical trial certificate duration

HONG KONG PHARMACISTS UNION
香 港 藥 劑 師 工 會
4/F, Duke of Windsor Social Service Building, 15 Hennessy Road, Wanchai, Hong Kong.
Tel: 8100 4226 E-mail: hkpharmacistsunion@gmail.com

監管影響評估 Regulatory Impact Assessment (RIA) 從業員對草案咨詢過程疑惑

當年藥物制度檢討委員會在2009年完成對規管藥物報告，及進行立法相關的討論，並提出了75項 建議，其中16項建議需循立法途徑修改。

局方委任了(IBM)顧問公司，IBM 隨即展開跟進，並就此舉辦了多場諮詢。局方委任顧問公司所做的顧問報告，局方從未公開這份報告內容給所有持份者參閱。

當年有很多主要持份者已向顧問公司表達了適當的意見，我們在場的會員、前線社區藥房藥劑師及專業團體代表，亦表示對修改藥劑條例新加入的建議內容，並不贊同。因為新加入的條例，違背了有效監控藥物安全的原則及保障病人的健康的本意。新條例亦對前線社區藥房藥劑師的工作帶來影響。

由於局方從未公開或提供RIA報告書內容給所有持份者參閱，這份顧問報告RIA的內容，可能包含了正反面的建議、亦可能提供重要數據，及對現時藥劑條例的保留或不用修改條例的建議。我們希望局方能公開RIA報告書內容給所有持份者參考。

1. 為何衛生署對在 4 月 10 日對藥劑師草案簡介會上，對一眾藥劑師要求，包括簡介簡短，可否做多次草案介紹，一律不回應?

2. 為何局方於簡介會上未能就法律字眼作解釋，卻拒絕工會聆聽局方法律代表解釋的要求?

3. 為何局方把工會及業界從業員對草案之疑惑扭曲成要求實行醫藥分家?

4. 為何局方不把大眾利益擺首位，以藥廠利益行先?

5. 政府與商家之間就這次條例草案過程中有沒有利益輸送?

6. 草案中修訂遠超過零九年藥物製度檢討委員會中，七十五條建議中同十六條需經立法程序修改，局方為何誤導議員，這份草案是基於零九年十六條建議而修訂？

7. 為何政府在沒有與業界達共識下急於通過修訂?

8. 為何政府說有咨詢過業界，實質上只是向業界透露過少量，甚至與草案無關其他資訊？

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Tel: 8100 4226 E-mail: hkpharmacistsunion@gmail.com

Regulatory Impact Assessment (RIA)

The Regulatory Impact Assessment Report (RIAR) has never disclosed to stakeholder. Upon completion of discussion of the Review committee on regulation on pharmaceutical products in Hong Kong in 2009, with their 16 recommendations to be implemented via legislation, the administration commissioned a consultant (IBM) to conduct a Regulatory Impact Assessment. Many stakeholders provided their options to the consultant and the Bureau has mentioned the RIA many times. Some of our members were there and reported not so many neither frontline pharmacists nor medical professionals agreed to the to-be imposed recommendations because they contrast with the frontline operations which were originally designed to benefit patient drug safety. However, the administration has never disclosed the RIA and there is no access for this document for stakeholders. The RIA assesses the positive and negative effects of proposed and existing regulations and non-regulatory alternative. The report provides important finding and recommendation. We urge the Bureau to disclose this important document.

1. Why was the feedback given to the government briefing session on the Bill for Pharmacists on 10 April 2014 about the concerns mentioned above not being responded to?
2. Why is a qualified legal person not able to be provided by the Drug Office to meet with the Legal Advisor of the HK Pharmacists Union in June 2014 despite complaints had been repeatedly raised that the representatives of the Drug Office are not able to answer our questions about legal implications of the law amendments?
3. Why are members of the Government misrepresenting the views of the HK Pharmacists Union and other stakeholders that our objections to the law amendment is merely an attempt to fight for Separation of Prescribing and Dispensing without any facts and evidence that the allegation is the truth?
4. Why is the government not placing public interests as first priority and has been pushing forward the interests of wealthy drug manufacturers?
5. Was there any form of disclosed or undisclosed trade offs between the government and the commercial entities in the law amendment process?
6. Why are there so many new amendments above an beyond the original 16 amendments of the 75 recommendations of the Review Committee being out forth to the LegCo for approval and claiming that the whole Bill is only for the 16 recommendations of the Review Committee?

7. Why is the government rushing the whole amendment process without having enough time to agree the contents with key stakeholders?
8. Why is the government claiming to have consulted stakeholders on all the issues when they have only consulted on some or on entirely different issues.

HONG KONG PHARMACISTS UNION
香 港 藥 劑 師 工 會
4/F, Duke of Windsor Social Service Building, 15 Hennessy Road, Wanchai, Hong Kong.
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獲授權毒藥銷售商（ ASP ）的定義

我們不理解草案裡對獲授權毒藥銷售商，即 ASP(Authorized Seller of Poisons)的定義。衛生處在四月十日的大會上面明確表示，ASP 的定義和修訂前的定義是沒有分別，只不過是更加清晰寫出。我們認為如果是和舊的定義在意式形態上是一樣的話，新的定義明顯令人感到十分模糊，令業界的同工感到非常困惑。所以我們建議不需要畫蛇添足，保留原來的定義

根據草案提出的修訂建議有以下疑問，希望局方澄清：

（一、）修例後，執法機關如何從定義中區分出分別於同一句子中出現兩次的“註冊藥劑師”？

（二、）為了什麼原因 ASP 的定義被改變是一個人，而不是現行法例的法律原意所指的“業務”？

（三、）如果 ASP 已經有一個名為 PIC 的一個特定的人（負責人）採取的 ASP 業務的全部責任，那為什麼在需要修改 ASP 定義為是一個人？

（四、）如果法律條文上 ASP 定義有不一致，那麼為什麼不能在法例的其他部分進行修改，將所有 ASP 視為一業務？

根據藥劑業及毒藥條例（ Cap138 ）第 11 條， “獲授權毒藥銷售商”的現有定義是“一個業務包括零售毒藥在內的業務”，由註冊藥劑師或法人團體或個人的非法人團體所经管的包括零售毒藥在內的業務，如毒藥的實際銷售是由註冊藥劑師或在其在場監督的情況下在根據本條例妥為註冊的處所內進行的，則該業務即為獲授權毒藥銷售商。

根據修訂草案第 2 條中，“獲授權毒藥銷售商”的定義被重新定義為“註冊藥劑師，法人團體或非法人團體所经營的被授權經營零售毒藥的業務根據第 11 條” 。

在新的版本，“獲授權毒藥銷售商”在定義的字眼不清楚。註冊藥劑師不能包括在內，因為“獲授權毒藥銷售商”應該是一個業務，而不是註冊藥劑師。我們認為，“獲授權毒藥銷售商”的定義應作修改。否則，“獲授權毒藥銷售商”的定義應該保持現狀。

HONG KONG PHARMACISTS UNION
香 港 藥 劑 師 工 會
4/F, Duke of Windsor Social Service Building, 15 Hennessy Road, Wanchai, Hong Kong.
Tel: 8100 4226 E-mail: hkpharmacistsunion@gmail.com

Definition of the Authorized Seller of Poisons (ASP)

The definition of ASP is unclear to confuse whether the ASP is a business as in the original existing law or a person or sometimes both. This lack of clear roles and responsibility between the owners of the business and employee pharmacists must be clarified before the law can be changed.

We would suggest to have the Bill withdrawn to start from the beginning to discuss key issues with stakeholders before the process of law change is put forward.

We request the Government to address there following queries we have on the Bill Amendments:

1. How can the law enforcement agencies differentiate the first Registered Pharmacist from the second Registered Pharmacist that appears in the definition?

2. For what reason the ASP definition being changed to be a person instead of the Business as in the original intent of the law and in the existing definition?

3. If the ASP already has a specific person called PIC (Person-in-charge) to take full responsibility of the ASP business then why does the ASP need to be a person?

4. If the law has inconsistency in the role of the ASP, then why can't other parts of the law be revised for ASP to be a business?

4/F, Duke of Windsor Social Service Building, 15 Hennessy Road, Wanchai, Hong Kong.
Tel: 8100 4226 E-mail: hkpharmacistsunion@gmail.com

「藥劑製品」的定義

I)目前「藥劑製品」的定義是明確的。然而，「藥劑製品」訂後的定義十分模糊。
請看(修訂後) 「藥劑製品」及藥物的定義 :

(a) 被表述為具有治療或預防人類或動物的疾病的特性；
或
(b) 可應用或施用於人類或動物，其目的是——
(i) 透過藥理、免疫或新陳代謝作用，以恢復、矯正或改變生理機能；或
(ii) 作出醫學診斷。”

我們對修訂後「藥劑製品」定義的問題:

1. *被表述為*定義是什麼？
2. 誰去界定什麼是被表述為？
3. 是否有一個國際準則，以幫助前線醫療人員判斷什麼是「藥劑製品」？
4. 請問附錄 1 兩個食品按照藥劑製品修訂後的定義，是否需要註冊為「藥劑製品」?
5. 現有「藥劑製品」的定義是明確及客觀的。為什麼否需修訂「藥劑製品」的定義?

II) 局方是太大意了，只抄歐盟「藥劑製品」的定義，而不考慮在香港的情況。

這種含糊的字眼不是一個國際慣例。國際國家，包括中國，美國，加拿大，新西蘭等都不使用這含糊的措辭***(被表述為)***。

我們對修訂後「藥劑製品」香港對「健康食品」影響的問題:

歐盟國家對「藥劑製品」註冊要求與香港的情況十分不同。

1. 局方是否知道在歐盟國家「藥劑製品」和「健康食品」都可以申請註冊?
2. 為什麼香港不能如同歐盟國家讓「藥劑製品」和「健康食品」都可以申請註冊?
若按照新的法例執行，便是將「健康食品」硬拉入「藥劑製品」的範疇
3. 那些不能註冊的健康食品如何不會被硬拉入「藥劑製品」的範疇?

