Our Ref : L/M to FHB/H/24/2 Pt.33 Tel : 3509 8956
Your Ref : CB2/PL/HS 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Review Committee on Regulation of Pharmaceutical Products in Hong Kong ("the Review Committee") and to update certain outdated provisions of the Pharmacy and Poisons Ordinances (Cap. 138) ("PPO") and its subsidiary legislation.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 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 emphasis 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