《2014 年藥劑業及毒藥（修訂）條例草案》委員會

政府與相關業界團體於 2013 年 1 月至 2014 年 6 月期間的會面概要

於二零一四年七月四日《2014 年藥劑業及毒藥（修訂）條例草案》（“《條例草案》”）委員會會議上，議員查詢政府當局就《條例草案》與業界團體所舉行的會面。有關摘要已臚列在**附表**內，以供議員備悉。

食物及衞生局
二零一四年七月十四日

附表

《2014 年藥劑業及毒藥（修訂）條例草案》委員會

政府與相關業界團體於 2013 年 1 月至 2014 年 6 月期間的會面概要

	會面日期	會面團體	於會上表達的主要關注
1.	2013 年 1 月 24 日（會面）	▪ 香港科研製藥聯會 ▪ 香港醫藥經銷業協會 ▪ 香港製藥商會有限公司 ▪ 大昌華嘉香港有限公司 ▪ 利豐亞洲(香港)有限公司 ▪ 裕利醫藥有限公司	– 對必須以書面方式訂購藥物的建議要求（包括可採用的電子方式）和推行時間表表示關注
2.	2013 年 1 月 7 日及 2013 年 3 月 15 日（會面）	▪ 香港科研製藥聯會 ▪ 香港醫藥經銷業協會 ▪ 香港製藥商會有限公司 ▪ 大昌華嘉香港有限公司 ▪ 利豐亞洲(香港)有限公司 ▪ 裕利醫藥有限公司	– 關注要求經營藥物外包裝業務的藥商推行生產質量管理規範（GMP）的時間表 – 對經營藥物外包裝業務的藥商的關鍵人員（包括獲授權人）的資歷要求表示關注 – 關注擴大保留製成品的對照樣本的要求至再包裝活動的影響（例如為符合現行標籤要求而在外盒上加上標籤或更換產品說明書），尤其是產品為用於拯救生命或進口極少量的藥物。（當局在考慮有關意見後，將會提出委員會審議階段修正案，就相關條文作出修訂。）
3.	2013 年 1 月 29 日、2013 年 3 月 20 日及	▪ 經營藥物外包裝業務的藥商	– 關注要求經營藥物外包裝業務的藥商推行生產質量管理規範

	會面日期	會面團體	於會上表達的主要關注
	2013 年 4 月 10 日（簡介會）		（GMP）的時間表 – 對經營藥物外包裝業務的藥商的關鍵人員（包括獲授權人）的資歷要求表示關注 – 關注擴大保留製成品的對照樣本的要求至再包裝活動的影響（例如為符合現行標籤要求而在外盒上加上標籤或更換產品說明書），尤其是產品為用於拯救生命或進口極少量的藥物。（因應有關意見，當局將會提出委員會審議階段修正案，就相關條文作出修訂。）
4.	2014 年 1 月 13 日（會面）	香港供應商協會有限公司	– 就目前對染髮劑、維他命及礦物補充劑的規管表達關注 （團體亦就相同事宜致函局方，局方已作出書面回應及澄清，見附件 1（只有英文版本）。）
5.	2014 年 2 月 6 日 (會面)	香港直銷協會	– 認為應把維他命及礦物補充劑從“藥劑製品”的分類中剔除，並在立法建議中豁免上述產品 （團體亦就相同事宜致函局方，局方已作出書面回應及澄清，見附件 2（只有英文版本）。）
6.	2014 年 2 月 7 日 (會面)	港九藥房總商會有限公司	– 關注獲授權銷售商必須在其所有營業時間設有註冊藥劑師駐場的建議要求（因應業界及立法會衞生事務委員會委員對有關建議要求的關注，以及考慮到註冊藥劑師在未來數年的人手供應很可能不足以應付上述建議的人手需求，有關建議要求現已取消，並

	會面日期	會面團體	於會上表達的主要關注
			已從《條例草案》移除有關的擬議條文） – 關注所有第I部毒藥均須貯儲在獲授權銷售商註冊處所的上鎖容器內，而容器的鑰匙必須由註冊藥劑師管有 – 對為相關藥商擬備的《執業守則》表示關注，包括當中訂立必須以書面方式訂購藥物的要求
7.	2014年2月11日(會面)	香港藥學會	– 關注獲授權銷售商必須在其所有營業時間設有註冊藥劑師駐場 （因應業界及立法會衞生事務委員會委員對有關建議要求的關注，以及考慮到註冊藥劑師在未來數年的人手供應很可能不足以應付上述建議的人手需求，有關建議要求現已取消，並已從《條例草案》移除有關的擬議條文） – 關注所有第I部毒藥均須貯儲在獲授權銷售商註冊處所的上鎖容器內，而容器的鑰匙必須由註冊藥劑師管有 – 對為相關藥商擬備的《執業守則》（包括當中訂立必須以書面方式訂購藥物的要求）及為註冊藥劑師擬備的《行為守則》表達關注
8.	2014年2月18日(會面)	香港執業藥劑師協會	– 關注獲授權銷售商必須在其所有營業時間設有註冊藥劑師駐場 （因應業界及立法會衞生事務委員會委員對有關建議要求的