其實政府修改這個法例，或者是希望某些健康食品的生產者如實做出宣傳，不誇大產品的效果，這其實是屬於對廣告標籤的規管。(不良醫藥廣告條例及商品說明條例) 若香港政府希望向歐盟學習，那麼就要學得徹底，將「藥劑製品」和「健康食品」分別規管，此舉有助於藥劑製品、健康製品的正常發展。

4/F, Duke of Windsor Social Service Building, 15 Hennessy Road, Wanchai, Hong Kong.
Tel: 8100 4226 E-mail: hkpharmacistsunion@gmail.com

4. 為什麼不將「藥劑製品」和「健康食品」分別規管?

「藥劑製品」的定義 附錄 1

首先，我們不同意，食物及衛生局悄悄地改變了在修訂條例內「藥劑製品」的定義。2009 年檢討委員會在報告中從來沒有建議更改「藥劑製品」的定義。局方沒有與業界磋商, 而是私自更改「藥劑製品」的定義。局方悄悄地在修訂條例內改變了「藥劑製品」的定義，而沒有與業界磋商。

目前「藥劑製品」的定義是明確的。目前，醫療人員判斷一個產品是否是一種「藥劑製品」是明確和客觀的。一般是基於產品的的成分，以及有關產品的說明。在一般情況下，當產品的成分中有藥性成分，或在其標籤、傳單、宣傳冊子、包裝、廣告或其它宣傳物品上載有“醫療”用途時，該產品會被列為符合藥劑製品的定義。例如，如附錄 1 所示，有兩個食品及根據現行法律，他們並不需要註冊為藥劑製品。然而，根據修訂後「藥劑製品」的定義，便不清楚這些產品是否需要註冊？現有「藥劑製品」的定義是明確及客觀的。

然而，「藥劑製品」訂後的定義十分模糊。修改後的定義採用了一種主觀和不明確的字眼***被表述為***。***被表述為***定義是什麼？誰去界定什麼是***被表述為***？是否有一個國際準則，以幫助前線醫療人員判斷什麼是「藥劑製品」？另外，「看似藥劑製品」這個定義帶有很多的主觀色彩，這將給藥劑製品的監管帶來很大的困難。如何公正、理智、客觀地評價一個產品是否藥劑製品，將全靠政府官員的眼力。同一產品「看似」或「不看似」藥劑製品，所有的監管人員都要有同樣的判定，這個難度是相當大的。若做不到這一點，人們會認為監管人員不秉公事，而把責任推到政府官員身上。 使用這種含糊的字眼(***被表述為***)對製藥行業是一種倒退而這個定義也不是什麼國際慣例。

此外，使用這種含糊的字眼不是一個國際慣例。國際國家，包括中國，美國，加拿大，新西蘭等都不使用這含糊的措辭***(被表述為)***。儘管一些歐盟國家使用***被表述為***字眼，然而，他們的「藥劑製品」註冊要求與香港的不同。首先，根據歐盟的相關法例，「藥劑製品」和「健康食品」都可以申請註冊。歐盟允許多種維生素，草藥提取物例如銀杏等的健康食品申請註冊。其次，這些非醫療產品 (健康食品) 可以通過簡化登記制度登記，縮短登記時間。而香港沒有對於「健康食品」註冊的相關法例，若按照新的法例執行，便是將「健康食品」硬拉入「藥劑製品」的範疇，與「藥劑製品」進行同樣的監管，這將給註冊、管理、銷售及購買的過程帶來極大的不便。局方這是太大意了，只抄「藥劑製品」的定義，而不考慮在香

4/F, Duke of Windsor Social Service Building, 15 Hennessy Road, Wanchai, Hong Kong.
Tel: 8100 4226 E-mail: hkpharmacistsunion@gmail.com

港的情況。

此外，「藥劑製品」修訂後的定義將會產生混亂。跟據 2014 年 3 月，藥物辦公室的文件 Guidance Notes on Registration of Pharmaceutical Products/ Substances" (http://www.drugoffice.gov.hk/eps/do/en/doc/guidelines_forms/guid.pdf)上指出：「藥劑製品」必需要 l)安全,2)有效 3)優質。而新的修定法例將「藥劑製品」的定義改為「看似藥劑製品」的製品，這使很多產品的定位出現問題。新例修定後，某些健康食品將會因為「似」藥劑製品而突然變了「藥劑製品」。這樣如何保持「藥劑製品」都一定"有效」呢?這不但做成混亂,而且對市民及業界也沒有幫助。

其實政府修改這個法例，或者是希望某些健康食品的生產者如實做出宣傳，不誇大產品的效果，這其實是屬於對廣告標籤的規管。(不良醫藥廣告條例及商品說明條例) 若香港政府希望向歐盟學習，那麼就要學得徹底，將「藥劑製品」和「健康食品」分別規管，此舉有助於藥劑製品、健康製品的正常發展。

學習先進國家的藥物規管制度是好的，但如果只學表面，像邯鄲學步、東施效顰，只會帶來更多問題。我們都希望香港有關藥劑的法例更加完善。

附錄 2

4/F, Duke of Windsor Social Service Building, 15 Hennessy Road, Wanchai, Hong Kong.
Tel: 8100 4226 E-mail: hkpharmacistsunion@gmail.com

藥劑及毒藥管理局的組成及有關行業守則的新職權

我們不同意法案中賦予藥劑及毒藥管理局新的職權，去制訂及隨時修改行業務守則及從業員的行為守則。

我們十分關注藥劑及毒藥管理局（PPB）的組成成份，沒有任何民主成份，這些大部份並非前線和業界工作，主要成員都是政府官員或政府委任人士，成立當時並無考慮到今次修訂條例草案所需要具備的功能。再者，局裡面的成員（包括英國醫學會的代表等等）並未能充份代表到四十年之後我們現在行業的主要持份者例如醫院藥劑師學會、執業藥劑師學會以及香港藥劑師工會等等。所以我們對局的代表性有所懷疑。
我們建議除非藥劑及毒藥管理局 的成員組成進行重組，能夠充分代表今天業界及市民不同持份者的聲音及意見之前，任由藥劑及毒藥管理局可以集發牌，制訂守則及執法所有功能於一身，並不恰當。
仿效先進國家的藥物規管制度沒有不妥，但如果取表不取裏，恐怕只是金肉其外，新制度並沒有以病人利益為依歸，反而處處桎梏了前線醫藥同業守護病人權益，為藥物把關守尾門。香港的法例，莫以方便執法者執法為本，應以大眾利益市民健康為依，為了病人，為了市民，不要捨本逐末。

就政府回應有關及另設監管註冊藥劑師的獨立法定機構，因應部分代表團體/個別人士提出另設獨立法定團體接管現時由管理局負責監管註冊藥劑師的功能的建議，表示上述建議將會由醫護人力規劃及專業發展策略檢討督導委員會（ “督導委員會” ） 轄下的藥劑師小組跟進。該小組會參考香港中文大學就醫護人員長遠專業發展進行的顧問研究結果， 並在今年年底前討論上述事宜。

但可惜，代表業界大部份前線從業員的藥劑師工會曾多次去信要求加入該督導委員會參與意見卻被食衛局拒絕。 工會嚴重抗議食衛局的態度及決定，一再拒絕聽取業界意見。

根據草案提出的修訂建議有以下疑問，希望局方澄清：
(一、）為何草案並無按 2009 年檢討委員會的建議及最後一次會議的承諾在同意給予藥劑及毒藥管理局有關行業業務守則的新法定權力前，先重組藥劑及毒藥管理局於今天已經過時的的架構？
(二、）作為官方機構，缺乏主流業界代表聲音，為何藥劑業及毒藥管理局能夠就行業業務守則，同時集制訂， 不定時修訂及執法所有權力於一身？

4/F, Duke of Windsor Social Service Building, 15 Hennessy Road, Wanchai, Hong Kong.
Tel: 8100 4226 E-mail: hkpharmacistsunion@gmail.com

(三、）是否會有一個公平公開的機制存在，監察藥劑業及毒藥管理局所有運作及決定？

(四、）由政府主導的藥劑及毒藥管理局，如何能平衡製定守則及執法時的利益衝突？

(五、）政府是否企圖透過行政手段，控制業界運作？為何不能參照業界建議，引用行內既有由業界制訂的業務守則，交由藥劑及毒藥管理局執行？

New Power of the Pharmacy and Poison Board (PPB) in regard to the Codes of Practice

The new power to be given to the Pharmacy and Poisons Board (PPB) is too powerful in that it may place the members of the Pharmacy and Poisons Board in a difficult position and be in conflict of interest situations.

The PPB would become a government-led body, which can single-handedly issue, revise, and enforce the Codes of Practice without any oversight by others. There is no mechanism to object to the Board and there is no accountability for being a member of the Board.

The composition of the Board is in lack of appropriate representation. Many important stakeholders are not included in the 11 representatives of the Board to speak the voice of the stakeholders such as the Hong Kong Pharmacist Union, Society of Hospital Pharmacists and The Practising Pharmacists Association are also not on the Board.

We request the Government to address there following queries we have on the Bill Amendments:

1. Why is the Pharmacy and Poisons Board not being re-organized as promised and agreed by the Regulatory Review Committee at the last meeting before changing law to give the Board a new power to issue Codes of Practice?
2. How can the Pharmacy and Poisons Board be capable to issue and revise from time to time the Code of Practice if the minority or no representatives from pharmacy profession is on the Board?
3. What are the Checks and Balance system for the decisions of the Board?
4. How can the conflict of interests of the regulator be balanced if the government led Pharmacy and Poisons Board be both the issuer of the Codes and also the law enforcement at the same time?
5. Why can't the Board adopt and make reference to the Codes of Practice that is issued by the pharmacy and pharmaceutical profession associations themselves rather than take over the control of the professional practice, which the government has no practical experience to do?

