Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014

Trade's concerns towards the legislative proposals to enhance the regulation of pharmaceutical products in Hong Kong and the Administration's responses

At the meeting of the Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014 held on 24 April 2014, Members enquired about the comments from the trade received by the Administration regarding the legislative proposals to enhance the regulation of pharmaceutical products in Hong Kong, as well as the Administration's responses. Relevant details are listed in the attached table for Members' reference.

Food and Health Bureau
16 May 2014

Pharmacy and Poisons (Amendment) Bill 2014 (PPAB) – Trade's concerns and the Administration's responses

	Clause no. in PPAB (Relevant provision in PPO / PPR)	Proposed amendments	Concerns from the trade received		The Administration's responses/remarks
Definitions					
1.	Clause 4(1) (PPO, Section 2(1))	<u>Revised definition of "Authorized Seller of Poisons" (ASP)</u>: - To align with section 11 of the PPO, the definition of ASP in section 2(1) of the PPO will be revised from "business" to "registered pharmacist, body corporate or unincorporated body of persons" to define ASP in terms of the entities that may carry on retail sales of poisons in the PPO.	Hong Kong General Chamber of Pharmacy Limited (HKGCPL) Notes 1, 2, 4 & 6 The Pharmaceutical Society of Hong Kong (PSHK) Notes 1, 2, 3, 4 & 5 The Practising Pharmacists Association of Hong Kong (PPAHK) Notes 1, 2, 3, 4 & 5 The Society	<u>Meeting with the Administration on 29 April 2014:</u> HKGCPL was concerned about the legal implication of the proposed revised definition of ASP. <u>Briefing session on the PPAB organized by the Administration with members of PSHK, PPAHK, SHPHK and HKPU on 10 April 2014:</u> Attendees expressed similar concerns about the potential legal implication of the proposed revised definition of ASP on registered pharmacists.	We propose to revise the definition of ASP to reflect the usage in the legislation as an entity that carries on a business of retail sales of poisons. Hence, the proposed revision is purely a technical amendment which seeks to accurately reflect the meaning of an ASP already adopted by the PPO. That is, an ASP should be a registered pharmacist, a body corporate or an unincorporated body of persons. It should be noted that according to existing PPO, if a natural person wants to carry on a business as an ASP, such person must be a registered pharmacist. After clarified by the Administration at the meeting on 29 April 2014, HKGCPL now understands and acknowledges that the technical changes would not lead to the imposition of extra legal liabilities.

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			of Hospital Pharmacists of Hong Kong (SHPHK) Notes 1, 3, 4 & 5 Hong Kong Pharmacists Union (HKPU) Note 5		
2.	Clause 4(2) (PPO, Section 2(1))	<u>Revised definition of "manufacture"</u>: - To cover expressly the packaging and repackaging activities of pharmaceutical products.	Consumer Council Notes 1, 2 & 4	<u>Special meeting of the Panel on Health Services (HS Panel) on 10 December 2013:</u> The deputation **supported** the revision to the definition of "manufacture" to explicitly include both primary and secondary packaging, such that these activities should only be carried out by a licensed manufacturer who has complied with the relevant GMP requirements. It supported the proposed exemption of certain secondary packaging activities which did not affect the safety, efficacy and quality of the products from licensing control.	To implement the Review Committee's recommendation that **secondary packaging** should only be carried out by licensed manufacturers *(Recommendation 20 refers*)*, we have proposed that the packaging activities should only be carried out by a licensed manufacturer who complies with the GMP requirements. To minimize the impact on the trade, certain secondary packaging activities which do not affect the safety, efficacy and quality of the products will be exempted from the licensing control for manufacturers. For examples, packaging activities that involve the labelling of "HK Registration No.", putting on the text "Prescription Drug", "Drug under supervised sales" or labelling to supplement the address of the manufacturers will be exempted from the licensing control for manufacturers (Please also see remarks in item 8 below).

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3.	Clause 4(3) (PPO, Section 2(1))	<u>Revised definition of "pharmaceutical product" and "medicine"</u>: - To include also substance/ combination of substances presented as having properties for treating or preventing disease (with reference to the definition adopted by the European Commission).	PSHK Notes 1, 2, 3, 4 & 5 PPAHK Notes 1, 2, 3, 4 & 5 SHPHK Notes 1, 3, 4 & 5 HKPU Note 5 Hong Kong Association of Pharmaceutical Industry (HKAPI) Notes 1, 2, 3, 4 & 7 Pharmaceutical Distributors Association of Hong Kong (PDAHK) Notes 1, 2, 3, 4 & 7 The Hong Kong Pharmaceutical Manufacturers Association (HKPMA) Notes 1, 2, 3, 4 & 7	<u>Briefing session on the PPAB organized by the Administration with members of PSHK, PPAHK, SHPHK and HKPU on 10 April 2014:</u> Attendees expressed concerns about the scope of products that would be regarded as "pharmaceutical product" by virtue of "presented as having properties for treating or preventing disease". <u>Briefing session on the PPAB organized by the Administration with members of HKAPI, PDAHK, HKPMA, HKSA, DSAHK and CPAHK on 14 April 2014</u>: Attendees expressed similar concern as to the scope of products that would be covered by "presented as having properties for treating or preventing disease".	To align with the international practice, we have proposed to revise the definition of "pharmaceutical product" in accordance with the definition of the European Commission and to put it on a par with similar definition adopted by Australia and the United Kingdom, etc. The **current guidance note** on registration of pharmaceutical product published by the Department of Health (DH) specifies that a product may fall within the definition of pharmaceutical product under the PPO if it contains a drug substance in its composition, <u>or</u> if **it carries "medicinal" claims in its label, leaflet, brochure, wrapper, advertisements and other promotional materials**. Therefore, the revised definition of pharmaceutical product as proposed by the PPAB includes "presented as having properties for treating or preventing disease" only aims to codify the current registration requirement.

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			Hong Kong Suppliers Association Limited (HKSA)[Note 4] Direct Selling Association of Hong Kong (DSAHK)[Note 4] The Cosmetics & Perfumery Association of Hong Kong Limited (CPAHK) [Note 4]		
Manufacture of pharmaceutical products					
4.	Clause 52 (PPR, Reg. 30A-F)	<u>The Authorized Persons (AP) system</u>: - A licensed manufacturer is required to employ at least one AP to ensure and certify that the pharmaceutical products are	College of Pharmacy Practice SHPHK [Note 1, 3, 4 & 5]	<u>HS Panel's special meeting on 10 December 2013:</u> The deputations **supported** the maintaining of an AP register for all pharmaceutical product manufacturers, and consider that the qualification requirements for AP should include being a registered pharmacist specialized in areas such as pharmaceutics, quality assurance	This proposal was recommended by the Review Committee *(Recommendation 6 refers*)*.

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		manufactured and checked in accordance with the GMP Guide for pharmaceutical products. The requirement to keep a register of AP is also imposed, with provisions setting out the application procedure and qualifications required for registration as an AP and other registration matters.		and medication safety.	
			Consumer Council [Notes 1, 2 & 4]	<u>HS Panel's special meeting on 10 December 2013:</u> The deputation was of the view that in case the AP of a licensed manufacturer was found incompetent to perform the AP role and was removed from the AP register, the manufacturer concerned could only be allowed to perform the manufacturing of pharmaceutical products when a new AP was appointed.	
			School of Pharmacy, The Chinese University of Hong Kong [Note 4]	<u>HS Panel's special meeting on 10 December 2013:</u> The deputation suggested the Administration to formulate different levels of qualifications for AP based on factors such as product complexity and risk.	The qualifications required for registration as an AP are listed in the new Reg. 30C of the PPR.
5.	Clause 53 (PPR, Reg. 31)	<u>Labelling requirements</u>: - To require licensed manufacturers to label the containers of pharmaceutical products with two additional particulars,	Consumer Council [Notes 1, 2 & 4]	<u>HS Panel's special meeting on 10 December 2013:</u> The deputation **supported** the proposal, and considered that the Administration should specify the required duration of keeping records relating to the manufacture, testing and sale or supply of pharmaceutical	To further tighten up the manufacturing of pharmaceutical products by aligning with the relevant GMP requirement (taking reference to Pharmaceutical Inspection Cooperation Scheme (PIC/S) GMP guide).

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		namely, the batch number and expiry date of the products.		products by the manufacturers. This duration should correspond to the expiry dates of these products.	
6.	Clause 55 (PPR, Reg. 33)	<u>Registrable particulars:</u> - To require licensed manufacturers to ensure that the registrable particulars of each batch of pharmaceutical products in a finished form correspond exactly with the registered particulars of the products.			To further tighten up the manufacturing of pharmaceutical products by aligning with the relevant GMP requirement (taking reference to PIC/S GMP guide).
		<u>Retention period of samples</u>: - To revise the period for which the control sample of finished pharmaceutical products is to be kept.	HKAPI [Notes 1, 2, 3, 4 & 7]	<u>Meeting with Administration on 2 May 2014:</u> HKAPI was concerned about the impact of extending the requirement of keep control sample of finished products to secondary packaging activities (e.g. over-labelling of statement or replacement of product inserts according to the prevailing labelling requirements) in particular if the products are life-saving products or imported in limited quantity.	To further tighten up the manufacturing of pharmaceutical products by aligning with the relevant GMP requirement (taking reference to PIC/S GMP guide). The Administration will consider HKAPI's concern.

