Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014

Summary of meetings between the Administration and relevant deputations of the trade during the period from January 2013 to June 2014

At the meeting of the Bills Committee on the Pharmacy and Poisons (Amendment) Bill 2014 ("the Bill") on 4 July 2014, Members inquired about the meetings between the Administration and relevant deputations of the trade in relation to the Bill. Summary of the meetings concerned is set out in the **Annex** for Members' reference.

Food and Health Bureau
14 July 2014

Annex

Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014

Summary of meetings between the Administration and the relevant deputations of the trade during the period from January 2013 to June 2014

	Dates	**Deputations**	**Major concerns raised**
1.	24 January 2013 (Meeting)	▪ The Hong Kong Association of Pharmaceutical Industry ▪ The Pharmaceutical Distributors Association of Hong Kong ▪ Hong Kong Pharmaceutical Manufacturers Association Limited ▪ DKSH Hong Kong Limited ▪ LF Asia (Hong Kong) Limited ▪ Zuellig Pharma Limited	– Concerned about the proposed requirement of placing orders of pharmaceutical products in written form (including the electronic means that can be used) and the timetable of implementation
2.	7 January 2013 and 15 March 2013 (Meetings)	▪ The Hong Kong Association of Pharmaceutical Industry ▪ The Pharmaceutical Distributors Association of Hong Kong ▪ Hong Kong Pharmaceutical Manufacturers Association Limited ▪ DKSH Hong Kong Limited ▪ LF Asia (Hong Kong) Limited ▪ Zuellig Pharma Ltd	– Concerned about the timetable for requiring drug dealers engaging in secondary packaging of drugs to compile with the Good Manufacturing Practice ("GMP"). – Expressed concern about the qualification requirements of the key personnel (including the authorized persons ("APs")) of the drug dealers engaging in secondary packaging of drugs. – 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, in particular if the products are for life-saving or imported in limited quantity. (After consideration of the views expressed, the Administration decided to move Committee Stage Amendments to amend the relevant provisions.)

	Dates	Deputations	Major concerns raised
3.	29 January 2013, 20 March 2013 and 10 April 2013 (Briefings)	▪ Drug dealers engaging in secondary packaging of drugs	– Concerned about the timetable for requiring drug dealers engaging in secondary packaging of drugs to compile with the GMP. – Expressed concern about the qualification requirements of the key personnel (including the APs) of the drug dealers engaging in secondary packaging of drugs. – 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, in particular if the products are for life-saving or imported in limited quantity. (After consideration of the views expressed, the Administration decided to move Committee Stage Amendments to amend the relevant provisions.)
4.	13 January 2014 (Meeting)	Hong Kong Suppliers Association	– Expressed concerns over the prevailing regulation of hair dyes, vitamins and mineral supplements. (The Association also sent a letter to the Food and Health Bureau ("FHB") on the same matter. The FHB already issued written response and clarification to the Association, see Appendix 1.)

	Dates	Deputations	Major concerns raised
5.	6 February 2014 (Meeting)	Direct Selling Association of Hong Kong Limited	– Considered that vitamins and mineral supplements should be excluded from the classification list of pharmaceutical products and exempted from the legislative proposal. (The Association also sent a letter to the FHB on the same matter. The FHB already issued written response and clarification to the Association, see Appendix 2.)
6.	7 February 2014 (Meeting)	Hong Kong General Chamber of Pharmacy Limited	– Concerned about the proposed requirement of the presence of a registered pharmacist in the premises of an authorized seller of poisons ("ASP") whenever the ASP is open for business (Given the concerns of the trade and Members of the Legislative Council Panel on Health Services ("HS Panel") on the proposed requirement, and having regard to the fact that the manpower supply of registered pharmacists in the coming few years may not be sufficient to cope with the demand arising from the above proposal, the proposed requirement has been withdrawn and the relevant provisions has been removed from the Bill.) – Concerned about the proposal that all Part I poisons are required to be stored in locked receptacles placed in the registered premises of an ASP and the keys of the receptacles must be possessed by registered pharmacists – Expressed concerns about the drafting of the codes of practice ("COPs") for relevant drug dealers, including the requirement of placing drug orders in written form