4/F, Duke of Windsor Social Service Building, 15 Hennessy Road, Wanchai, Hong Kong.
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第 13 條. 修訂第 13 條(處所的註冊)

“ (6) 在第 13(7)之後

加入

“(7A) 任何獲授權毒藥銷售商可向秘書申請批准，更改載於處所註冊紀錄冊內的、關於就該銷售商註冊的任何處所的記項。

(7B)如秘書處批准有關更改，有關獲授權毒藥銷售商須為該項更改，繳付訂明費用。”

現時獲授權毒藥銷售商負責人可以是獲授權 毒藥銷售商（藥房）僱員，萬一僱員不出現一段時間，或無故突然辭工，僱主並沒有機會預先申請更改 獲授權毒藥銷售商負責人 並獲得批准，加上有關人士需要資歷背景乎合資格以及需要通過局方面試方獲批准成為 獲授權毒藥銷售商負責人，現實情況下所有乎合這個資格的人士成為 獲授權毒藥銷售商負責人 之前都需要時間作準備，所以希望政府將之前通知更改獲授權毒藥銷售商負責人改為予寬限期 6 個月內通知。

追討與定罪有關的開支

修例建議- 30. 為加強阻嚇效果,法庭將獲賦權發出命令,向被告人追討因定罪而進行的任何藥物樣本抽取、檢驗及分析所引起的全部開支。” (立法會 CB(2) 254/13-14(03) 號文件)

有關建議,與現行其他違法行為的法律懲處完全不一致,違反公平公正原則,即使毒犯被定罪亦毋須為政府化驗毒品支付費用,何況現行法例已對違法行為有相關懲罰,包括罰款及/或監禁。

香港是法治社會,有完善的法律制度,法律的制定,公平公正之外,背後的法理必須貫徹一致,合情合理。

香港的藥物監管制度向來框架健全,背後的理念合理,檢討委員會亦于以認同,今次

4/F, Duke of Windsor Social Service Building, 15 Hennessy Road, Wanchai, Hong Kong.
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因私家醫生診所肇事而建議改善規管制度雖然有所必要,並無迫切性,所以修訂"條例"。

對持牌製藥商中"獲授權人 Authorized Person"(AP)的資歷要求

我們認為本地持牌製藥商的 "獲授權人(Authorized Person)" 有必要由具製藥經驗的註冊藥劑師擔任。

如根據局方建議,容許由只完成相關課程的非專業人仕擔任的話,一般的技術人員並不能全面堅持及維護 專業標準水平。如此倒退,不但未能 保障病人/用家 健康及安全,更違反局方修改法案希望推動藥物安全的原意。(請參考附錄參考資料－*香港藥物監管制度檢討委員會報告原文節錄。*)

政府法案中可能對病人安全產生負面影響的例子有:

(一、)修改現行對本土藥物製造商的規定,不需要求註冊藥劑師守最後一關,為獲授權人監督藥物製造商運作。

目前, 本港共有二十多間符合(GMP) 藥品優良製造作業規範資格的藥廠,每間藥廠均實行嚴謹製藥檢定程序,製成的藥製製品先由製造、品質控制經理檢定,最後需由所聘獲授權人」的藥劑師簽署認可,才可出售有關製品。現時註冊藥劑師在藥物生產的相關經驗是強制性的,獲授權人(Authorized Person - AP)在本地製造商中擔當重要的把關角色以確保藥品所有批次符合質量標準要求。現時法例要求 AP 必須是藥劑師,而製造及品質控制無須藥劑師(即最低要求得一個藥劑師),如果連 AP 都不是藥劑師,那關乎藥物安全及市民健康的產品就完全没有專業人士監察,完全不能接受。

如果修訂草案獲得通過,加入「獲授權人」註冊制度,當中除註冊藥劑師合資格外,任何非專業人員或一般職員只需經過短期培訓,持有指定課程資格也可註冊成為「獲授權人」擔任守最後一關的崗位。目前香港中文大學設有相關指定課程,兩年且兼讀形式的藥物製造及品質學理學碩士課程 (中大藥劑學院助理教授李偉業證實,有關指定課程尚未正式獲得政府認可),持相關理科學位的人士便可報讀。缺乏具高水平專業資歷操守的註冊藥劑師充當把關,未來市民可能會面對質量不合格的藥劑製品的風險無法預計。對於最近將的法案修定,將取消香港本地持牌製藥商廠中「獲受權人」(Authorized Person, AP) 必需為香港註冊藥劑師的現定,我們不贊成這種做法。其原因有三:

4/F, Duke of Windsor Social Service Building, 15 Hennessy Road, Wanchai, Hong Kong.
Tel: 8100 4226 E-mail: hkpharmacistsunion@gmail.com

（二、）香港的藥廠不能缺少藥劑師的參與。雖然政府希望學習歐盟，不需要藥劑師作為 AP，來監管藥物的上市、發行，但歐盟的做法並不適合香港。歐盟的藥廠規模較大，在不同部門，有數十位藥劑師參與藥物的研發、品質檢驗等工作。AP 遇到與藥物相關的專業問題，可以隨時與藥廠中的藥劑師溝通，所以 AP 一職不再需要藥劑師擔任。而香港的情況不同，香港的藥廠規模較小，藥廠中只有一至兩位藥劑師對藥物的安全品質進行把關。若取消這規定，這僅有的藥劑師，勢必被開除。在整個需要高度專業知識引領的藥物生產線中，沒有專業人員參與。這其中如果出現問題，造成的後果將是不堪設想的。

（三、）藥劑師比非專業人員更成勝任這 AP 一職。首先藥劑師經過多年的學習、培訓，具有豐富的專業知識，有能力迅速處理突如其來的各種問題，這是僅上過一、兩個培訓課程的人無法相比的。在藥品安全的問題上，解決問題的速度小則關乎企業利益，大則關係到眾多使用者的生命安全。藥劑師這一行業的存在，歸根結底就是為了香港市民可以安全使用藥物而存在的。所以藥劑師在藥廠中的地位無法取代。

（四、）即使只考慮個人的利益，藥劑師也會對藥物的監管更加盡職盡責。試想若 AP 在藥品監管問題上與藥廠的老闆出現意見不和，他可能妥協或堅持，妥協的後果是藥品的品質下降，而堅持的後果可能是被降職或解雇，但這都不影響他今後的工作生涯。但若藥劑師做 AP 一職，他不可能妥協，因為妥協的後果是他將失去做一名藥劑師的資格，多年時間與金錢的投入將付諸東流。

因此，不管從社會利益或各人利益上考慮，香港藥廠都不應該取消藥劑師的職位。

培訓一個藥劑師，必須全面了解整個製藥過程，藥劑師已學習了專業的知識，如藥理學 Pharmacology，毒理學 Toxicology，藥劑學 Pharmaceutics，微生物學 Microbiology，藥物動力學 Pharmacokinetic，專業實務 Ethical issue，臨床測試 Clinical Trail，優良生產程序 GMP (Good Manufacture Practice)，藥物測試 QC tests 等等。
藥劑師是一個適當的專業人仕去擔任 "獲授權人（Authorized Person）"這個職位。然而局方建議的非專業人仕或特有理科學位並完成一個短期課程的人仕可獲資格擔任"獲授權人 "這個職位，我們認為並不合當。因為生產藥物，並不等同於生產食物；藥劑師的專職是藥物安全，而特有理科學位的人仕對藥物的認識並不深入、對藥物安全的意識並不如藥劑師。如非專業人仕獲聘任 AP 職位，所生產的藥物並沒有保證，藥物的品質將會下降，最終的受害者就是病人本身。

4/F, Duke of Windsor Social Service Building, 15 Hennessy Road, Wanchai, Hong Kong.
Tel: 8100 4226 E-mail: hkpharmacistsunion@gmail.com

而局方不斷強調要跟歐盟接軌，但是局方現正申請的歐盟標準 PIC/S，而這標準香港的藥廠並未達到歐盟的認可。香港怎樣能跟歐盟看齊？
歐盟所建立的藥廠，每個主要部門都聘任了多名藥劑師監察整個生產過程，藥物測試等等工作，確保了藥物安全，然後由 AP 簽發銷售。
因為歐盟的藥廠已經有多名藥劑師在不同崗位上把關，藥物出錯的機會相對減低。所以，歐盟的藥廠 (如英國容許部份已有 Royal Society of Chemistry, Society of Biology 學會資格的人仕申請為 Qualify Person，即是香港的 AP。

然而香港的藥廠規模比較小型，多數藥廠只聘任一位藥劑師做 AP，監督生產，做最後藥物把關的工作。如跟據局方要求開放給非專業人擔任 AP，藥廠有可能不用聘任藥劑師，對藥物安全亦開始嚮起了警號。

自 1995 年香港引入 GMP 制度，香港製藥行業都維持在 3 頭馬車制度，即是有 1 Authorized person AP 下面 2 位，1 位是管製藥 Manufacturing, 1 位負責 Quality control。 20 年來 AP 位置一直是由註冊藥劑師擔任。AP 除了審批藥物的安全，批次，有效日期，有 AP 簽署才能出廠。今次的條例修訂，主題應該是加強藥劑製品的製造，儲存和銷售，藥劑業同盟十分贊成，我們建議政府這 3 頭馬車負責人，應由註冊藥劑師負責。藥劑師為註冊專業人士，有自己專業守則，3 位藥劑師能互相制衡，不可能為了私利或疏忽而造成醫療事故。而且藥劑師有一套嚴謹的專業守則和監察制度，假如有錯誤，懲罰是很嚴重，除了停牌，除牌或被永久取消資格。而我們對今次政府的行動十分驚訝，因這是反其道而行，竟建議將如此重要的監管取消職位的資格限制取消，我們覺得藥廠會變得無王管。新方案容許**非**藥劑師，只需要有三年工作經驗及修讀完一個兼職課程的**非專業人仕**出任重要的崗位，明顯是一個立法監管上的倒退。草案裡面並沒有提及任何部分去監管這類人仕，他們不用承擔任何專業的責任。對此，我們對香港藥品的未來感到非常擔心。相信社會人士會明白，藥劑師在社會上功能是在藥物安全，儲存，運輸方面為社會把關，我們建議政府維持對 AP 的資格限制。

本會就政府於立法會《2014 藥劑及毒藥（修訂）條例草案》委員會上的失實回應作以下聲明：

（一）建議修訂本地持牌製藥商 “ 獲授權人” "Authorised Person" (AP) 的資格。名為提升對藥物製造的監管，實為放寬要求，容許非註冊藥劑師擔任AP。