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7.	Clause 57 (PPR, Reg. 35)	<u>Period for completing records</u>: - To revise or state clearly the time by which licensed manufacturers must complete the records relating to the manufacture, sale or supply, testing of, and complaints relating to, pharmaceutical products.			To further tighten up the manufacturing of pharmaceutical products by aligning with the relevant GMP requirement (taking reference to PIC/S GMP guide).
8.	Clause 50(3) (PPR, Reg. 29(2))	<u>Manufacturing of pharmaceutical products must be carried out by licensed manufacturer</u>: - To repeal Reg. 29(2) of PPR such that an ASP is no longer exempted from the requirement of a licence to manufacture pharmaceutical products.	HKGCPL Notes 1, 2, 4 & 6	<u>Meeting with the Administration on 29 April 2014:</u> HKGCPL was concerned about the rationale for the proposal of repealing the existing provision which allows ASPs to conduct manufacturing at registered premises.	Please see remarks in item 2 above. The Administration clarified at the meeting that to ensure the quality of the pharmaceutical products, any compounding and/or preparation by ASPs should be freshly made in accordance with prescription or individual needs of the patient. Manufacturing of pharmaceutical products other than extemporaneous preparations should be conducted by licensed manufacturer that complies with GMP for quality assurance to protect public health. Under the existing PPO, individual dispensing on a prescription or otherwise of any pharmaceutical product has already been exempted from the definition of "manufacture"

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					(section 2 of PPO refers). As such, after the repeal of Reg. 29(2) of the PPR, ASPs will still be allowed to carry out the above dispensing activities.
Import / export and wholesale dealing					
9.	Clause 22 (PPO, Section 28A)	<u>Import / export of pharmaceutical products</u>: - To replace the existing registration system for importers and exporters of pharmaceutical products with a licensing system allowing only a licensed wholesale dealer or licensed manufacturer to import or export pharmaceutical products.			We have also taken this opportunity to streamline the licensing arrangements. By taking reference from the Chinese Medicine Ordinance (Cap. 549), we propose to merge the proposed licensing of wholesalers of non-poisons, with the existing registration of importers or exporters of pharmaceutical products and the licensing of wholesalers of poisons and subject these traders to the same set of licensing control and inspection.
10.	Clause 45 (PPR, Reg. 25) Consequential change: Clause 46 (PPR, Reg.	<u>Expanded control of wholesale dealing</u>: - To expand the licensing control on the sale or supply of poisons <u>by way of wholesale dealing</u> to	Consumer Council [Notes 1, 2 & 4] Department of Pharmacology and Pharmacy, The	<u>HS Panel's special meeting on 10 December 2013:</u> The deputations **supported** the proposals to tighten up the regulatory control over wholesalers of non-poison pharmaceutical products.	The Review Committee has considered that pharmaceutical products classified as non-poisons, though less dangerous, could also endanger patient health if they are not stored and handled properly. It is therefore essential to monitor their quality and maintain a complete record to facilitate recall, if necessary. Moreover, as <u>wholesalers of non-poisons</u>

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	26)	cover pharmaceutical products (covering both poisons and pharmaceutical products). [Under the revised provision, sale or supply of a pharmaceutical product, or a substance or article consisting of or containing any poison can only be carried out by the following three types of persons: (1) wholesale dealer licensees; (2) ASPs; or (3) licensed manufacturers selling or supplying pharmaceutical products manufactured by them.]	University of Hong Kong		usually handle pharmaceutical products in large quantity and are therefore an important link in the supply chain and an important player in quality maintenance of pharmaceutical products, we propose to impose licensing control on wholesalers of non-poisons (*Recommendation 18 refers**).
			DSAHK [Note 4] HKSA [Note 4]	HS Panel's special meeting on 10 December 2013; letters to the HS Panel and/or the Administration in December 2013 / January 2014: At the HS Panel's special meeting, the deputations **opposed** the imposition of the proposed inspection and licensing control over the wholesalers of non-poison pharmaceutical products. **DSAHK** considered that vitamin preparations and minerals dietary supplements without any disease treatment indications should be regarded as food. **HKSA** was of the view that hair dye products should be regarded as cosmetic products. In their views, wholesalers of these products should not be subject to the proposed regulatory control.	In response to their letters, the Administration met with the HKSA (on 13 January 2014), DSAHK (on 6 February 2014) and CPAHK (on 19 February 2014) respectively. Moreover, the Administration gave a written response to DSAHK, HKSA and CPAHK respectively, see **Annexes I**, **II** and **III**. In short, **vitamins preparations** have always been regarded as pharmaceutical products and subject to control under the existing regulatory regimen. Such control will remain intact under our legislative proposals. As regards **minerals dietary supplements**, they are not regarded as poisons or pharmaceutical products under the PPO, hence not subject to any regulations under the PPO and will continue to

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			CPAHK [Note 4]	Letter to the Administration in December 2013: **CPAHK** was of the view that hair dye products should be regarded as cosmetic products, and therefore should not be placed under the proposed control on wholesale dealing, such as written order of drugs, retention of product samples and relevant penalty.	be outside the scope of the regulatory regime for pharmaceutical products as enhanced by our proposed amendments. For **hair dye products** containing diamines such as phenylene diamines or toluene diamines, they are Part II poisons under the PLR, hence the wholesale and retail sales of the above hair dye products have already been subject to licensing/inspection controls under the existing PPO and such controls would remain the same under our legislative proposals. Since the above hair dye products are not regarded as pharmaceutical products by the PPO, the proposed transaction record keeping requirement (see item 11 below) will not affect hair dye products. DSAHK, HKSA and CPAHK are largely **content** with the Administration's clarification.
11.	Clause 48 (PPR, Reg. 28)	Keeping of transaction records: - To require licensed wholesale dealers or licensed manufacturers to keep transaction records of not only poisons in Part I of the Poisons List but also any pharmaceutical products. Additional	DSAHK, HKSA and CPAHK [Note 4]	See their comments in item 10.	To enhance traceability and facilitate recall of pharmaceutical products if necessary, we have adopted the Review Committee's recommendation to introduce new provisions to require wholesalers to keep transaction records for all pharmaceutical products (including both poisons and non-poisons) (*Recommendation 19 refers**). Please see responses/remarks in item 10 above.

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		particulars, such as the batch number and pack size of the pharmaceutical products, are also required to be recorded.			
Retail: ASPs					
12.	Clause 14 (PPO, Section 15) Clause 15 (PPO, Section 16)	If an ASP has been convicted of a serious drug offence, the Board is empowered to appoint a Disciplinary Committee to inquire into the conduct of the ASP, and the Committee may disqualify the ASP or remove its premises from the register of premises after the disciplinary inquiry.	Consumer Council [Notes 1, 2 & 4] Department of Pharmacology and Pharmacy of The University of Hong Kong PSHK [Notes 1, 2, 3, 4 & 5] HKGCPL [Notes 1, 2, 4 & 6]	<u>HS Panel's special meeting on 10 December 2013:</u> The deputations **supported** the proposal, so as to protect the safety of consumers. The Department of Pharmacology and Pharmacy of The University of Hong Kong and the PSHK are of the view that any cases of conviction should go through a Disciplinary Committee of the Board. HKGCPL **opposed** this legislative proposal.	To adopt the Review Committee's recommendation to heighten control, we propose to tighten up the regulation of the ASP by providing for the direction of Disciplinary Committee to, at the conclusion of a disciplinary inquiry of an ASP convicted of offence under the relevant provisions, disqualify the ASP and remove its premises from the register of premises to take effect immediately if it is in the public interest to do so (*Recommendation 33 refers**). The Administration subsequently met with HKGCPL on 29 April 2014 to clarify, among others, that the Disciplinary Committee would exercise such power only if it is in the public interest to do so, usually for severe cases of misconduct. The Administration also clarified that the ASP to which the direction related would still have the right to appeal to the Court of First Instance against the decision. HKGCPL understood and was satisfied with the clarification.

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13.	Clause 38 (PPR, Reg. 19)	<u>Storage of Part I poisons under the PLR in locked receptacle</u>: - To require that all poisons listed in Part I of the Poisons List (instead of only First Schedule poisons under the PPR as required currently) as kept at retail shops must be stored in locked receptacles and in areas not accessible to customers with the keys retained by the registered pharmacists.	Hong Kong Retail Management Association Individual registered pharmacists College of Primary Healthcare Pharmacy Hong Kong Academy of Pharmacy HKGCPL Notes 1, 2, 4 & 6	<u>HS Panel's special meeting on 10 December 2013:</u> The deputation **supported** the proposed requirement so as to enhance protection to consumers. <u>Letters to HS Panel Chairman and the Administration:</u> They were of the view that if registered pharmacists were required to have the only key to the locked receptacle of the registered pharmacy, it was not reasonable to expect the registered pharmacist, as the employee, to ensure that the key given to him by the owner of the ASP was the only key without any duplicate keys kept by the ASP owner or other persons. <u>HS Panel's Special Meeting on 10 December 2013:</u> The deputations **opposed** to the proposed requirement that only key to the locked receptacle should be kept by the registered pharmacist. The reason put forward by the College of Primary Healthcare Pharmacy, the Hong Kong Academy of Pharmacy and the PSHK was that that it was impractical for most registered pharmacists, who were	To implement the recommendation of the Review Committee (*Recommendation 31 refers**). As a matter of fact, the retention of the key by registered pharmacist has been an existing requirement under the PPR. Our legislative proposal does not introduce any change to such requirement and neither the current nor revised Reg. 19(2)(a) includes the phrase "the only key". The proposed change is rather to expand the types of poisons to be kept in such locked receptacle (from First Schedule poisons to all Part I poisons). One of the objectives of Reg. 19 of the PPR is to limit the access to the poisons if they are stored in the retail shop, and according to existing section 12 of the PPO, each set of premises of an ASP where poisons are kept for the purpose of retail sale shall be under the personal control of a registered pharmacist. On the other hand, it is the legal obligation of ASPs under the existing PPO to ensure that all Part I poisons could only be sold by registered pharmacists or in their presence and under their supervision. As the restriction in relation to the possession of key merely regulates the conduct of poisons business and the ASP owner still retains the ownership of the poisons and may request the registered pharmacist concerned to open the receptacle if he needs to have access to them,