	會面日期	會面團體	於會上表達的主要關注
			關注，以及考慮到註冊藥劑師在未來數年的人手供應很可能不足以應付上述建議的人手需求，有關建議要求現已取消，並已從《條例草案》移除有關的擬議條文） – 關注所有第I部毒藥均須貯儲在獲授權銷售商註冊處所的上鎖容器內，而容器的鑰匙必須由註冊藥劑師管有 – 對為相關藥商擬備的《執業守則》（包括當中訂立必須以書面方式訂購藥物的要求）及為註冊藥劑師擬備的《行為守則》表達關注 – 對賦予《執業守則》/《行為守則》法律地位表達關注 – 就獲授權銷售商及其職員（包括註冊藥劑師）違反《藥劑業及毒藥條例》的法律責任表示關注
9.	2014年2月19日(會面)	香港化粧品同業協會	– 要求從建議法例修訂中剔除含有第II部毒藥的染髮劑，並把相關第II部毒藥從毒藥表中移除 （團體亦就相同事宜致函局方，局方已作出書面回應及澄清，見附件3。）

	會面日期	會面團體	於會上表達的主要關注
10.	2014 年 4 月 10 日（簡介會）	▪ 香港藥學會 ▪ 香港執業藥劑師協會 ▪ 香港醫院藥劑師學會 ▪ 香港藥劑師工會	– 關注對“獲授權毒藥銷售商”定義的建議修訂 – 關注對“藥劑製品”及“藥物”定義的建議修訂 – 關注藥劑業及毒藥管理局（管理局）修訂任何《執業守則》時向業界進行的諮詢工作
11.	2014 年 4 月 14 日（簡介會）	▪ 香港科研製藥聯會 ▪ 香港醫藥經銷業協會 ▪ 香港製藥商會有限公司 ▪ 香港供應商協會有限公司 ▪ 香港直銷協會有限公司 ▪ 香港化粧品同業協會有限公司	– 關注對“藥劑製品”及“藥物”定義的建議修訂 – 關注規定在有關藥劑製品或物質的註冊續期時，須提供指明關於該等製品或物質的資料 – 就以“Prescription Drug 處方藥物”或“Drug under Supervised Sales 監督售賣藥物”取代“Poison 毒藥”一詞的建議要求，關注相關過渡性安排
12.	2014 年 4 月 29 日 (會面)	港九藥房總商會有限公司	– 關注對“獲授權毒藥銷售商”定義的建議修訂 – 就取消現行容許獲授權毒藥銷售商在其註冊處所進行製造的條文，查詢有關修訂的理據 – 關注管理局修訂任何《執業守則》時向業界進行的諮詢工作 – 就賦權管理局可以在更多情況下委任紀律委員會，就註冊藥劑師及獲授權毒藥銷售商的行為操守進行研訊的建議修訂表達關注 – 關注賦權法庭向被定罪人追討

	會面日期	會面團體	於會上表達的主要關注
			與定罪有關的開支的建議 – 關注目前管理局的組成未有足夠來自零售界的代表
13.	2014 年 5 月 2 日 (會面)	香港科研製藥聯會	– 關注把保留製成品的對照樣本的要求擴大至再包裝活動的影響(例如為符合現行標籤要求而在外盒上加上標籤或更換產品說明書),尤其是產品為用於拯救生命或進口極少量的藥物。 (當局在考慮有關意見後,將會提出委員會審議階段修正案,就相關條文作出修訂。)
14.	2014 年 5 月 12 日 (會面－取消)	香港藥劑師工會	– 衞生署原已安排與團體於該日會面;惟團體表示因需要諮詢法律意見和工會成員意見,而未能出席。
15.	2014 年 6 月 20 日 (會面－取消)	香港藥劑師工會	– 衞生署原已安排與團體於該日會面;惟團體要求政府派出法律顧問出席會議,而基於該次會議只安排了衞生署代表出席,團體決定取消會面。 – 衞生署正繼續與團體安排會面。

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

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
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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

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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