第一，實際情況 藥廠乃商業機構，藥廠需要藥劑師去把關，權衡經濟效益之餘醫療道德行先，保障病人安全；若法定連AP（獲授權人）位也不一定由藥劑師就任，為了減省支出，好可能將來全港藥廠的景況全廠一個專業藥劑師也沒有。

4/F, Duke of Windsor Social Service Building, 15 Hennessy Road, Wanchai, Hong Kong.
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藥劑師為獲授權人，把關確保藥物高質素及安全，以免危害市民。

第二，藥劑師知識全面，難以取締 藥劑師於製藥生產過程人面擁有全面知識和經驗，遠超過所有技術人員。至於官員會上提及微生物學，藥理學，生物化學，病理，方劑學，藥劑動理學等等專業知識，早在藥劑師的大學課程內包含。而且只有藥劑師才會有全面知識，確保藥物達至質量、效用、安全三方面全面達標。非藥劑師擔任AP，質量管理不會跟足，醫療道德不充足，亦沒有藥劑師基本藥物知識的時候，難以找藥廠衍生出來的問題的核心。

第三，制度漏洞 新例下非藥劑師，持指定相關學位的畢業學生只需三年GMP香港或以外藥廠工作經驗便可擔藥廠的AP位置。大陸也有嚴謹GMP製藥制度，可是同時，我們看見有非常多的內地人南下到香港買與內地同一個牌子的藥品。這並非大陸藥廠做藥制度不夠高，而是正正顯示出，沒有了專業人士把關，病人對藥物質素無法信任。若香港藥劑制品製造商讓次一等的質素管理，非藥劑師，去擔任獲授權人，我們製藥監管上的優勢便會流失，更讓我們的病人有危險。

第四，政府亦知悉現階段需要藥劑師擔任AP於二零零九年藥物制度檢討委員會報告中，「食物及衞生局二零零九年十二月 香港藥物監管制度檢討委員會報告

iii 摘要 檢討結果和建議

7. 檢討委員會共提出75項建議，涵蓋各個不同範疇，現於下文以及附件D和E概述。

(a) 監管藥物製造商和提升「生產質量管理規範」計劃的標準(第三章)

(i) 把香港現行的「生產質量管理規範」標準提升至符合更高的國際標準:「生產質量管理規範」是一套為全球製藥業廣泛採用的品質保證方法， 用以確保在整個製藥過程中劃一生產和監控藥劑製品。根據「生產質量管理規範」的原則， 在衡量藥劑製品是否品質良好時， 應着重對製造過程的監察， 而非只限於製成品檢測。香港現正採用世界衞生組織（ 世衞） 在一九九五年公布的「生產質量管理規範」標準。檢討委員會建議香港的「生產質量管理規範」標準應在約兩年內首先提升至世衞於二零零七年公布的標準， 然後在其後的約兩年內再提升至符合「國際醫藥品稽查協約組織(Pharmaceutical Inspection Co-operation Scheme)(PIC/S)制訂的更高標準，即協約組織標準。協約組織標準包括更嚴格監控製藥過程中使用的有效藥劑成分， 更嚴格的負責監控整個製藥過程的獲授權人士的資歷要求， 改善巡查和發牌安排， 以及為進行「生產質量管理規範」所涉的各級人員制訂一套更全面的培訓架構。這項建議應優先實施。

委員會報告中亦認為－

檢討結果及建議

I. 「生產質量管理規範」顧問的建議

3.14 檢討委員會經研究後通過了「生產質量管理規範」顧問的大部分建議， 詳情如下：

4/F, Duke of Windsor Social Service Building, 15 Hennessy Road, Wanchai, Hong Kong.
Tel: 8100 4226 E-mail: hkpharmacistsunion@gmail.com

(a) 提升香港「生產質量管理規範」的標準

3.15 顧問建議衞生署採取分階段的方式， 提升香港現時的「生產質量管理規範」發牌標準， 務求在大約四年內達到「國際醫藥品稽查協約組織」(Pharmaceutical Inspection Co-operation Scheme) (PIC/S) (下稱「協約組織」)的標準， 以反映行業技術的轉變， 同時與國際最佳做法接軌。在過渡期內， 香港的「生產質量管理規範」發牌標準應在大約兩年內首先提升至世衞二零零七年的標準。」

3.21 在現階段， 獲授權人士一職仍須由具備相關經驗的藥劑師擔任。檢討委員會察悉， 由藥劑師擔任獲授權人士， 會同時受到「生產質量管理規範」所訂的獲授權人士責任， 以及藥劑業及毒藥管理局對藥劑師專業地位所訂的紀律處分機制所約束。這套「雙重把關機制」對保障公眾健康有利。

香港政府規定藥廠需要達GMP standard, 但有的藥廠還真的只是GMP standard, 1995年的GMP standard，連較新的cGMP也達不到，所以香港造的藥賣不到美國大陸。更可況現在說要行PIC/S，因為歐盟行的制度為PIC/S，而香港藥廠亦未行到。政府自己亦吾肯定幾時可以全港廿幾間藥廠行晒PIC／S 。未達標收緊製藥制度，先放寬獲授權人士要求，此舉港府恐怕為全球首創。

我們要求局方回應：

1. 為什麼只跟歐盟標準的中的AP不要求藥劑師，而不是要求其他PIC／S的規定局方如何釐定什麼標準能保障市民用藥安全？
2. 為什麼不要求所有本地持牌製藥商於各方面需達歐盟標準？
3. 藥廠AP由非藥劑師擔任, 能否提高藥物出的安全性?
4. 香港一些藥廠的GMP水平遠遠低於國際水平,我們應否先提高藥廠水平, 才放寬對AP的要求?
5. 除了政府聲稱要「跟歐盟接軌」之外, 有沒有其他原因決定修改此例呢?
6. 食衛局報告在過去3年對本地製造商有多少例行及突擊巡查
7. 巡查中發現製造商能否符合GMP的要求？
8. 有否對本地藥劑製品進行測試？ 有否發現有多少不符合規定？

附錄：參考資料

根據食物及衞生局二零零九年十二月發表的“香港藥物監管制度檢討委員會報告”的檢討結果和建議摘要：

7. 檢討委員會共提出75 項建議，涵蓋各個不同範疇，現於下文以及附件D 和E概述。

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*(i) 把香港現行的「生產質量管理規範」標準提升至符合更高的國際標準:「生產質量管理規範」是一套為全球製藥業廣泛採用的品質保證方法，用以確保在整個製藥過程中劃一生產和監控藥劑製品。根據「生產質量管理規範」的原則，在衡量藥劑製品是否品質良好時，應着重對製造過程的監察，而非只限於製成品檢測。香港現正採用世界衞生組織（世衞）在一九九五年公布的「生產質量管理規範」標準。**檢討委員會建議香港的「生產質量管理規範」標準應在約兩年內首先提升至世衞於二零零七年公布的標準，然後在其後的約兩年內再提升至符合「國際醫藥品稽查協約組織」(Pharmaceutical Inspection Co-operation Scheme)(PIC/S)制訂的更高標準**，即協約組織標準。協約組織標準包括更嚴格監控製藥過程中使用的有效藥劑成分，更嚴格的負責監控整個製藥過程的獲授權人士的資歷要求，改善巡查和發牌安排，以及為進行「生產質量管理規範」所涉的各級人員制訂一套更全面的培訓架構。這項建議應優先實施。*

檢討結果及建議

I．「生產質量管理規範」顧問的建議

3.14 檢討委員會經研究後通過了「生產質量管理規範」顧問的大部分建議，詳情如下：

(a) 提升香港「生產質量管理規範」的標準

3.15 顧問建議衞生署採取分階段的方式，提升香港現時的「生產質量管理規範」發牌標準，務求在大約四年內達到「國際醫藥品稽查協約組織」1(Pharmaceutical Inspection Co-operation Scheme)(PIC/S)(下稱「協約組織」)的標準，以反映行業技術的轉變，同時與國際最佳做法接軌。在過渡期內，香港的「生產質量管理規範」發牌標準應在大約兩年內首先提升至世衞二零零七年的標準。

3.16 顧問建議衞生署委託顧問協助本地製藥業邁向協約組織的標準。此外，衞生署應採納國際「生產質量管理規範」指引文件，要求業界執行，並設立資訊網站及成立有業界參與的業界聯絡小組。

3．21 在現階段，獲授權人士一職仍須由具備相關經驗的藥劑師擔任。檢討委員會察悉，由藥劑師擔任獲授權人士，會同時受到「生產質量管理規範」所訂的獲授權人士責任，以及藥劑業及毒藥管理局對藥劑師專業地位所訂的紀律處分機制所約束。這套「雙重把關機制」對保障公眾健康有利。

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第67條. 修訂附表5 (為本條例第 27(c)條的施行而根據本規例第15 條訂明的說明)
(4) 附表5——
加入
"12. 須加上標籤標明"**Prescription Drug 處方藥物**"的字句——
含有附表 3所列毒藥的藥物
13. 須加上標籤標明"**Drug under Supervised Sales 監督售賣**藥物"的字句

"Drug under Supervised Sales 監督售賣藥物"並沒有表明在誰人的監管之下可以售賣，名稱非常含混

在全球大多數先進國家，如英美澳紐，藥物分類清晰，大致分為以下 4 項，市民可以一目了然 –

1. General Sales Products (eg. Panadol)

2. Pharmacy only Medicines - 顧名思義，是在藥房的監管下售賣，等同現時的第一部毒藥

3. Pharmacist only Medicines -顧名思義，是在藥劑師的監管下售賣，等同現時的第一部第一附表毒藥

4. Prescription Medicines -處方藥物，需要醫生紙才可購買

希望政府貫徹始終，制度合乎情理，依國際標準。

第 59 條 36B Clinical trial certificate duration 臨床試驗證書有效期

臨床試驗證書的有效期不應由 2 年延長至 5 年。現時並沒有機制去確保，該研究的整個過程中，是根據 臨床試驗證書申請背景下進行的， 研究人員可以在不通知衛生署情況下，在研究期間內改變研究的細節。