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			PSHK [Notes 1, 2, 3, 4 & 5] PPAHK [Notes 1, 2, 3, 4 & 5]	employees of ASPs, to ensure that the key they held was the only key to the locked receptacle in the premises of the ASPs concerned. There was a view from the PPAHK that registered pharmacists employed by ASPs did not have the legal rights over the tenancy of the ASP premises and the ownership of the locked receptacles and of the property locked inside the receptacles. Hence, these registered pharmacists should not be required to perform due diligence to ensure that they held the only key to the receptacles concerned.	we are of the view that the restriction would unlikely constitute de facto deprivation of property. The Administration met with the HKGCPL on 7 February 2014 to discuss, among others, the extension of the existing storage control of First Schedule poisons to Part I poisons. The HKGCPL was satisfied with the clarification.
COC / COP, and other licensing, registration & disciplinary matters					
14.	Clause 6 (PPO, Section 4B)	To empower the Board to issue COC/COP for providing guidelines for various types of licensed and listed traders, and registered pharmacists.	Consumer Council [Notes 1, 2 & 4] Hong Kong Academy of Pharmacy	<u>HS Panel's Special Meeting on 10 December 2013:</u> Consumer Council **supported** the proposal, and considered that the Board should assess if the applicant and/or the directors of the company had been convicted of any drug offence in considering a licence application. The deputations **opposed** the proposal of monitoring the ASP and listed sellers of poisons ("LSPs")	As recommended by the Review Committee, we propose to empower the Board to promulgate corresponding COC and 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) *(Recommendations 11, 21 and 32 refers*).* The proposed section 4B of the PPO is similar to section 26 of the Supplementary Medical

			HKGCPL Notes 1, 2, 4 & 6 Pharmaceutical Trade Alliance (PTA)	through the COPs promulgated by Board. The reason put forward by the Hong Kong Academy of Pharmacy and PTA was that the Board could at any time make amendments to the COPs without going through a legislative process with the Legislative Council.	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). The Administration reassured the trade that the Board has a well-established mechanism in place for consultation with the trade and relevant stakeholders in drafting, issuing and revision of any COPs or COC.
			SHPHK Notes 1, 2, 3, 4 & 5	The SHPHK considered it inappropriate for the Board to introduce a COC for registered pharmacists. The Administration should instead facilitate the setting up of a pharmacy council to oversee the registration, conduct and discipline of registered pharmacists, including the promulgation of a code of ethics or conduct.	Since January 2012, the Board has set up different working groups, with trade representatives and stakeholders as members, to provide comments on the revision/formulation of COC/COPs for the relevant drug traders. In addition, during the process of revising/formulating the COC/COPs, the Administration gathered views through a number of consultation meetings, public consultation and briefing sessions. Many attendees of these meetings/sessions were trade representatives. Details and progress of the relevant work are set out at **Annex IV**. The Administration also provided similar information to the HS Panel on 15 January 2014 (LC Paper No. CB(2)694/13-14(01) refers).
			PTA	<u>Letters to HS Panel Chairman and Food and Health Bureau in March 2014:</u> Individual retailers of the PTA were of the view that the COPs should not have a legal status, and should be made to provide guidance for good practice, rather than for regulating the operation of the ASPs / LSPs.	The Administration also met with the PSHK on

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			HKGCPL Notes 1, 2, 4 & 6 PSHK Notes 1, 2, 3, 4 & 5 PPAHK Notes 1, 2, 3, 4 & 5 SHPHK Notes 1, 3, 4 & 5 HKPU Note 5	<u>Meeting with the Administration on 29 April 2014:</u> HKGCPL expressed concern about whether the Board was obliged to consult the trade before issuing or revising any COPs. After noting that the Board has a well-established mechanism in place for consultation with the trade and relevant stakeholders in drafting, issuing and revision of any COPs, HKGCP **has not expressed further concern**. <u>Briefing session on the PPAB organized by the Administration with members of PSHK, PPAHK, SHPHK and HKPU on 10 April 2014:</u> Attendees expressed similar concerns and were of the view that the Board should consult the trade before issuing or revising any COPs or COC.	12 February 2014 and PPAHK on 18 February 2014 in relation to COC/COPs.
15.	Clause 13 (PPO, Section 13)	Update/clarify the provisions governing the registration of premises of ASPs (e.g. payment of fees)	See item 14	See item 14	We propose to update and clarify the provisions governing the issuance, suspension and revocation of various licences issued under or registrations maintained by the PPO and the PPR so as to ensure that the Board and its executive committees are empowered to impose licensing or registration conditions and vary such conditions, issue directions to revoke or suspend a licence or registration, suspend such directions, or issue warning letters to the
16.	Clause 14 (PPO, Section 15)	To expand the circumstances in which a Disciplinary Committee may be appointed by the	See item 14 HKGCPL Notes 1, 2, 4 & 6	See item 14 <u>Meeting with the Administration on 29 April 2014:</u>	

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	Clause 15 (PPO, Section 16)	Board to inquire into the conduct of registered pharmacists and ASPs. <u>Disciplinary actions against **registered pharmacists / ASPs**:</u> - To give the Disciplinary Committee additional powers, including the powers to give a direction to issue warning letters to registered pharmacists, to remove the registration of any premises of an ASP, to vary conditions relating to the registration of those premises, and to provide when a direction made by it in a disciplinary inquiry is to take effect. The clause also empowers the Disciplinary Committee to suspend some of its directions (such as a direction to		The Administration clarified that under the current provision of the PPO, the Board may appoint a Disciplinary Committee if the Board received a complaint on the conduct of a registered pharmacist, an ASP or its employee or if the Board considers when it otherwise appears necessary or desirable to inquire into the conduct of any such person even though if the person has not been convicted of offences under relevant Ordinance. The PPAB has proposed that contravention of the COP by ASP may also lead to appointment of a Disciplinary Committee by the Board based on objective findings of pharmacist inspectors of the DH. HKGCPL understood and noted the explanation.	relevant licence or registration holders on non-compliance with the COC or COPs or licensing or registration conditions or on conviction of the relevant offences. This also serves to implement the Review Committee's recommendation to give the Board the authority to disqualify an ASP or deregister the premises of an ASP at any time after such ASP has been convicted of serious drug office *(Recommendation 33 refers*),* and to tighten the licensing conditions for the refusal or renewal of ASP or LSP applications *(Recommendation 34 refers*).* As stated item 14 above, since January 2012, the Board has set up different working groups, with trade representatives and stakeholders as members, to provide comments on the revision/formulation of COC/COPs for the relevant licensed drug traders. The Working Group on the COC for **registered pharmacists** was set up in August 2013 and a subgroup was established to facilitate the drafting of the COC. The subgroup held three meetings from March 2014 to April 2014 (please refer to **Appendix D to Annex IV** for membership) The Working Group on the COP for **ASPs** was set up between January to May 2012 (please refer to **Appendix A to Annex IV** for

		remove the registration of a pharmacist or to disqualify a person from being an ASP).			membership). Between July to December 2012, public consultation on the revised COP for ASPs was launched, and views were invited from associations/organisations. On 20 August 2012, ASPs were briefed on the revised COP for ASPs. A total of 66 participants attended the briefings. On 27 September 2012, HKGCPL and ASPs were briefed on the revised COP for ASPs. A total of 147 participants attended the briefings. After public consultation, the revised COP for ASPs was amended based on the comments received. Subsequent to legal advice and amendment proposed by the Board, the revised COP for ASPs was endorsed by the Board in November 2013 and will replace the existing COP for ASPs with effect from January 2015. From October 2012 to April 2013, the Working Group on the COP for **LSPs** was set up (please refer to **Appendix B to Annex IV** for membership). Between July and September 2013, public consultation on the draft COP for LSPs was launched, and views were invited from associations/organisations. On 28 August 2013, a briefing on the draft COP for LSPs was held and attended by 27 participants. After public consultation, the COP for LSPs was revised based on the comments received. Subsequent to legal advice, amendment proposed by the Pharmacy and Poisons (Listed Sellers of Poisons) Committee and the Board,
17.	Clause 20 (PPO, Section 25)	<u>Disciplinary actions against **LSPs**:</u> - To expand the disciplinary powers of the Board in relation to LSPs. It empowers the Board to impose conditions subject to which a person may enjoy the status of an LSP. It also empowers the Board to give a direction to issue warning letters to any LSP, or vary conditions imposed in respect of any LSP, if the LSP has contravened COPs or any such conditions. It also expands the circumstances in which the Board may remove a person from the list of LSP (including	See item 14	See item 14	

		contraventions of COPs or conditions of being an LSP).			the finalized COP for LSPs is scheduled for endorsement by the Board in June 2014. From April to November 2013, the Working Group on COP for Holders of **Wholesale Poisons** Licence and Holders of Certificate of Registration as an **Importer and Exporter** of Pharmaceutical Products was set up (please refer to **Appendix C to Annex IV** for membership). Subsequent to the amendment proposed by the Pharmacy and Poisons (Wholesale Licences/Registration of Importers & Exporters) Committee and the Board, public consultation on the draft COP was launched in April 2014 and will last until July 2014. Views were invited from associations/organisations. 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.
18.	Clause 46 (PPR, Reg. 26)	Disciplinary actions against **licensed wholesale dealers**: - To provide for the disciplinary powers of the Pharmacy and Poisons (Wholesale Licences) Committee (the Committee) in relation to licensed wholesale dealers. It empowers the Committee to suspend or revoke a wholesale dealer licence, issue warning letters to a licensed wholesale dealer or vary conditions of a licence in circumstances such as a contravention of COPs or conviction of offences under certain Ordinances. [Since the proposed	See item 14	See item 14	

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		wholesale dealer licence will then cover importers/ exporters, such powers will be applicable to importers/ exporters operating under a wholesale dealer licence as well.]			
19.	Clause 50 (PPR, Reg. 29)	<u>Disciplinary actions against **licensed manufacturers**</u>: - To expand the circumstances in which a licence to manufacture pharmaceutical products may be revoked or suspended. The circumstances include a contravention of COPs or the GMP Guide or a conviction of offences under specified Ordinances. The amendment also provides for the issue of warning letters to licensed manufacturers and the suspension of	See item 14	See item 14	The Working Group on the COP for **licensed manufacturers and APs** was set up from September to December 2013 (please refer to **Appendix E to Annex IV** for membership). On 13 September 2013, 11 March 2014 and 7 April 2014, three briefing sessions on the draft COP for licensed manufacturers and APs were held and were attended by a total of 206 participants.