	Dates	Deputations	Major concerns raised
7.	11 February 2014 (Meeting)	Pharmaceutical Society of Hong Kong	– Concerned about the proposed requirement of the presence of a registered pharmacist in the premises of an ASP whenever the ASP is open for business (Given the concerns of the trade and Members of the HS Panel on the proposed requirement, and having regard to the fact that the manpower supply of registered pharmacists in the coming few years may not be sufficient to cope with the demand arising from the above proposal, the proposed requirement has been withdrawn and the relevant provisions has been removed from the Bill) – Concerned about the proposal that all Part I poisons are required to be stored in locked receptacles placed in the registered premises of an ASP and the keys of the receptacles must be possessed by registered pharmacists – Expressed concerns about the drafting of the COPs for relevant drug dealers (including the requirement of placing drug orders in written form) and the codes of conduct ("COC") for registered pharmacists
8.	18 February 2014 (Meeting)	The Practising Pharmacists Association of Hong Kong	– Concerned about the proposed requirement of the presence of a registered pharmacist in the premises of an ASP whenever the ASP is open for business (Given the concerns of the trade and Members of the HS Panel on the proposed requirement, and having regard to the fact that the manpower supply of registered pharmacists in the coming few years may not be sufficient to cope with the demand arising

	Dates	Deputations	Major concerns raised
			from the above proposal, the proposed requirement has been withdrawn and the relevant provisions has been removed from the Bill) – Concerned about the proposal that all Part I poisons are required to be stored in locked receptacles placed in the registered premises of an ASP and the keys of the receptacles must be possessed by registered pharmacists – Expressed concerns about the drafting of the COPs for relevant drug dealers (including the requirement of placing drug orders in written form) and the COC for registered pharmacists – Expressed concerns about providing legal status for the COPs/ COC – Expressed concerns about legal responsibilities of ASPs and their staff (including registered pharmacists) for violating the Pharmacy and Poisons Ordinance ("PPO")
9.	19 February 2014 (Meeting)	The Cosmetic and Perfumery Association of Hong Kong Limited	– Requested for the exclusion of hair dyes containing Part II poisons from the proposed legislative amendments and the removal of the relevant Part II poisons from the Poisons List (The Association also sent a letter to the FHB on the same matter. The FHB already issued written response and clarification to the Association, see Appendix 3 (Chinese version only).)
10.	10 April 2014 (Briefing)	▪ Pharmaceutical Society of Hong Kong ▪ The Practising Pharmacists Association of Hong Kong ▪ The Society of Hospital	– Concerned about the proposed amendment to the definition of "ASP" – Concerned about the proposed

	Dates	Deputations	Major concerns raised
		Pharmacists of Hong Kong ▪ Hong Kong Pharmacists Union	amendment to the definition of "pharmaceutical product" and "medicine". – Concerned about the consultation with the trade by the Pharmacy and Poisons Board ("PPB") when amending any COP
11.	14 April 2014 (Briefing)	▪ The Hong Kong Association of the Pharmaceutical Society ▪ The Pharmaceutical Distributors Association of Hong Kong ▪ The Hong Kong Pharmaceutical Manufacturers Association Ltd ▪ Hong Kong Suppliers Association ▪ The Direct Selling Association of Hong Kong Limited ▪ The Cosmetic and Perfumery Association of Hong Kong Ltd	– Concerned about the proposed amendment to the definition of "pharmaceutical product" and "medicine" – Concerned about the requirement of the production of specified information regarding the pharmaceutical product or substance concerned when renewing the registration of the product or substance – Concerned about the transitional arrangements in connection with the proposed requirement to replace the term "Poison" with "Prescription Drug" or "Drug under Supervised Sales"
12.	29 April 2014 (Meeting)	Hong Kong General Chamber of Pharmacy Limited	– Concerned about the proposed amendment to the definition of "ASP" – Inquired about the justifications for repealing the existing provisions that allow the ASP to perform manufacturing process in the registered premises – Concerned about the consultation with the trade by the Pharmacy and PPB when amending the codes of practice – Expressed concerns about the proposed amendment to increase the circumstances in which a disciplinary committee may be appointed by the PPB to inquire into the conduct of registered pharmacists and ASPs

	Dates	Deputations	Major concerns raised
			– Concerned about the proposal to empower the courts to recover the expenses related to the conviction from the convicted persons – Concerned about the inadequate representation from the retail sector in the existing composition of the PPB
13.	2 May 2014 (Meeting)	Hong Kong Pharmaceutical Manufacturers Association	– 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, in particular if the products are for life-saving or imported in limited quantity. (After consideration of the views expressed, the Administration decided to move Committee Stage Amendments to amend the relevant provisions.)
14.	12 May 2014 (Meeting - cancelled)	Hong Kong Pharmacists Union	– A meeting with the Union was originally arranged by the Department of Health ("DH"). However, the Union was unable to attend the meeting because it had to seek legal advice and gather views from its members.
15.	20 June 2014 (Meeting - cancelled)	Hong Kong Pharmacists Union	– A meeting with the Union was arranged by the DH on 20 June 2014. The Union requested for the presence of Government legal advisors on the meeting. Since only DH representatives were arranged to attend the meeting, the union decided to call off the meeting. – DH is continuing to line up a meeting with the Union.

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

Tel : 3509 8956
Fax : 2840 0467

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

---

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

附件2
Annex 2

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

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

---

[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