在現時情況下，若果實驗比 證明書的有效期為長，
研究人員會被要求更新 臨床試驗證書，這給監管機構機會，去檢討研究試驗細節是否乎合病

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人的利益和患者安全。
如果到期期限為 5 年，很多研究的細節可能會在監管者不知情之情況下改變。

例如，AVIHA（商品名癌思停 Avastin 在醫管局）的臨床試驗證明書是由衛生署去年發出，但試驗從未開始。已知的是該研究的所有重要元素已經改變，包括研究設計和主要研究者，但臨床試驗證明書已發出，試驗一樣能夠開始，直至證書明年屆滿。
直至只研究員有需要就 AVIHA 試驗更新臨床試驗證明書， 監管員始有機會就試驗進行檢討，並可能發現很多重要的試驗細節都被改變了。若證書到期的期限延長至 5 年，監管機構將永遠不會知道， 在長達半世紀研究的裡面， 試驗的細節已經改變 。

問題要求官立回應：

1·食物及衛生局請提供該 CTC（臨床試驗證書）提供的 2 年有效期結束前 無法完成的試驗臨床試驗的次數

2.有幾多研究因為證書有效期內遲開始而需要更生？

3 ·衛生署怎樣監察研究，確保有效期內，研究的所有細節都是安全的？

4 ·如果沒有監察，如何衛生署確保病人安全在 2 年期間內得到最高水平保障？

5 ·就 AVIHA（商品名癌思停 Avastin 在 HA）試驗，請提供原本應用程序的細節和 AVIHA 試驗 詳細信息 供立法會議員參考的當前(如：研究方案，主要研究者姓名，藥品質量保證等)？

6·怎樣才能衛生署確保審批的研究，細節 2 年間不會改變？

7 ·如果有效期延長至 5 年，醫管局怎樣能確保研究細節於證書的有效期內不變？

8 ·若原來的獲審批的臨床試驗的應用內容細節在期限內有變化，更改，而不向衛生署報告，申報，署方會否有罰則？

9.為何草案內並沒有就不申報變更加上罰則？

The validity of the clinical trial certificate should not be extended to 5 years from 2 years. As there is no other mechanism to check that studies are conducted within the context of the CTC application during the entire course of the study, investigators may change the details of the study without notifying the Dept of Health within the study period. At this moment, the investigator will be required to renew the CTC if the study continues for longer than the

4/F, Duke of Windsor Social Service Building, 15 Hennessy Road, Wanchai, Hong Kong.
Tel: 8100 4226 E-mail: hkpharmacistsunion@gmail.com

expiry date of the certificate which gives the regulator a chance to review the details of the study for the interests and safety of patients.

If the expiry period is 5 years, many of the details of the study may be changed without the knowledge of the regulator.

For example, the AVIHA (Avastin in HA) clinical trial was issued a CTC clinical trial certificate last year by the Department of Health but the trial never commenced. All the important elements of the study is know to have changed including the study design and principle investigator but the trial is able to started with the CTC that was issued until the expiry of the certificate next year. Only upon the need for the investigator to renew the CTC for the AVIHA trial would the regulator have the opportunity to conduct a review and may find out many important details have been changed. If the period of expiry is extended to 5 years, the regulator would never know that the details of the trial had been changed as the study is likely to be completed on half a decade time.

Question Require Govt to respond:

1· FHB please provide the number of clinical trials that have not been able to complete the trial by end of 2 years expiration date provided by the CTC (Clinical Trial Certificate)
2· How many of those trials that needed the renewal of CTC because of late commencement of trial?
3· How does the DH monitor that all details of study are the same within the period of CTC validity?
4· If not monitored, how does the DH ensure that the patients are provided with the highest levels of safety within the course of the 2 years?
5· In regards to the AVIHA (Avastin in HA) trial, please provide the original application details and the current details of the AVIHA trial for reference of legco mbers (eg: study protocol, names of principle investigator, drug quality assurance etc) ?
6· How can the DH ensure that the trial details are not changed during the duration of the trial of 2 years?
7· If the period is extended to 5 years, how can the HA ensure that the study details have not been changed within the valid period of CTC?
8· Is there any penalty for not updating or reporting to the DH about changes of the details of the study if there are changes from the original application which was approved by the DH for the CTC?
9· Why is the law not adding the penalty for not reporting changes?

HONG KONG PHARMACOLOGY SOCIETY
香 港 藥 理 學 學 會
Professor Bernard Cheung
c/o Department of Medicine
The University of Hong Kong

3 July 2014

Professor the Honorable Joseph Lee Kok-long, SBS, JP, PhD, RN
Chairman
Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014
Legislative Council Complex
1 Legislative Council Road
Central, Hong Kong

Dear Professor Lee

Pharmacy and Poisons (Amendment) Bill 2014

On behalf of the Hong Kong Pharmacology Society, I am writing in support of the bill.

Our Society believes that it is essential to maintain good records, which may be written or electronic, of orders of drugs. This would reduce errors in the requisition of drugs and facilitate the tracing of drugs.

We also believe that the Authorized Person overseeing the manufacture of pharmaceutical products in Hong Kong should be a person who has the appropriate training and experience. While this person may or may not be a pharmacist, to ensure the quality of the manufactured drug, the input of a pharmacist is essential.

Although we understand the practical difficulties of having a registered pharmacist on the premises at all times when the store is open, we believe that the presence of a pharmacist is desirable when Part I Poisons are dispensed.

Lastly, we support extending the validity of clinical trial certificates to a maximum of five years, because many trials nowadays are of this duration.

Yours sincerely

Professor Bernard M Y Cheung
President
Hong Kong Pharmacology Society

LC Paper No. CB(2)2042/13-14(01)

From:
To: bc_54_13@legco.gov.hk

Date: Friday, July 11, 2014 02:04PM
Subject: 病人權益協會 藥物安全聯盟 讓各委員傳閱

Dear Honorary Legco Bills Comm Members,

Drug Safety Consortium is a patient group jointly founded by Patients, Drs and Pharmacists straightly after drug incidents happened in 2009.

Patients do have lots of concerns towards the Bill, take brief example,

"放寬藥產藥標準，香港藥物質數下降，我地病人第一個受影響。但政府竟然掉轉話安全左，試問轉左非藥劑師做負責人，點樣會安全左？"

"另外，衛生署講到明話藥劑製品係有確定療效，宜家改成不倫不類的定義，我地病人連什麼是藥，什麼是健康食品都分不清楚。

政府成日話安全左，你話比我聽有改例後有乜安全左?"

Below letter is written by Mr Kin Ping TSANG, a well known international patient group leader.

Thanks a lot for your kindest consideration and help. If you would like to meet up with Mr TSANG, please do not hesitate to contact us at

Cordially,
Drug Safety Consortium

11 July 2014

Dear Legco Members,

Re: Concerns of Patients, Doctors, and Pharmacists in the Drug Safety Consortium - Patients at Risk from Inappropriate Changes in Pharmacy Law

On behalf of the Drug Safety Consortium, a non-profit organization established in 2009 by patients, doctors, and pharmacists, to address the issues pertaining to medication safety, we would like to express our concerns on the recently proposals in the Pharmacy and Poisons Amendment Bill 2014.

As human health and safety is of the highest importance in every society, proposals to change the pharmacy laws in Hong Kong should be evaluated in a thorough and comprehensive manner. During the course of the past few Bills Committee Meeting, we have observed that the government has only been trying to rush through the process to get the Bill passed without thorough understanding of the issues and concerns raised by a huge number of professionals and patients. The public is at risk of having laws that does not enhance safety but lower the standards of safety in the current healthcare system.

The numerous letters from organizations with wide representation which raised concerns have been ignored and not tabled for discussion at the Bills Committee. It is inappropriate to continue to mislead Legco members with the opinions of the few individuals which blindly support the government and which may not comprehend the full implications of the Bill on medication safety.

Patients and healthcare professionals from USA , Malaysia, and around the world have attended to observe the Bills Committee recently and have found this unfair way to discuss the Bill proposals to be very unprofessional.

Please find the key points of our concerns attached for your reference and hope you can ensure that a fair process is provided to discuss the issues with the current Bill and in any case, the Bill should not be rushed to be approved if issues are not resolved. You will find that better and more thorough understanding of the implications of the Bill will result in best results to protect the public in the long term.

Tsang Kin-ping
Patient Group Leader
Drug Safety Consortium

Annex

《2014 年藥劑業及毒藥(修 訂)條例草案》

	草案條目	業界要求需詳細討論及修改的條目
1	第2部 第4條. 修訂第 2條(釋義)	(1) 第2(1) 條，獲授權毒藥銷售商的定義
2	第2部 第4條. 修訂第 2條(釋義)	(3) 第2(1) 條，藥劑製品及藥物的定義
3	第2部 第4條. 修訂第 2條(釋義)	(6) 第2(1) 條 **“《行為守則》(code of conduct) 指根據第 4B條發出的、不時根據該條修訂的《行為守則》；** **《執業守則》(code of practice) 指根據第4B 條發出的、不時根據該條修訂的《執業守則》**
3	第2部 第5條. 修訂第 3條 (藥劑業及毒藥管理局)	6. 加入第 4B條 “4B. 《行為守則》及《執業守則》
3	第2部 第14條. 修訂第 15條(紀律委員會的委出)	在第15(1A) 條之前—— 加入 a) 管理局接到投訴，而投訴是關於某註冊藥劑師或某註冊藥劑師的僱員的行為操守，或管理局覺得，某註冊藥劑師已違反適用於該藥劑師的《行為守則》；
4	第2部 第30條. 加入第 34A條	“34A. 追討收集或化驗毒藥或藥劑製品等的費用及開支
5	第3部 第52條. 加入第 30A至30F條	30C. 申請註冊為獲授權人 (ii) 持有在修畢委員會認可的課程後頒授的資格；
6	第3部 第67條. 修訂附表5 (為本條例第 27(c)條的施行而根據本規例第15 條訂明的說明)	(4) 附表5—— 加入 “12. 須加上標籤標明“Prescription Drug 處方藥物”的字句—— 含有附表 3所列毒藥的藥物 13. 須加上標籤標明“Drug under Supervised Sales 監督售賣藥物”的字句
8	第59條 36B	Clinical trial certificate duration change from 2 to 5 years
9	RIA report	We urge government to disclose the RIA report