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		a decision to suspend or revoke a licence.			
Registration of pharmaceutical products / substances					
20.	Clause 58(2) (PPR, Reg. 36(1)(a))	<u>Registration:</u> - To allow a licensed wholesale dealer to register pharmaceutical products if he has entered into a manufacturing contract with a licensed manufacturer.	HKPMA [Notes 1, 2, 3, 4 & 7]	<u>HS Panel's special meeting on 10 December 2013:</u> The deputation considered that only those licensed wholesalers who had contracted out the manufacturing activities to local, rather than overseas, GMP manufacturers could be allowed to register the pharmaceutical products so produced with the Board.	The legislative amendments proposed in Clause 58(2) only apply to pharmaceutical product or substance that is manufactured in Hong Kong.
21.	Clause 58(8) & (10) (PPR, Reg. 36(1A))	<u>Exemption for registration</u>: - To exempt from registration pharmaceutical products or substances that are possessed or to be used for treatment by certain medical professionals or to be administered for clinical trials or medicinal tests.			To update the relevant provision by making reference to similar overseas regulations, such as "The Human Medicines Regulations 2012" of United Kingdom and the "The Medicine Act Chapter 176" of Singapore.

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22.	Clause 58(15) (PPR, Reg. 36(7))	<u>Renewing of registration</u>: - To require the production of up-to-date specified information regarding the pharmaceutical products or substances concerned on renewing the registration of the products or substances.	HKAPI [Notes 1, 2, 3, 4 & 7] PDAHK [Notes 1, 2, 3, 4 & 7] HKPMA [Notes 1, 2, 3, 4 & 7] HKSA [Note 4] DSAHK [Note 4] CPAHK [Note 4]	<u>Briefing session on the PPAB organized by the Administration with members of HKAPI, PDAHK, HKPMA, HKSA, DSAHK and CPAHK on 14 April 2014:</u> Attendees expressed concerned on the type of information to be submitted.	To update the relevant provision by making reference to similar overseas regulations such as "The Human Medicines Regulations 2012" of United Kingdom. The up-to-date information required would be related to the safety, quality and efficacy of the pharmaceutical products or substances concerned.
23.	Clause 58(13) (PPR, Reg. 36(5))	<u>Imposition of conditions</u>: - To empower the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee to impose any			To update the provisions governing the issuance of certificate of pharmaceutical product registration so as to ensure that the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee is empowered to impose registration conditions and vary such conditions on registration or renewal of registration of pharmaceutical products.

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		conditions on registration or renewal of registration of pharmaceutical products or substances, and to vary such conditions.			
24.	Clause 58(17) (PPR, Reg. 36(8))	<u>Disciplinary actions against registration of pharmaceutical products etc.</u>: - To provide for the deregistration and suspension of the registration of pharmaceutical products or substances, and the issuance of warning letters.			To update and clarify the provisions governing the suspension and revocation of certificate of pharmaceutical product registration so as to ensure that the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee is empowered to deregister or suspend a certificate of pharmaceutical product registration, or to issue warning letters to the holder of certificate of pharmaceutical product registration on non-compliance with the condition of registration.
Clinical trials and medicinal tests					
25.	Clause 59 (PPR, Reg. 36B)	<u>Offence to conduct clinical trials/ medicinal tests without certificate</u>: - To provide that it is an offence to	HKAPI [Notes 1, 2, 3, 4 & 7]	<u>Letter to Chairman of HS Panel in January 2014</u> HKAPI **supported** extending the maximum validity period of clinical trial certificate from 2 years to 5 years.	To address the Review Committee's concern that the current two-year validity of the clinical trial certificate/ medicinal test certificate is often too short for the completion of a clinical trial/ medicinal test, we propose to extend the validity of clinical trial certificate/ medicinal

		conduct a clinical trial on human beings or medicinal test on animals without a clinical trial certificate or medicinal test certificate. - To extend the maximum validity period of any clinical trial certificate or medicinal test certificate from 2 years to 5 years. - To empower the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee to impose any conditions on issuing clinical trial			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 (*Recommendation 16 refers**). In addition, it is proposed that any person who conducts a clinical trial/ medicinal test without a clinical trial certificate/ medicinal test certificate will be subject to penalty upon conviction.

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		certificate or medicinal test certificate and to vary such conditions. The cancellation or suspension of these certificates, and the issuance of warning letters are also provided for.			
Labelling and storage of medicines and poisons					
26.	Clause 21 (PPO, Section 27) Clause 37 (PPR, Reg. 15) Clause 67 (PPR, Fifth Schedule)	<u>Labelling of pharmaceutical products:</u> - 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	Consumer Council Notes 1, 2 & 4 HKPMA Notes 1, 2, 3, 4 & 7	<u>HS Panel's special meeting on 10 December 2013:</u> Consumer Council considers that the Administration should step up publicity and public education to enhance public awareness on the proposed replacement of the word "Poison 毒藥" by "Prescription drug 處方藥物" or "Drug under supervised sale 監督售賣藥物", and the respective restrictions on their sale. HKPMA **agreed** to the need to replace the term "Poison". However, it would be more appropriate to introduce a provision to empower the Board to specify the	To implement the Review Committee's recommendation to replace the text "Poison 毒藥" by "Prescription drug 處方藥物" or "Drug under supervised sale 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 *(Recommendation 14 refers*).*

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		consumption.	HKAPI [Notes 1, 2, 3, 4 & 7] PDAHK [Notes 1, 2, 3, 4 & 7] HKPMA [Notes 1, 2, 3, 4 & 7] HKSA [Note 4] DSAHK [Note 4] CPAHK [Note 4]	term to be labeled on pharmaceutical products classified as poisons, rather than stipulating the term in the legislation, in order to obviate the need to amend the PPO from time to time to reflect the latest development in this regard. <u>Briefing session on the PPAB organized by the Administration with members of HKAPI, PDAHK, HKPMA, HKSA, DSAHK and CPAHK on 14 April 2014</u>: Attendees expressed concerned on any transitional arrangement.	The Administration will provide traders with a transitional period of at least 12 months to facilitate the trade to change the labels concerned according to the relevant revised provisions. DH will notify relevant licensed traders of the relevant transitional arrangements.
27.	Clause 39 (PPR, Reg. 22) Clause 40 (PPR, Reg. 23) Clause 41 (PPR, Reg. 24)	<u>Requirements for medicines and poisons in institutions</u>: - To relax certain requirements on the labelling and storage of medicines and poisons applicable in relation to certain institutions such as clinics/ hospitals , e.g. either English			This is in response to the requests and to cater for the practical operation of the Hospital Authority.

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		or Chinese instructions to be labelled on medicines; and storage of poisons in a cupboard solely reserved for the storage of poisons will not be required.			
Miscellaneous amendments					
28.	Clause 33 (PPR, Reg. 2A) Clause 70 (PPR, Tenth Schedule)	Relocation of Poisons List from the PLR to PPR; and to repeal the PLR.			Technical amendments
29.	Clause 23 (PPO, Section 29(1B))	<u>Legislative process for registering poisons and pharmaceutical products</u>: - To provide that the Poisons List or any list of any substances / articles made in a regulation made under section 29(1) of the PPO may be amended by the Board by	HKAPI [Notes 1, 2, 3, 4 & 7]	<u>Letter to Chairman of HS Panel in January 2014:</u> HKAPI **supported** to proposal.	To follow up on the Review Committee's recommendation to expedite the registration process of pharmaceutical products *(Recommendation 17 refers*)*

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		regulation with the approval of the Secretary for Food and Health, and subject to negative vetting by LegCo.			
30.	Clause 30 (PPO, Section 34A)	<u>Recovery of conviction-related expenses</u>: - To 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, analysing or examining any poison, pharmaceutical product or other substance for the criminal proceedings.	HKGCPL Notes 1, 2, 4 & 6	<u>HS Panel's Special Meeting on 10 December 2013:</u> HKGCPL **opposed** this legislative proposal. <u>Meeting with the Administration on 29 April 2014:</u> HKGCPL **opposed** the new section 34A of PPO as proposed by the PPAB and regarded it as a double penalty. HKGCPL also considered it unfair that such penalty was not required in other criminal cases and sited murder case as an example. HKGCPL was deeply concerned on the potential financial liability if the case involved a large number of exhibits (such as cases in which hundreds of drugs are not stored in locked receptacles).	To implement the Review Committee's recommendation to increase the deterrent effect, we propose 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 **<u>the conviction is based</u>** *(Recommendation 74 refers*).* In line with the concept on recovery of costs, the amount to be granted would be compensatory in nature. To reflect the correct intention, the Administration will propose Committee stage amendments to rectify that the sum ordered to be paid under this provision is recoverable in the same manner as a "civil debt" (rather than a "fine"). We would like to emphasize that the proposed legislation would only be applicable to convicted traders. Currently section 11 of Cap. 492 (Costs in Criminal Cases Ordinance) empowers a magistrate to recover costs, which could include the expenses referred to in this clause, from a convicted defendant. In order to provide a clearer message to the trade and

					increase the deterrent effect, we propose to add a specific provision for the recovery of investigation-related cost in the PPO. Indeed, there are also precedent cases in which specific provisions are made on recovering investigation-related expenses, e.g. – ● Section 74 under Public Health and Municipal Services Ordinance (Cap. 132); ● Section 184(5) under Securities and Futures Ordinance (Cap. 571); ● Section 43 under Unsolicited Electronic Messages Ordinance (Cap. 593).
31.	Clause 5 (PPO, Section 3)	<u>Update the composition of the Board</u>: - From the Chief Pharmacist to the Assistant Director of Health in the Drug Office	HKGCPL Notes 1, 2, 4 & 6	<u>Meeting with the Administration on 29 April 2014:</u> HKGCPL was of the view that the current composition of the Board does not have adequate representation from the retail sector.	The Administration reiterated that the functions of the Board include the registration of pharmacists, pharmaceutical products, and the licensing/registration of the pharmaceutical trade etc. While we consider that the current composition of the Board is effective in delivering its various functions, we shall keep in view the development of the pharmaceutical industry and, if necessary, consider if it merits a review on the composition of the Board in future.
32.	Clause 16 (PPO, Section 16A)	<u>Update the penalty levels for certain offences</u>: - To replace a specific amount of penalty			

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		with the appropriate level of penalty (e.g. "a fine at level 3" instead of "a fine of $500")			
33.	Clause 64 (PPR, Reg. 41)	To replace prescribed forms in the Eighth Schedule to the PPR with specified forms (to be made by the Board).			
34.	Clause 69 (PPR, Ninth Schedule)	<u>Update the payment of fees in the Ninth Schedule to the PPR</u>: - Consequential to the addition of APs and the merging of importers/ exporters license with wholesale dealer license.			