Contacts of the Legislative Council Secretariat
Attn: Ms Yu Wing-chi
Fax: 2105 7045 Email: bc-54_13@legco.gov.hk

Contacts of the office of the Chief Executive,
Hong Kong Special Administrative Region
Fax: 25090580 Email: ceo@ceo.gov.hk

尊敬的特首，立法會議員，

促請政府收回《2014 年藥劑業及毒藥(修訂)條例草案》請願信

我們支持立法會議員促請政府全面收回《2014 年藥劑業及毒藥(修訂)條例草案》，（會議時間及日期：2014 年 5 月 20 日，下午 2 時 30 分，立法會 1 號會議室）。我們需要一個透明度高、公平、公開，並有效地顧及所有持份者的諮詢程序。

我們提出這個訴求，主要的原因是因為藥劑業及毒藥管理局在草擬《2014 年藥劑業及毒藥(修訂)條例草案》時，沒有諮詢業界及主要持份者的意見。草案內有很多細節內容，政府用了保密原則處理。直至這份草案於 2014 年 3 月 21 日刊登於憲報，公開給公眾閱讀。憲報刊登三天後，草案瞬速地於 2014 年 3 月 26 日，經由立法會通過一讀及二讀的立法程序。我們覺得藥劑業及毒藥管理局的做法不合理，有違立法原意。沒有給予持份者足夠時間和空間討論這個關於藥物安全、公共健康的重要議題。基於公平原則，我們不希望政府繼續堅持，常試通過這份草案的立法程序，而不顧及、並不給予所有持份者足夠時間、平等機會去表達意見、復核草案，並發表意願。

我們看到藥劑業及毒藥管理局沒有提供適當的機會，給所有主要持份者去理解條例草案的含意，亦沒有提供足夠的資訊，給持份者去討論這份草案的內容。
所以，我們希望政府能夠專重各主要持份者的意願及權利，能夠保持開放及持平的態度，給予我們一個公平、公開及適當的諮詢(修訂)條例草案程序。

我們希望政府能夠重新草擬一份（白皮書），並重新諮詢所有持份者的意見，然後再修訂《藥劑業及毒藥(修訂)條例草案》。

多謝你們關注這個議題，並感謝你們對我們的支持！

姓名:
簽名:
日期:

Dear Legislative Council Members,

Re: Petition Letter for the Government to Withdraw the Pharmacy and Poisons (Amendment) Bill 2014 (the Bill)

We would like to support the motion made by legislative Council members (at the meeting on 20 May at 2:30pm in Conference Room 1 of Bills Committee on Pharmacy and Poisons Amendment Bill 2014) that this Amendment Bill should be retracted so that a fair, effective, and thorough consultation process with all stakeholders involved can be properly conducted.

We would like to raise the complaint that many of the details of the Pharmacy and Poisons Amendment Bill 2014 were drafted without any consultation with key stakeholders and many of the details of " the Bill " had been kept confidential until being gazzetted for public viewing on 21 March 2014. Then, only after 3 working days, " the Bill" was presented to the Legislative Council for the process of first read and second read on 26 March 2014. It is impossible and unreasonable for the government to expect stakeholders to be able to give due consideration to " the Bill " of such importance and gravity to public health and safety and provide quality feedback to the government in such short space of time. In all fairness, we believe the government should not continue to attempt to pass " a Bill " that all stakeholders had not been given sufficient time to understand, review, and comment.

We are of the strong view that all important stakeholders including doctors, pharmacists, pharmaceutical traders, consumers, and patients have not been afforded with a fair and proper consultation process by the government to understand the implications of the proposed Bill and have not been provided with the necessary information to make informed decisions about the proposed amendments of the Bill.

Therefore, we believe we have the right to be respected by the government as an important stakeholder and have the right to be provided with a fair and proper process in the bill amendment process from the very beginning of the bill amendment process..

We look forward to the government to initiate a new consultation for amending the Pharmacy and Poisons Ordinance together with the subsequent development of the drafting of a "White Bill" for discussion by all stakeholders.

Thank you for your attention to this important matter and your follow-up support is most appreciated.

cc: Honorable CY Leung, Chief Executive, HKSAR

Yours truly,

Name:

Signature:

Date:

LC Paper No. CB(2)1543/13-14(01)

Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014

Consultation work carried out by the Administration when drafting the legislative proposals to enhance the regulation of pharmaceutical products in Hong Kong

At the meeting of the Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014 held on 24 April 2014, Members enquired about the consultation work carried out by the Administration when drafting the legislative proposals to enhance the regulation of pharmaceutical products in Hong Kong. The paper aims to provide Members with the relevant information.

2. The main objective of the Administration's current legislative proposals is to implement some of the recommendations put forth by the Review Committee on the Regulation of Pharmaceutical Products in Hong Kong ("the Review Committee"), which seek to enhance the safety of pharmaceutical products in Hong Kong and protect public health. In early 2009, a series of incidents relating to the safety of pharmaceutical products caused widespread concern in the community. In response, the Government set up in March 2009 the Review Committee to conduct a comprehensive review on the existing regulatory regime for pharmaceutical products. The Review Committee was chaired by the Permanent Secretary for Food and Health (Health) and comprised of members from various representative sectors, including the pharmaceutical sector, medical profession, academia, patient groups and consumer representatives. In consideration of the wide range and complexity of the issues to be examined, the Review Committee set up two Subcommittees, one on quality management of drug manufacturing and another on drug distribution and procurement, to conduct in-depth study on various issues. The memberships of the Review Committee and the above two Subcommittees are set out at columns (a) to (c) of **Annex 1**.

3. The Review Committee issued its report with 75 recommendations in December 2009 and submitted it to Legislative Council Panel on Health Services ("the Panel") in January 2010. Among these recommendations, the Administration is required to amend the existing Pharmacy and Poisons Ordinance (Cap. 138) and its subsidiary legislation in order to implement 16 recommendations. To assess the impacts of the proposed legislative amendments on various stakeholders and to ensure transparency of the legislative process, the Administration commissioned a consultant in January

2011 to conduct a Regulatory Impact Assessment ("RIA"). The assessment methods included (i) soliciting stakeholders' views in consultation meetings and workshops and (ii) gauging public sentiments towards the proposed legislative amendments through a public opinion survey carried out by the University of Hong Kong. During the period from February to March 2011, the consultant held a total of 24 in-depth consultation meetings and 12 interactive workshops with major stakeholders (the list is in column (d) of **Annex 1**). Subsequently, the consultant completed the RIA report in January 2013.

4. At the meeting of the Panel held on 18 November 2013, the Administration tabled a paper (LC Paper No. CB(2)254/13-14(03)) on the legislative proposals to enhance the regulation of pharmaceutical products in Hong Kong. The paper provides Members with information on the background, objective and proposed modus operandi of the suggested requirements. Subsequently, the Administration attended the special meeting of the Panel held on 10 December 2013 to listen to views and concerns of the relevant stakeholders on the legislative proposals (list of deputations which attended the special meeting can be found in column (e) of **Annex 1**).

5. The consultation work mentioned in paragraphs 2 to 4 above involved a total of **57 organisations/enterprises from different sectors**. Besides, the Administration also met with individual organisations respectively, and/or provided them with written responses (list of the relevant organisations can be found in columns (g) and (i) of **Annex 1**).

6. Apart from amending the Pharmacy and Poisons Ordinance and its subsidiary legislation for the purpose of implementing some recommendations of the Review Committee, the Administration has planned to revise or formulate Codes of Practice ("COPs") for relevant licensed/registered drug traders (including drugs manufacturers, wholesalers and retailers) and Code of Conduct ("COC") for registered pharmacists in order to implement the other recommendations of the Review Committee. Since January 2012, the Pharmacy and Poisons Board ("PPB") has set up different working groups, with trade representatives and stakeholders as members, to provide comments on the revision/formulation of relevant COPs/COC In addition, during the process of revising/formulating the relevant COPs/COC, the Administration gathered views through a number of consultation meetings, public consultation and briefing sessions. Attending/participating parties included many trade representatives (including **a total of 40 organisations/enterprises from different sectors, all authorized sellers of poisons, all listed sellers of poisons, all licensed**

wholesalers of poisons and importers/exporters of pharmaceutical products as well as all licensed manufacturers[1]). Details and progress of the relevant work are set out at column (f) of **Annex 1** and **Annex 2**.

7. After numerous consultations and exchanges with different trade parties and relevant stakeholders through various channels, we have concluded that the trade and stakeholders are supportive of the Administration's legislative amendments to enhance the regulation of pharmaceutical products in Hong Kong, so as to provide better protection for the public. The information provided in this paper shows that the processes of drafting the legislative proposals and revising/formulating the relevant COPs/COC are both open and transparent. Apart from engaging trade representatives and stakeholders in the drafting work, the Administration has also conducted extensive consultation and reported to the relevant parties from time to time the latest updates and progress of these proposals. The Administration has also responded actively to the concerns raised by Members and the trade, and made appropriate adjustments to the legislative proposals.

8. As mentioned above, the proposals and implementation details for enhancing the regulation of pharmaceutical products in Hong Kong have been formulated after extensive discussions and studies by organisations and individuals from various sectors since March 2009, with appropriate adjustments in response to the concerns raised by the trade, stakeholders and the public expressed through various channels. We consider that the current legislative proposals have suitably addressed the urgent need of enhancing the regulation of pharmaceutical products in Hong Kong, and have also taken account of and responded as appropriate to concerns of the trade, stakeholders and the public. We hope to implement the recommendations of the Review Committee as early as possible, with a view to perfecting the regulatory regime of pharmaceutical products in Hong Kong and providing better protection to the general public.

Food and Health Bureau
16 May 2014

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[1] As the "COC for registered pharmcists" is still being formulated, PPB will consult at later stage the relevant stakeholders, including registered pharmacists.