Other concerns raised				
35.	Placing drug orders in written form	The Administration has repeatedly emphasized that, in response to the concern of the trade, the requirement of placing drug orders in written form would be incorporated into the COPs for the relevant licenced drug traders (including manufacturers, wholesalers and retailers of pharmaceutical products) by the Board after consultation with the trade and the relevant stakeholders. Such requirement would become one of the compliance requirements for the relevant licensed drug traders. In other words, the above requirement would not be regulated by the law. Hence, **the current legislative proposals do not cover the requirement of written orders of drugs**. We are pleased to note that Members of the HS Panel and some organisations/individuals supported the above arrangement. We trust that as a compliance requirement for the trade, placing drug orders in written form would help enhance the monitoring of the drug supply system and minimize the potential risk in every step of the drug supply chain. This serves to provide the best protection for the public. *(LC Paper No. CB(2)541/13-14(01) dated 16 December 2013 refers).*			
36.	Requiring registered pharmacist employed by an ASP be present whenever the ASP is opened for business	As a matter of fact, in formulating the proposal for requiring the presence of registered pharmacist in the registered premises of an ASP whenever the ASP is opened for business, the Administration has already taken into account the current manpower supply of the registered pharmacists. In this regard, we have stated in the LC Paper No. CB(2)254/13-14(03) dated 18 November 2013 that the relevant provision for such requirement would be implemented at a later stage. In response to views of some Members and the trade and considering that the manpower supply of registered pharmacists in the coming few years may not be sufficient to cope with the manpower demand arising from the above proposal, coupled with the fact that our original intention is not to implement the above proposal shortly, we consider that there is no imminent need to amend the relevant legislation at this stage. As a result, the Administration has decided to remove the relevant provision from the legislative proposals. *(LC Paper No. CB(2)541/13-14(01) dated 16 December 2013 refers).*			
37.	To upgrade Hong Kong's current GMP licensing standards by a phased approach to the standard devised by the	HKPMA Notes 1, 2, 3, 4 & 7	<u>HS Panel's special meeting on 10 December 2013:</u> Taking into account the rapid advancement in medicine technology, the deputation considered that the PIC/S standard should be a licensing but not a statutory requirement.	Under the proposed amendment, all licensed manufacturers would be required to comply with GMP Guide issued or adopted by the Board. The Board intends to

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	Pharmaceutical Inspection Cooperation Scheme, i.e. the PIC/S standard			adopt the PIC/S GMP Guide to be the GMP standard for manufacturing of pharmaceutical products by licensed manufacturers.
38.	To strengthen the monitoring of ASPs and LSPs by means of more frequent and detailed inspections	Hong Kong Dental Association	HS Panel's special meeting on 10 December 2013: The Administration should conduct more frequent inspections to ASPs and LSPs and step up its enforcement actions against cases of non-compliance.	The DH adopts a risk-based approach in conducting inspections against ASPs and LSPs. More frequent inspections are conducted against convicted ASPs.
		The Hong Kong Medical Association	HS Panel's special meeting on 10 December 2013: The deputation considered that the penalty level for the sale of prescription drugs without a prescription should be raised to achieve sufficient deterrent effect. More frequent test purchases and inspections should be conducted.	The current maximum penalty under the PPO is a fine of HK$100,000 and 2 years of imprisonment. The DH includes more aggravating factors in the facts of the case submitted to the Court to reflect the seriousness of the offence concerned for the Court to impose an appropriate sentence. To increase the deterrent effect, we have proposed a new section 34A of the PPO to empower the Court to order recovery of all expenses incidental to the taking, examination and analyses of any sample of pharmaceutical products incurred (see item 30 above).
39.	To require that more information on drugs and patient-oriented advice be	Hong Kong Dental Association	HS Panel's Special Meeting on 10 December 2013: While not objecting to the proposed requirement, the deputation considered that the Administration should give due	The Administration takes note of the comments.

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	provided along with drugs dispensed to patients at hospitals or clinics		regard to the possible behavioural change in patients' use of medicines; and engage the professional bodies, such as The Medical Council of Hong Kong and Hong Kong Dental Association, in drawing up the relevant guidelines.	
40.	Separation of prescribing from dispensing of medicines	HKGCPL Notes 1, 2, 4 & 6 PSHK Notes 1, 2, 3, 4 & 5 Professor Vivian LEE Wing-yan PSHK Notes 1, 2, 3, 4 & 5 PPAHK Notes 1, 2, 3, 4 & 5 SHPHK Notes 1, 3, 4 & 5 HKPU Note 5 HKGCPL	<u>HS Panel's Special Meeting on 10 December 2013:</u> The deputations urged the Administration to expeditiously implement the separation of prescribing from dispensing of medicines. The HKGCPL and the PSHK considered that that the Administration should conduct a public consultation exercise to gauge the view of the public on the subject. <u>Briefing session on the PPAB organized by the Administration with members of PSHK, PPAHK, SHPHK and HKPU on 10 April 2014:</u> Attendees voiced similar concern and urged the Administration to expeditiously implement the separation of prescribing from dispensing of medicines. <u>Meeting with the Administration on 29 April 2014:</u> HKGCPL stressed that any success of the proposed amendment would depend on the realization of the separation of prescribing and dispensing. In this regards, HKGCPL voiced their strong desire in the pursuit of separation of prescribing and dispensing.	The Administration takes note of the comments.
41.	Increase the first-year intake of students for Bachelor of	School of Pharmacy, The	<u>HS Panel's Special Meeting on 10 December 2013:</u> The deputation called on the Administration to increase the	The Administration takes note of the comments.

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	Pharmacy	Chinese University of Hong Kong	first-year intake of students for Bachelor of Pharmacy. In addition, the curriculum should cover the manufacturing and regulation of pharmaceutical products.	
42.	Cease the issuance of LSP license to protect public health	SHPHK Note 1, 3, 4 & 5	<u>HS Panel's Special Meeting on 10 December 2013:</u> Pointing out that the number of LSPs was currently more than six times of that of ASPs but the retail sale of poisons listed in Part II of the PLR by LSPs was not required to be supervised by registered pharmacists, the deputation called on the Administration to cease the issuance of LSP license to protect public health.	Under the current provisions of the PPO, drugs with more serious side effects are classified as Part I Poisons and should therefore only be sold at the registered premises of ASPs in the presence or under the supervision of registered pharmacists. Drugs with less serious side effects are classified as Part II Poisons, which could be sold by LSPs. Since medicines classified as Part II Poisons are considered as relatively low risk to the public, the retail sale of such medicines is not required to be carried out under the supervision of registered pharmacists. To avoid the misuse of Part II Poisons, the current legislation requires the dosage, route and frequency of administration of such poisons to be labelled clearly in both English and Chinese.
43.	Set up a Centre for Drug and Medical Device Safety	SHPHK Note 1, 3, 4 & 5	<u>HS Panel's Special Meeting on 10 December 2013:</u> The deputation also urged the Administration to set up a Centre for Drug and Medical Device Safety to be headed by a registered pharmacist in order to enhance medication and	The Administration takes note of the comments.

<u>Abbreviations</u>: ***PPO*** *– Pharmacy and Poisons Ordinance (Cap 138);* ***PPR*** *– Pharmacy and Poisons Regulations (Cap 138A);* ***PLR*** *– Poisons List Regulations (Cap 138B);* ***the Board*** *– the Pharmacy and Poisons Board;* ***COC*** *– Code of Conduct;* ***COP*** *– Code of Practice;* ***GMP*** *– Good Manufacturing Practice;* ***Review Committee*** *– Review Committee on Regulation of Pharmaceutical Products in Hong Kong;* ***DH*** *– the Department of Health*

			medical device safety.	

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

Note 1 *Non-official member of the Review Committee*

Note 2 *Non-official member of the Subcommittee on Drug Distribution and Procurement of the Review Committee*

Note 3 *Non-official member of the Subcommittee on Drug Manufacturing of the Review Committee*

Note 4 *Participated in the consultation meetings conducted under the Regulatory Impact Assessment*

Note 5 *Non-official member of the Working Group on the COC for registered pharmacists*

Note 6 *Non-official member of the Working Group on the COP for ASP*

Note 7 *Non-official member of Working Group on COP for Holders of Wholesale Poisons Licence and Holders of Certificate of Registration as an Importer and Exporter of Pharmaceutical Products*

Abbreviations: ***PPO*** *– Pharmacy and Poisons Ordinance (Cap 138);* ***PPR*** *– Pharmacy and Poisons Regulations (Cap 138A);* ***PLR*** *– Poisons List Regulations (Cap 138B);* ***the Board*** *– the Pharmacy and Poisons Board;* ***COC*** *– Code of Conduct;* ***COP*** *– Code of Practice;* ***GMP*** *– Good Manufacturing Practice;* ***Review Committee*** *– Review Committee on Regulation of Pharmaceutical Products in Hong Kong;* ***DH*** *– the Department of Health*

Annex I
附件 I

中華人民共和國香港特別行政區政府總部食物及衞生局
Food and Health Bureau, Government Secretariat
The Government of the Hong Kong Special Administrative Region
The People's Republic of China

Our Ref : L/M to FHB/H/23/6 Pt.29
Your Ref : CB2/PL/HS

Tel : 3509 8956
Fax : 2840 0467

23rd January 2014

The Direct Selling Association of Hong Kong Limited
P.O. Box No. 20072
Hennessy Road Post Office
Hong Kong

Dear Sir/Madam,

Legislative Proposals to Enhance the Regulation of Pharmaceutical Products in Hong Kong

Thank you for your letter dated 23 December 2013 in which your Association has provided some views on the Administration's legislative proposals to enhance the regulation of pharmaceutical products in Hong Kong. We note that the Department of Health has contacted your Association and lined up a meeting in early February 2014 to address your Association's concerns. Before the meeting, we would like to take this opportunity to provide your Association with relevant information on the purpose, scope and modus operandi of the Administration's legislative proposals.

2. The legislative proposals set out in LC Paper No. CB(2)254/13-14(03), which was tabled to the Legislative Council Panel on Health Services ("the Panel") on 18 November 2013, seek to implement certain recommendations put forth by the Review Committee on Regulation of Pharmaceutical Products in Hong Kong ("the Review Committee") and to update certain outdated provisions of the Pharmacy and Poisons Ordinance (Cap. 138) ("PPO") and its subsidiary legislation. The purpose of introducing the legislative proposals is to enhance Hong Kong's regulatory regime for pharmaceutical products to better protect public health.

3. We wish to assure you that in considering the Review Committee's recommendations made in December 2009 and in formulating related legislative amendments subsequently, the Administration has always in mind the impacts of such proposals on the traders concerned and commissioned a Regulatory Impact Assessment ("RIA") in January 2011 for that purpose. Your Association was amongst those major stakeholders consulted in the RIA study and we are grateful for your Association's views provided at the RIA study as well as in other occasions including the Panel's special meeting held on 10 December 2013.

4. We note your Association's concerns about the likely impacts of recommendation to impose a certain degree of controls over non-poison pharmaceutical products. Indeed, similar concerns were raised during the above RIA study. We wish to emphasize that the ultimate objective of the above recommendation is to safeguard public health as the Review Committee has stated clearly that non-poison pharmaceutical products, though less dangerous, could also endanger patient health if they are not stored and handled properly. It is therefore essential to monitor the quality of and maintain a complete set of transaction records for all pharmaceutical products (regardless of whether they are poisons or non-poisons) so as to facilitate recall whenever necessary. As wholesalers of pharmaceutical products usually handle drugs in large quantity and are therefore an important link in the supply chain and important players in drug quality maintenance, the Administration therefore considers it prudent to subject wholesalers of pharmaceutical products to licensing/inspection controls and the requirement of keeping

transaction records. In view of the above and to safeguard public health, we have proposed to require –

(a) wholesalers of non-poison pharmaceutical products to be subject to the licensing and inspection controls (at present, wholesalers/importers/exporters of Part I poisons and Part II poisons [1], as well as importers/exporters of non-poison pharmaceutical products, have already been subject to licensing and inspection controls under the PPO); and

(b) all wholesalers to keep transactions records of not only all Part I poisons as currently required, but also all Part II poisons and non-poisons if the latter two are regarded as pharmaceutical products.

5. You may wish to note that in our legislative proposals stated in paragraph 4(a) and (b) above, the Administration has already taken into account the comments and findings of the above RIA study. During the RIA study, although some stakeholders considered the proposed licensing and inspection controls for wholesale of non-poison pharmaceutical products, which are regarded as low risk products, a major change to the current regulatory regime, consultation with the majority of the stakeholders revealed that most of the wholesalers trading non-poison pharmaceutical products are well aware of the existing regulations and control on the wholesale business of poisons in Hong Kong, and have been adopting work practices similar to the wholesalers of poisons, such as monitoring and control of storage conditions, product recall procedures and reporting of adverse drug reactions. The RIA study has not observed major differences between the existing practices of wholesalers of poisons and wholesalers of non-poison pharmaceutical products, in terms of complying with the proposed licensing/inspection controls.

6. With regard to the requirement to keep transaction records for all pharmaceutical products (including both poisons and non-poisons), we note that according to the RIA study most of the distributors with well-established wholesale operations have already kept their transaction

[1] Part I poisons and Part II poisons are poisons listed respectively in Part I and Part II of the Schedule of the Poison List Regulations (Cap. 138B).

records (for poisons and non-poisons) on IT system and their main concerns are related to the content of the transaction records required as well as the time-frame and mode for furnishing such records to the Department of Health. The RIA study has recommended the Administration to implement this proposed requirement with clear guidelines on the types of information required to be kept in the transaction records. Our proposal in paragraph 4(b) above has already taken into consideration the view of the stakeholders and made reference to the similar record keeping requirements of wholesalers of food as stipulated by Part 3 of the Food Safety Ordinance (Cap. 612). The format of the transaction records for pharmaceutical products will be similar to the format stipulated by the existing Pharmacy and Poisons Regulations (Cap. 138A). To address the concern of the trade, the Administration will also provide clear guidance to relevant wholesalers to facilitate their compliance with the proposed requirement.

7. Regarding your Association's concerns towards the control of **minerals dietary supplements**, we would like to point out that they are not regarded as poisons or pharmaceutical products under the PPO. In this regard, minerals dietary supplements are **not** subject to any regulations under the PPO and will continue to be outside the scope of the regulatory regime for pharmaceutical products as enhanced by our proposed amendments.

8. For **vitamin preparations**, they have all along been regarded as non-poison pharmaceutical products under the PPO and are subject to, among others, registration requirements before they could be sold in Hong Kong. Vitamin preparations will remain classified as non-poison pharmaceutical products under our legislative proposals. As such, under our legislative proposals wholesalers of vitamin preparations will be subject to proposed requirements stated in paragraph 4(a) and (b).

9. The Department of Health stands ready to provide your Association with any further clarification or other information relating to our legislative proposals. Thank you once again for your Association's interest in the subject.

Yours sincerely,

(Miss Ophelia Lui)
for Secretary of Food and Health

c.c. Hon Vincent FANG Kang, SBS, JP
Ms Linda WOO, Assistant Director (Drug), the Department of Health

中華人民共和國香港特別行政區政府總部食物及衞生局
Food and Health Bureau, Government Secretariat
The Government of the Hong Kong Special Administrative Region
The People's Republic of China

Our Ref : L/M to FHB/H/24/2 Pt.33
Your Ref : CB2/PL/HS

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16 January 2014

Mr Albert TANG
Chairman
Hong Kong Suppliers Association
P.O. Box No. 33692
Sheung Wan Post Office, Hong Kong

Dear Mr TANG,

Legislative Proposals to Enhance the Regulation of Pharmaceutical Products in Hong Kong

I refer to your letter dated 2 January 2014 addressed to the Chairman of the Legislative Council Panel on Health Services ("the Panel"), Dr Hon LEUNG Ka-lau, and copied to, among others, the Secretary for Food and Health. We note that the Department of Health have subsequently met your Association on 13 January 2014 to clarify some of the issues as mentioned in your above letter.

2. The legislative proposals set out in LC Paper No. CB(2)254/13-14(03), which was tabled to the Panel on 18 November 2013, seek to implement certain recommendations put forth by the Review Committee on Regulation of Pharmaceutical Products in Hong Kong ("the Review Committee") and to update certain outdated provisions of the

enhance Hong Kong's regulatory regime for pharmaceutical products to better protect public health.

3. We wish to assure you that in considering the Review Committee's recommendations made in December 2009 and in formulating related legislative amendments subsequently, the Administration has always in mind the impacts of such proposals on the traders concerned and commissioned a Regulatory Impact Assessment ("RIA") in January 2011 for that purpose. Your Association was amongst those major stakeholders consulted in the RIA study and we are grateful for your Association's views provided at the RIA study as well as in other occasions including the Panel's special meeting held on 10 December 2013.

4. We note your Association's concerns about the likely impacts of Recommendations 18 and 19[1] put forth by the Review Committee on traders. Indeed, similar concerns were raised during the above RIA study. We would like to emphasize that the above two recommendations seek to impose a certain degree of controls over pharmaceutical products which are either Part II poisons[2] or non-poisons and the ultimate objective is to safegaurd public health as the Review Committee has stated clearly that non-poison pharmaceutical products, though less dangerous, could also endanger patient health if they are not stored and handled properly. It is therefore essential to monitor the quality of and maintain a complete set of transaction records for all pharmaceutical products (regardless of whether they are poisons or non-poisons) so as to facilitate recall whenever necessary. As wholesalers of pharmaceutical products usually handle drugs in large quantity and are therefore an important link in the supply chain and important players in drug quality maintenance, the Administration therefore considers it prudent to subject wholesalers of pharmaceutical products to licensing/inspection controls and the requirement of keeping transaction records. In view of the above and to

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1 Recommendation 18 of the Review Committee suggests that all wholesalers of non-poisons shall be subject to inspection and licensing control, whereas Recommendation 19 proposes requiring all wholesalers to (i) keep transactions records of all pharmaceutical products, including Part II poisons and non-poisons, in the same manner as for Part I poisons; and (ii) keep samples of each batch of drugs handled to facilitate investigation when needed.

2 Part II poisons are poisons listed in Part II of the Schedule of the Poison List Regulations (Cap. 138B).

safeguard public health, we have proposed, in response to the Review Committee's Recommendations 18 and 19, to require –

(a) wholesalers of non-poison pharmaceutical products to be subject to the licensing and inspection controls (at present, wholesalers/importers/exporters of Part I poisons[3] and Part II poisons, as well as importers/exporters of non-poison pharmaceutical products, have already been subject to licensing and inspection controls under the PPO); and

(b) all wholesalers to keep transactions records of not only all Part I poisons as currently required, but also all Part II poisons and non-poisons if the latter two are regarded as pharmaceutical products.

5. You may wish to note that in our legislative proposals stated in paragraph 4(a) and (b) above, the Administration has already taken into account the comments and findings of the above RIA study. During the RIA study, although some stakeholders considered the proposed licensing and inspection controls for wholesale of non-poison pharmaceutical products, which are regarded as low risk products, a major change to the current regulatory regime, consultation with the majority of the stakeholders revealed that most of the wholesalers trading non-poison pharmaceutical products are well aware of the existing regulations and control on the wholesale business of poisons in Hong Kong, and have been adopting work practices similar to the wholesalers of poisons, such as monitoring and control of storage conditions, product recall procedures and reporting of adverse drug reactions. The RIA study has not observed major differences between the existing practices of wholesalers of poisons and wholesalers of non-poison pharmaceutical products, in terms of complying with the proposed licensing/inspection controls.

6. With regard to the requirement to keep transaction records for all pharmaceutical products (including both poisons and non-poisons), we note that according to the RIA study most of the distributors with

[3] Part I poisons are poisons listed in Part I of the Schedule of the Poison List Regulations (Cap. 138B).

well-established wholesale operations have already kept their transaction records (for poisons and non-poisons) on IT system and their main concerns are related to the content of the transaction records required as well as the time-frame and mode for furnishing such records to the Department of Health. The RIA study has recommended the Administration to implement this proposed requirement with clear guidelines on the types of information required to be kept in the transaction records. Our proposal in paragraph 4(b) above has already taken into consideration the view of the stakeholders and made reference to the similar record keeping requirements of wholesalers of food as stipulated by Part 3 of the Food Safety Ordinance (Cap. 612). The format of the transaction records for pharmaceutical products will be similar to the format stipulated by the existing Pharmacy and Poisons Regulations (Cap. 138A). To address the concern of the trade, the Administration will also provide clear guidance to relevant wholesalers to facilitate their compliance with the proposed requirement.