Annex 1

Consultation efforts by the Administration and the Pharmacy and Poisons Board with relevant organisations on the Pharmacy and Poisons (Amendment) Bill 2014

	Review Committee on Regulation of Pharmaceutical Products in Hong Kong (Review Committee) (Mar to Dec 2009) (a)	Subcommittee on Drug Manufacturing (Mar to Dec 2009) (b)	Subcommittee on Drug Distribution and Procurement (Mar to Dec 2009) (c)	Stakeholders participating in Consultation Meetings conducted under the Regulatory Impact Assessment (*) (Feb to Mar 2011) (d)	**Special meeting of the Panel on Health Services of the Legislative Council** (10 Dec 2013) (e)	**Consultation efforts by the Pharmacy and Poisons Board for revising/formulating the Codes of Practice (COP) for relevant licensed drug traders / formulating the Code of Conduct (COC) for registered pharmacists** (Please refer to the Annex 2 for the consultation details) (Jan 2012 to present) (f)	**The Administration's written response** (g)	**Meeting with the Administration** (h)
Trade associations								
Hong Kong Association of the Pharmaceutical Industry 香港科研製藥聯會	✓	✓	✓	✓	✓	✓		
The Hong Kong Pharmaceutical Manufacturers Association Limited 香港製藥商會有限公司	✓	✓	✓	✓	✓	✓		
The Pharmaceutical Distributors Association of Hong Kong Limited 香港醫藥經銷業協會有限公司	✓	✓	✓	✓	✓	✓		
Hong Kong Suppliers Association Limited 香港供應商協會有限公司				✓	✓	✓	16 Jan 2014	
The Hong Kong Medicine Dealers Guild 香港藥行商會				✓ (Written comments)		✓		
The Direct Selling Association of Hong Kong 香港直銷協會				✓	✓	✓	23 Jan 2014	6 Feb 2014
Hong Kong Retail Management Association 香港零售管理協會					✓ (Written comments)	✓		
The Hong Kong Health Food Association 香港保健食品協會				✓		✓		
The Cosmetic and Perfumery Association of Hong Kong 香港化粧品同業協會				✓		✓	23 Jan 2014	19 Feb 2014
Federation of Beauty Industry Hong Kong 香港美容業總會				✓		✓		
The Hong Kong General Chamber of Commerce 香港總商會						✓		
The Chinese General Chamber of Commerce 香港中華總商會						✓		

	Review Committee on Regulation of Pharmaceutical Products in Hong Kong (Review Committee)	Subcommittee on Drug Manufacturing	Subcommittee on Drug Distribution and Procurement	Stakeholders participating in Consultation Meetings conducted under the Regulatory Impact Assessment (*)	**Special meeting of the Panel on Health Services of the Legislative Council**	**Consultation efforts by the Pharmacy and Poisons Board for revising/formulating the Codes of Practice (COP) for relevant licensed drug traders / formulating the Code of Conduct (COC) for registered pharmacists** (Please refer to the Annex 2 for the consultation details)	**The Administration's written response**	**Meeting with the Administration**
	(Mar to Dec 2009)	(Mar to Dec 2009)	(Mar to Dec 2009)	(Feb to Mar 2011)	(10 Dec 2013)	(Jan 2012 to present)		
	(a)	**(b)**	**(c)**	**(d)**	**(e)**	**(f)**	**(g)**	**(h)**
Hong Kong General Chamber of Pharmacy Limited 港九藥房總商會有限公司	✓		✓	✓	✓	✓		7 Feb 2014; 29 Apr 2014
Hong Kong Chinese Medicine Merchants Association 香港中藥聯商會						✓		
Pharmaceutical Trade Alliance 藥業商聯盟					✓			
Pharmacists Associations								
The Practising Pharmacists Association of Hong Kong 香港執業藥劑師協會	✓	✓	✓	✓	✓	✓		18 Feb 2014
The Society of Hospital Pharmacists of Hong Kong 香港醫院藥劑師學會	✓	✓	✓	✓	✓	✓		
The Pharmaceutical Society of Hong Kong 香港藥學會	✓	✓	✓	✓	✓	✓		11 Feb 2014
College of Pharmacy Practice 藥劑專科學院					✓			
Hong Kong Academy of Pharmacy 香港藥劑專科學院					✓			
College of Primary Healthcare Pharmacy 基層醫療藥劑專科學院					✓			
Hong Kong Pharmacists Union (established in 2014) 香港藥劑師聯盟 (2014年成立)						✓		June 2014 (tentative)
Patients/ Consumers Groups								
Care for your Heart – Cardiac Patients Mutual Support Association 關心您的心 – 心臟病友互助組織	✓	✓	✓	✓				
Alliance for Renal Patients Mutual Help Association 腎友聯	✓	✓	✓	✓				
Hong Kong Alliance for Patients' Organizations 香港病人組織聯盟					✓			
Consumer Council 消費者委員會	✓		✓	✓	✓ (Written comments)	✓		

	Review Committee on Regulation of Pharmaceutical Products in Hong Kong (Review Committee)	Subcommittee on Drug Manufacturing	Subcommittee on Drug Distribution and Procurement	Stakeholders participating in Consultation Meetings conducted under the Regulatory Impact Assessment (*)	**Special meeting of the Panel on Health Services of the Legislative Council**	**Consultation efforts by the Pharmacy and Poisons Board for revising/formulating the Codes of Practice (COP) for relevant licensed drug traders / formulating the Code of Conduct (COC) for registered pharmacists** (Please refer to the Annex 2 for the consultation details)	**The Administration's written response**	**Meeting with the Administration**
	(Mar to Dec 2009)	(Mar to Dec 2009)	(Mar to Dec 2009)	(Feb to Mar 2011)	(10 Dec 2013)	(Jan 2012 to present)		
	(a)	**(b)**	**(c)**	**(d)**	**(e)**	**(f)**	**(g)**	**(h)**
Academia								
School of Pharmacy The Chinese University of Hong Kong (CUHK) 香港中文大學藥劑學院	✓	✓	✓	✓	✓	✓		
Faculty of Medicine, CUHK 香港中文學醫學院				✓ (Written comments)				
Li Ka Shing Faculty of Medicine, University of Hong Kong (HKU) 香港大學李嘉誠醫學院				✓ (Written comments)				
Department of Pharmacology and Pharmacy, HKU 香港大學藥理及藥劑學系					✓	✓		
Medical / Veterinary Professionals								
Hong Kong Academy of Medicine 香港醫學專科學院				✓ (Written comments)				
Hong Kong Medical Association 香港醫學會	✓	✓	✓	✓	✓	✓		
Hong Kong Doctors Union 香港西醫工會	✓	✓	✓	✓	✓	✓		
Association of Doctors in Aesthetic Medicine (Hong Kong) 香港醫療美容醫生協會					✓			
Association of Medical Practitioners of Societies' Clinics 社團診所醫生協會					✓			
Hong Kong Dental Association 香港牙醫學會					✓	✓		
China (Hong Kong) Veterinary Association 中國 (香港) 獸醫學會				✓ (Written comments)				
Hong Kong Veterinary Association 香港獸醫學會				✓ (Written comments)		✓		
Hospital groups								
Hong Kong Private Hospitals Association 香港私家醫院聯會	✓		✓	✓	✓			
Hospital Authority 醫院管理局				✓				

	Review Committee on Regulation of Pharmaceutical Products in Hong Kong (Review Committee)	Subcommittee on Drug Manufacturing	Subcommittee on Drug Distribution and Procurement	Stakeholders participating in Consultation Meetings conducted under the Regulatory Impact Assessment (*)	**Special meeting of the Panel on Health Services of the Legislative Council**	**Consultation efforts by the Pharmacy and Poisons Board for revising/formulating the Codes of Practice (COP) for relevant licensed drug traders / formulating the Code of Conduct (COC) for registered pharmacists** (Please refer to the Annex 2 for the consultation details)	**The Administration's written response**	**Meeting with the Administration**
	(Mar to Dec 2009)	(Mar to Dec 2009)	(Mar to Dec 2009)	(Feb to Mar 2011)	(10 Dec 2013)	(Jan 2012 to present)		
	(a)	**(b)**	**(c)**	**(d)**	**(e)**	**(f)**	**(g)**	**(h)**
Government departments								
Customs and Excise Department 香港海關				✓ (Written comments)				
Government Laboratory 政府化驗所				✓				
Licence holders / Registered pharmacists								
All ASPs 所有獲授權毒藥銷售商						✓		
All LSPs 所有列載毒藥銷售商						✓		
All licensed wholesalers of poisons and importers/ exporters of pharmaceutical products 所有持牌毒藥批發商及藥劑製品進/出口商						✓		
All licensed manufacturers 所有持牌製造商						✓		
Registered pharmacisits 註冊藥劑師						Drafting of the COC is in progess; to consult relevant stakeholders, including registered pharmacists in due course.		
Individual Enterprises								
Cheung Tai Dispensary (H.K.) Limited 長泰西藥房 (香港) 有限公司						✓		
Mannings - Hong Kong Dairy Farm Company 萬寧 - 香港牛奶公司						✓		
Watsons's The Chemist - A.S. Watson Group 屈臣氏大藥房						✓		
Activecare Pharmacy Limited 明心大藥房有限公司						✓		
The Dairy Farm Company Limited 牛奶公司						✓		
China Resources Vanguard (Hong Kong) Company Limited 華潤萬家 (香港) 有限公司						✓		
CR Care Company Limited 華潤堂						✓		