7. Regarding your Association's concerns towards the control of **hair dye products**, the Administration would like to clarify that under the existing PPO, hair dye products containing diamines such as phenylene diamines or toluene diamines are Part II poisons, hence the wholesale and retail sales of **the above hair dye products have already been subject to licensing/inspection controls under the existing PPO** (please refer to paragraph 4(a) above) and such controls would remain the same under our legislative proposals. Since hair dye products containing diamines such as phenylene diamines or toluene diamines are not regarded as pharmaceutical products by the PPO, our proposed legislative amendments stated in paragraph 4(b) above **will not affect** hair dye products.

8. As regards **minerals dietary supplements**, we would like to point out that they are not regarded as poisons or pharmaceutical products under the PPO. In this regard, minerals dietary supplements are **not** subject to any regulations under the PPO and will continue to be outside the scope of the regulatory regime for pharmaceutical products as enhanced by our proposed amendments.

9. For **vitamin preparations**, they have all along been regarded as non-poison pharmaceutical products under the PPO and are subject to, among others, registration requirements before they could be sold in Hong Kong. Vitamin preparations will remain classified as non-poison pharmaceutical products under our legislative proposals. As such, under our legislative proposals wholesalers of vitamin preparations will be subject to proposed requirements stated in paragraph 4(a) and (b).

10. We understand that the Department of Health has made the above clarification in their meeting with you which has largely addressed your Association's concerns. The Department of Health stands ready to provide your Association with any further clarification or other information relating to our legislative proposals. Thank you once again for your Association's interest in the subject.

Yours sincerely,

(Miss Ophelia Lui)
for Secretary of Food and Health

c.c. Dr Hon LEUNG Ka-lau, Chairman, Legislative Council Panel on Health Services
Hon Vincent FANG Kang, SBS, JP
Dr CHAN Hon-yee, Constance, JP, Director for the Department of Health

中華人民共和國香港特別行政區政府總部食物及衞生局
Food and Health Bureau, Government Secretariat
The Government of the Hong Kong Special Administrative Region
The People's Republic of China

本函檔號: L/M to FHB/H/23/6 Pt.29 *電話號碼:* 3509 8956
來函檔號: *傳真號碼:* 2840 0467

香港化粧品同業協會
九龍尖沙咀山林道 46-48 號
運通商業大廈 308 號室

敬啟者,

加強規管香港藥劑製品的立法建議

貴會二零一三年十二月二十日的來信收悉。就 貴會在信中對政府當局修訂《藥劑業及毒藥條例》(第 138 章)("《條例》")及其附屬法例的建議("立法建議")所提出的意見,現謹覆如下。

政府當局在二零一三年十一月十八日提交予立法會衞生事務委員會的文件(立法會 CB(2)254/13-14(03)號文件)所提出的立法建議,旨在落實及推行香港藥物監管制度檢討委員會("檢討委員會")就加強規管香港藥劑製品的建議,目的是加強藥物安全和保障公眾健康。政府當局在草擬上述的立法建議時,亦已審慎考慮有關建議會否影響業界的營運,並就此於二零一一年一月委託了顧問公司進行有關的規管影響評估。我們感謝 貴會參與上述評估工作的諮詢會議並提出寶貴的意見。

我們理解 貴會特別就有關建議加強第 II 部毒藥[1]和非毒藥的藥劑製品的規管表示關注。其實,上述的規管影響評估亦有提及類似的關注。就批發商而言,目前的規定是凡經營第 I 部毒藥[2]和第 II 部毒藥,或含有該等毒藥成分的藥劑製品的批發商須根據《條例》申領相關牌照,並受到巡查監管。而經營第 I 部毒藥或含有該等毒藥成分的藥劑製品的批

[1] 第 II 部毒藥是指列載在《毒藥表規例》(第 138B 章)的附表第 II 部內的毒藥。

[2] 第 I 部毒藥是指列載在《毒藥表規例》的附表第 I 部內的毒藥。

發商更須要按《條例》的要求保存該等毒藥或藥劑製品的交易記錄。所以，目前的規管機制是沒有規管非毒藥的藥劑製品的批發業務。正如檢討委員會所指，不妥善處理及存儲藥劑製品（無論是毒藥與否）可能會危及公眾健康。為進一步提升藥劑製品的安全，我們須要就所有藥劑製品建立一套完整的交易紀錄，以便在有需要時可以對有問題的藥劑製品（包括非毒藥）作出即時回收行動，保障市民的安全。由於批發商一般會處理大量藥劑製品，是藥物供應鏈中的重要一環，而且在確保藥物質量方面扮演重要的角色，因此政府當局認爲有需要進一步就經營藥劑製品的供應商採取以下的措施，以保障公眾健康：

（一）對經營非毒藥的藥劑製品的批發商實施發牌、巡查和交易記錄保存的要求；及

（二）經營含有第 II 部毒藥成分的藥劑製品的持牌批發商須要保存該等藥劑製品的交易記錄。

就染髮劑的監管方面，由於染髮劑中常見的有效成份苯二胺（phenylene diamines）及甲苯二胺（toluene diamines）屬於《毒藥表規例》第 II 部 B 分部的毒藥（即通常作非醫藥用途的物質），而含有苯二胺、甲苯二胺或其他烷化苯二胺的染髮劑可使某些人士的皮膚嚴重發炎，故現行《條例》已要求含有上述物質的染髮劑必須標明《藥劑業及毒藥規例》（第 138A 章）附表 5 內指定的相關警告字句，而這項標籤要求亦與歐盟國家的標籤要求一致。 此外，為保障公眾健康，現行《條例》已要求經營第 II 部毒藥及含有該等毒藥的產品（包括染髮劑）的批發商及零售商必須領有相關牌照，才可合法銷售有關產品。

我們的立法建議不會更改有關第 II 部毒藥及含有該等毒藥的產品（包括染髮劑）的發牌及巡查監管安排。然而，由於染髮劑並不屬於《條例》所指的藥劑製品，所以經營染髮劑的批發商並不會受到備存藥劑製品交易記錄的建議要求（見上文第（二）項）所影響。

另外，有關以書面訂購藥物的建議亦是以藥劑製品／藥物作為規管對象，故此該建議要求並不適用於非藥劑製品，包括一般染髮劑。另外，我們在提交予立法會的文件[3]中已多次表明，有關以書面訂購藥物的要求將會被納入由藥劑業及毒藥管理局經諮詢業界和相關持份者後就相

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[3] 立法會 CB(2)414/13-14(01)號文件（二零一三年十二月十日）及立法會 CB(2)541/13-14(01)號文件（二零一三年十二月十六日）。

關持牌藥商（包括藥物製造商、批發商和零售商）編制的執業守則內，作爲相關持牌藥商的其中一項遵從守則。換言之，上述要求並不是以立法方式作出規管。在編制上述的執業守則時，藥劑業及毒藥管理局會進行充足的諮詢。

我們留意到 貴會的信件中亦提到有關備存所處理每批藥物的樣本的建議要求。就此，我們在立法會 CB(2)254/13-14(03)號文件已表示政府當局已因應規管影響評估的結果而不會推行部分檢討委員會的建議，包括不會推行備存所處理每批藥物的樣本的要求。有關詳情請參閱上述文件的附件 A。

我們再次強調是次的立法建議並**不會影響**現時《條例》對染髮劑的規管。我們得悉衞生署的同事已與 貴會聯繫，並安排在今年二月初會面，就 貴會關注的事宜再作解釋。我們在此感謝 貴會對是次立法建議的支持和關注，並提出寶貴的意見。

食物及衞生局局長

（呂幸倫 代行）

二零一四年一月二十三日

副本抄送： 立法會方剛議員, SBS, JP
衞生署助理署長(藥物) 吳婉宜女士

Annex IV

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

January to May 2012	The Working Group on the **Code of Practice ("COP") for Authorised Seller of Poisons ("ASP")** was set up. Three meetings were held to work on the revision of the COP. The membership of the working group is at Appendix A.
July to December 2012	Public consultation on the revised COP for ASP was launched, and views were invited from associations/organisations, including: ▪ the Hong Kong Medical Association ▪ Hong Kong Doctors Union ▪ Hong Kong Dental Association ▪ Hong Kong Veterinary Association ▪ Consumer Council ▪ Hong Kong General Chamber of Pharmacy Ltd ▪ the Pharmaceutical Society of Hong Kong ▪ the Practising Pharmacists Association of Hong Kong ▪ all ASPs
20 August 2012	ASPs were briefed on the revised COP for ASP. A total of 66 participants attended the briefings (one in the morning and another in the afternoon).
27 September 2012	Hong Kong General Chamber of Pharmacy Ltd and ASPs were briefed on the revised COP for ASP. A total of 147 participants attended the briefings.
October 2012 to April 2013	The Working Group on the **COP for Listed Seller of Poisons ("LSP")** was set up. Three meetings were held to work on the drafting of the COP. The membership of the working group is at Appendix B.
July to September 2013	Public consultation on the draft COP for LSP was launched, and views were invited from associations/organisations, including: ▪ Hong Kong Health Food Association

	▪ The Cosmetic and Perfumery Association of Hong Kong ▪ Federation of Beauty Industry Hong Kong ▪ Hong Kong General Chamber of Commerce ▪ Hong Kong Retail Management Association ▪ the Chinese General Chamber of Commerce ▪ the Hong Kong Medical Association ▪ Hong Kong Doctors Union ▪ Hong Kong Dental Association ▪ Hong Kong Veterinary Association ▪ Consumer Council ▪ Hong Kong General Chamber of Pharmacy Ltd ▪ the Pharmaceutical Society of Hong Kong ▪ the Practising Pharmacists Association of Hong Kong ▪ the Society of Hospital Pharmacists of Hong Kong ▪ all LSPs
28 August 2013	A briefing on the draft COP for LSP was held and attended by a total of 27 participants.
April to November 2013	The Working Group on the **COP for Importer/Exporter and Wholesaler of Poisons** was set up. Six meetings were held to work on the drafting of the COP. The membership of the working group is at Appendix C.
August 2013 to April 2014	The Working Group on **Code of Conduct ("COC") for pharmacists** was established and a sub-group to facilitate the drafting of the COC was established and so far, three meetings were held. The membership of the working group is at Appendix D.
September 2013 to December 2013	The Working Group on the **Code of Practice ("COP") for Licensed Manufacturers and Authorized Persons** was set up. Three meetings were held for the drafting of the COP. The membership of the working group is at Appendix E.
13 September 2013	A briefing on the draft COP for Licensed Manufacturers and Authorized Persons was held and attended by a total of 56 participants.

11 March 2014	A briefing on the draft COP for Licensed Manufacturers and Authorized Persons was held and attended by a total of 31 participants.
April 2014 to July 2014	Public consultation on the draft COP for Importer/Exporter and Wholesaler of Poisons was launched. ▪ Hong Kong Association of the Pharmaceutical Industry ▪ The Hong Kong Pharmaceutical Manufacturers Association Ltd. ▪ The Pharmaceutical Distributors Association of Hong Kong ▪ the Pharmaceutical Society of Hong Kong ▪ the Practising Pharmacists Association of Hong Kong ▪ the Society of Hospital Pharmacists of Hong Kong ▪ Consumer Council ▪ Wholesale and Retail Task Force ▪ Hong Kong General Chamber of Pharmacy Ltd ▪ The Hong Kong Medicine Dealers Guild ▪ Hong Kong Suppliers Association ▪ The Direct Selling Association of Hong Kong ▪ The Cosmetic and Perfumery Association of Hong Kong ▪ the Hong Kong Medical Association ▪ Hong Kong Doctors Union ▪ Hong Kong Dental Association ▪ Hong Kong Veterinary Association
7 April 2014	A briefing on the draft COP for licensed manufacturers (secondary packaging) and authorized persons was held and attended by a total of 119 participants.
April 2014 to May 2014	Three briefing sessions was held on 9 April 2014 and 25 April 2014 for the draft COC for Importer/Exporter and Wholesaler of Poisons. A total of 204 representatives attended the briefing sessions. Three more briefing sessions will be held in May 2014.

Appendix A

Membership of

Working Group on the Code of Practice for Authorised Seller of Poisons

Chairperson:

- Dr Heston KWONG, Assistant Director (Drug), Drug Office, Department of Health

Official members:

- Mr Thomas TAM, Chief Pharmacist, Drug Office, Department of Health
- Ms Linda WOO, Chief Pharmacist, Drug Office, Department of Health
- Mr Edwin LAM, Senior Pharmacist (Retailers Regulatory Unit), Drug Office, Department of Health

Non-official members:

- Mr LAU Oi-kwok, Chairman, Hong Kong General Chamber of Pharmacy Ltd
- Mr Samuel HUI, Vice Chairman, Hong Kong General Chamber of Pharmacy Ltd
- Mr Alex CHEUNG, Pharmacist, Cheung Tai Dispensary (H.K.) Ltd.
- Mr Philip CHIU, Senior Pharmacist, Mannings-Hong Kong Dairy Farm Company
- Ms Margaret LAU, Chief Pharmacist, Watsons's The Chemist - A.S. Watson Group
- Mr Peter SUEN Yiu-chan, Pharmacist, Activecare Pharmacy Ltd

Appendix B

Membership of
Working Group on the Code of Practice for Listed Seller of Poisons

Chairperson:

- Ms Linda WOO, Assistant Director (Drug), Drug Office, Department of Health

Official members:

- Mr Lot CHAN, Chief Pharmacist, Drug Office, Department of Health
- Mr Frank CHAN, Chief Pharmacist, Drug Office, Department of Health
- Mr Dominic YUEN, Senior Pharmacist (Licensing and Compliance – Retailers), Drug Office, Department of Health

Non-official members:

- Ir Prof Chi-ming NG, Health and Safety Manager, The Dairy Farm Co. Ltd.
- Mr Ken HAU, Deputy District Pharmacist, Watson's The Chemist - A.S. Watson Group *
- Mr Alan WONG, Area Manager Designate, Watson's The Chemist - A.S. Watson Group **
- Ms Samantha TSANG, Assistant Controller, China Resources Vanguard (Hong Kong) Co. Ltd.
- Ms. King-yan KONG, Quality Management, CR Care Co. Ltd.
- Ms Winnie LAI, Operation Manager, Tung Fong Hung Medicine Company Limited *
- Mr Dicky CHENG, Assistant Purchasing Manager, Tung Fong Hung Medicine Company Limited **
- Mr Yiu-cho CHEUNG, General Manager, Culture Homes (Outlet Stores Wholesale Centre) Ltd.
- Mr Fei-yee YEUNG, Deputy Managing Director, Kai Tai Chinese Medicine (holdings) Co. Ltd.
- Mr Hei-hing LIN, Head of the Proprietary Chinese Medicine Group, Hong Kong Chinese Medicine Merchants Association
- Mr Philip CHIU, Senior Pharmacist, Mannings- Hong Kong Dairy Farm Company Limited **

* Withdrew before the third meeting

** Joined at the third meeting

Appendix C

Working Group on Codes of Practice for Holders of Wholesale Poisons Licence and Holders of Certificate of Registration as an Importer and Exporter of Pharmaceutical Products

Chairperson:

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

Official members:

- Mr Lot CHAN, Chief Pharmacist, Department of Health
- Mr Vincent CHOW, Senior Pharmacist (Licensing and Compliance -Wholesalers), Department of Health

Non-official members:

- Ms Sabriba CHAN, The Hong Kong Association of the Pharmaceutical Industry
- Ms Annette CHIU, The Hong Kong Association of the Pharmaceutical Industry
- Ms Celine CHENG, President, The Hong Kong Pharmaceutical Manufacturers Association
- Mr Alex CHEUNG, Vice President, The Hong Kong Pharmaceutical Manufacturers Association
- Mr William TSUI, The Pharmaceutical Distributors Association of Hong Kong (HKPDA)
- Mr William LO, The Pharmaceutical Distributors Association of Hong Kong
- Ms Yvonne CHAN, Head of Quality & Medical Affairs, DKSH Hong Kong Ltd.
- Ms Amie KWAN, Compliance Manager and Company Pharmacist, DKSH Hong Kong Ltd.
- Mr William YIU, Manager-Regulatory Affairs, LF Asia (Hong Kong) Limited
- Mr Sean LEE, Quality Assurance Manager, LF Asia (Hong Kong) Limited
- Mr Andrew WONG, Senior Director of Operations and IT, Zuellig Pharma Ltd.
- Mr Gordon LEE, Regulatory Services Manager and Company Pharmacist, Zuellig Pharma Ltd.
- Mr Tyson NG, Nutritionist, Usana Hong Kong Ltd.

- Ms Doris LO, Regulatory and Technical Relations Supervisor, Nu Skin Enterprises Hong Kong Inc.
- Ms Polly WAN, Logistics Supervisor, Nu Skin Enterprises Hong Kong Inc.

Appendix D

Working Group on Codes of Practice for Pharmacists

Chairperson:

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

Members:

School of Pharmacy, The Chinese University of Hong Kong	Dr YU Chui-yu, Jennifer
	Prof. LEE Wing-yan, Vivian
	Dr LEE Chui-ping
	Dr ZHOU Rui, Keary
	Dr EWIG Lom-ying, Celeste
The University of HK	Dr LAM Pui-san, May
The Practising Pharmacists Association of Hong Kong	Ms CHANG Iris Jacqueline
	Mr CHAN Cho-hung, Philip
	Ms CHAN LAU Charm-ming, Charmaine
	Mr CHEUNG Tak-wing, Alex
	Mr POON Poe-meng, Steeve
The Pharmaceutical Society of Hong Kong	Mr LEUNG Kai-lok, Peter
	Ms YAN Che-yin, Cadence
	Ms KWOK Ching-chi, Ritchie
	Mr SUEN Yiu-chan, Peter
	Mr YAU Fook-wing, Edward William
The Society of Hospital Pharmacists of Hong Kong	Mr CHUI Chun-ming, William
	Mr LING Ho-ming, Michael
	Ms CHAN Wing-lam, Phoebe
	Ms CHIANG Sau-chu
	Mr SO Yiu-wah

The Hong Kong Pharmacists Union	Mr CHEUNG Kin-man, Kevin
	Ms CHEUNG Wan-sze, Jenny
	Mr TAM Po-chun, Patrick
	Mr. SUNG Ming-tat, Dick
	Ms YUNG Wai-lan, Anna

Secretary:

Ms Kitty YEUNG, Executive Officer, Drug Office, Department of Health

Appendix E

Working Group on Codes of Practice for Licensed Manufacturers and Authorized Persons

Chairperson:

- Mr Lot CHAN, Chief Pharmacist, Department of Health

Official members:

- Mr Joseph LEE, Senior Pharmacist(Licensing and Compliance –Manufacturers), Department of Health
- Mr Edwin LAM, Senior Pharmacist(Licensing and Compliance –Manufacturing Quality Assurance), Department of Health
- Mr Edek KO, Pharmacist, Department of Health
- Mr Vincent Chiang, Pharmacist, Department of Health

Non-official members:

Dr. Celine CHENG, President of the Hong Kong Pharmaceutical Manufacturers Association

Mr. Alex CHEUNG Vice President, The Hong Kong Pharmaceutical Manufacturers Association

Dr. Helen CHAN, Executive Members of The Hong Kong Pharmaceutical Manufacturers Association

Mr. WONG Cheong-moon, Executive Members of The Hong Kong Pharmaceutical Manufacturers Association

Mr. Raymond YEUNG. Executive Members of The Hong Kong Pharmaceutical Manufacturers Association

Ms. Polly TANG Yin-yi, Executive Members of The Hong Kong Pharmaceutical Manufacturers Association

Mr. Chris WOO Pui-hong, Executive Members of The Hong Kong Pharmaceutical Manufacturers Association

Secretary:

- Mr Kevin LO, Pharmacist, Department of Health