	Review Committee on Regulation of Pharmaceutical Products in Hong Kong (Review Committee)	Subcommittee on Drug Manufacturing	Subcommittee on Drug Distribution and Procurement	Stakeholders participating in Consultation Meetings conducted under the Regulatory Impact Assessment (*)	**Special meeting of the Panel on Health Services of the Legislative Council**	**Consultation efforts by the Pharmacy and Poisons Board for revising/formulating the Codes of Practice (COP) for relevant licensed drug traders / formulating the Code of Conduct (COC) for registered pharmacists** (Please refer to the Annex 2 for the consultation details)	**The Administration's written response**	**Meeting with the Administration**
	(Mar to Dec 2009)	(Mar to Dec 2009)	(Mar to Dec 2009)	(Feb to Mar 2011)	(10 Dec 2013)	(Jan 2012 to present)		
	(a)	**(b)**	**(c)**	**(d)**	**(e)**	**(f)**	**(g)**	**(h)**
Tung Fong Hung Medicine Company Limited 東方紅藥業有限公司						✓		
Culture Homes (Outlet Stores Wholesale Centre) Limited 文化村 (長者用品展銷中心) 有限公司						✓		
Kai Tai Chinese Medicine (Holdings) Company Limited 啟泰藥業集團有限公司						✓		
DKSH Hong Kong Limited 大昌華嘉香港有限公司				✓		✓		
LF Asia (Hong Kong) Limited 利豐亞洲香港有限公司				✓		✓		
Zuellig Pharma Limited 裕利醫藥				✓		✓		
Usana Hong Kong Limited Usana香港有限公司						✓		
Nu Skin Enterprises Hong Kong Incorporation 美國如新企業香港分公司						✓		

(*) The consultant held a total of 24 in-depth consultation meetings and 12 interactive

Annex 2

Consultation efforts by the Pharmacy and Poisons Board for revising / formulating the Codes of Practice for relevant licensed drug traders and formulating Code of Conduct for registered pharmacists

	Code of Practice ("COP") for Authorised Seller of Poisons ("ASP")		COP for Listed Seller of Poisons ("LSP")		COP for Wholesalers and Importers/ Exporters		COP for licensed manufacturers and authoirzed persons		Code of Conduct ("COC") for Registered Pharmcists	
	Working Group	Consultation	Working Group	Consultation	Working Group	Consultation	Working Group	Consultation	Working Group	Consultation
	(Jan to May 2012)	(Jul to Dec 2012)	(Oct 2012 to Apr 2013)	(Jul to Sep 2013)	(Apr to Nov 2013)	(April and July 2014)	(Sep to Dec 2013)	(Sep 2013 to Apr 2014)	(Aug 2013 - Now)	(Drafting in progress - Consultation has not commenced)
Trade associations										
Hong Kong Association of the Pharmaceutical Industry 香港科研製藥聯會					2 representatives	Views invited during the public consultation				
The Hong Kong Pharmaceutical Manufacturers Association Limited 香港製藥商會有限公司					2 representatives	Views invited during the public consultation	7 representatives			
The Pharmaceutical Distributors Association of Hong Kong Limited 香港醫藥經銷業協會有限公司					2 representatives	Views invited during the public consultation				
Hong Kong Suppliers Association Limited 香港供應商協會有限公司						Views invited during the public consultation				
The Hong Kong Medicine Dealers Guild 香港藥行商會						Views invited during the public consultation				
The Direct Selling Association of Hong Kong 香港直銷協會						Views invited during the public consultation				
Hong Kong Retail Management Association 香港零售管理協會				Views invited during the public consultation						
The Hong Kong Health Food Association 香港保健食品協會				Views invited during the public consultation						
The Cosmetic and Perfumery Association of Hong Kong 香港化粧品同業協會				Views invited during the public consultation		Views invited during the public consultation				
Federation of Beauty Industry Hong Kong 香港美容業總會				Views invited during the public consultation						
The Hong Kong General Chamber of Commerce 香港總商會				Views invited during the public consultation						
Hong Kong General Chamber of Pharmacy Limited 港九藥房總商會有限公司	2 representatives	Views invited during the public consultation		Views invited during the public consultation		Views invited during the public consultation				
The Chinese General Chamber of Commerce 香港中華總商會				Views invited during the public consultation						
香港中藥聯商會 Hong Kong Chinese Medicine Merchants Association			1 Representative							

	Code of Practice ("COP") for Authorised Seller of Poisons ("ASP")		COP for Listed Seller of Poisons ("LSP")		COP for Wholesalers and Importers/ Exporters		COP for licensed manufacturers and authoirzed persons		Code of Conduct ("COC") for Registered Pharmcists	
	Working Group	Consultation	Working Group	Consultation	Working Group	Consultation	Working Group	Consultation	Working Group	Consultation
	(Jan to May 2012)	(Jul to Dec 2012)	(Oct 2012 to Apr 2013)	(Jul to Sep 2013)	(Apr to Nov 2013)	(April and July 2014)	(Sep to Dec 2013)	(Sep 2013 to Apr 2014)	(Aug 2013 - Now)	(Drafting in progress - Consultation has not commenced)
Pharmacists Associations										
The Practising Pharmacists Association of Hong Kong 香港執業藥劑師協會		Views invited during the public consultation		Views invited during the public consultation		Views invited during the public consultation			5 Representatives	
The Society of Hospital Pharmacists of Hong Kong 香港醫院藥劑師學會				Views invited during the public consultation		Views invited during the public consultation			5 Representatives	
The Pharmaceutical Society of Hong Kong 香港藥學會		Views invited during the public consultation		Views invited during the public consultation		Views invited during the public consultation			5 Representatives	
Hong Kong Pharmacists Union (established in 2014) 香港藥劑師聯盟 (2014年成立)									5 Representatives	
Patients/ Consumers Groups										
Consumer Council 消費者委員會		Views invited during the public consultation		Views invited during the public consultation		Views invited during the public consultation				
Academia										
School of Pharmacy, The Chinese University of Hong Kong 香港中文大學藥劑學院									5 Representatives	
Department of Pharmacology and Pharmacy, University of Hong Kong 香港大學藥理及藥劑學系									1 Representative	
Medical / Veterinary Professionals										
Hong Kong Medical Association 香港醫學會		Views invited during the public consultation		Views invited during the public consultation		Views invited during the public consultation				
Hong Kong Doctors Union 香港西醫工會		Views invited during the public consultation		Views invited during the public consultation		Views invited during the public consultation				
Hong Kong Dental Association 香港牙醫學會		Views invited during the public consultation		Views invited during the public consultation		Views invited during the public consultation				
Hong Kong Veterinary Association 香港獸醫學會		Views invited during the public consultation		Views invited during the public consultation		Views invited during the public consultation				
Licence holders / Registered pharmacists										
All ASPs 所有獲授權毒藥銷售商	Views from all the ASPs were invited during the public consultation. ASPs were briefed on the revised COP for ASP on 20 Aug 2012 and 27 Sep 2012. A total of 66 and 147 representatives attended the briefings respectively.									

	Code of Practice ("COP") for Authorised Seller of Poisons ("ASP")		COP for Listed Seller of Poisons ("LSP")		COP for Wholesalers and Importers/ Exporters		COP for licensed manufacturers and authoirzed persons		Code of Conduct ("COC") for Registered Pharmcists	
	Working Group	**Consultation**	**Working Group**	**Consultation**	**Working Group**	**Consultation**	**Working Group**	**Consultation**	**Working Group**	**Consultation**
	(Jan to May 2012)	(Jul to Dec 2012)	(Oct 2012 to Apr 2013)	(Jul to Sep 2013)	(Apr to Nov 2013)	(April and July 2014)	(Sep to Dec 2013)	(Sep 2013 to Apr 2014)	(Aug 2013 - Now)	(Drafting in progress - Consultation has not commenced)
All LSPs 所有列載毒藥銷售商			Views from all the licensed LPSs were invited during the public consultation. LSPs were briefed on the draft COP for LSP on 28 Aug 2013. A total of 27 representatives attended the briefing.							
All licensed wholesalers of poisons and importers/ exporters of pharmaceutical products 所有持牌毒藥批發商及藥劑製品進/出口商					Views from all the licensed wholesaler and importers/ exporters were invited during the public consultation. Three briefing sessions was held on 9 April 2014 and 25 April 2014. A total of 204 representatives attended the briefing. Three more briefing sessions will be held in May 2014.					
All licensed manufacturers 所有持牌製造商							Views from all licensed manufacturers were invited during the public consultation. Three briefing sessions were held on 13 Sep 2013, 11 Mar 2014 and 7 Apr 2014. A total of 206 representatives attended the sessions.			
Registered pharmacists 註冊藥劑師									Drafting of COC is in progess; to consult relevant stakeholders, including registered pharmacists in due course.	
Individual Enterprises										
Cheung Tai Dispensary (H.K.) Limited 長泰西藥房 (香港) 有限公司	1 Representative									
Mannings - Hong Kong Dairy Farm Company 萬寧 - 香港牛奶公司	1 Representative		1 Representative							
Watsons's The Chemist - A.S. Watson Group 屈臣氏大藥房	1 Representative		1 Representative							
Activecare Pharmacy Limited 明心大藥房有限公司	1 Representative									
The Dairy Farm Company Limited 牛奶公司			1 Representative							
China Resources Vanguard (Hong Kong) Company Limited 華潤萬家 (香港)有限公司			1 Representative							
CR Care Company Limited 華潤堂			1 Representative							
Tung Fong Hung Medicine Company Limited 東方紅藥業有限公司			1 Representative							
Culture Homes (Outlet Stores Wholesale Centre) Limited 文化村 (長者用品展銷中心) 有限公司			1 Representative							
Kai Tai Chinese Medicine (Holdings) Company Limited 啟泰藥業集團有限公司			1 Representative							

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	Working Group	**Consultation**	**Working Group**	**Consultation**	**Working Group**	**Consultation**	**Working Group**	**Consultation**	**Working Group**	**Consultation**
	(Jan to May 2012)	(Jul to Dec 2012)	(Oct 2012 to Apr 2013)	(Jul to Sep 2013)	(Apr to Nov 2013)	(April and July 2014)	(Sep to Dec 2013)	(Sep 2013 to Apr 2014)	(Aug 2013 - Now)	(Drafting in progress - Consultation has not commenced)
DKSH Hong Kong Limited 大昌華嘉香港有限公司					2 Representative					
LF Asia (Hong Kong) Limited 利豐亞洲香港有限公司					2 Representative					
Zuellig Pharma Limited 裕利醫藥					2 Representative					
Usana Hong Kong Limited Usana 香港有限公司					1 Representative					
Nu Skin Enterprises Hong Kong Incorporation 美國如新企業香港分公司					2 Representative					