HONG KONG Suppliers Association HKSA
香港供應商協會有限公司 http://www.hksuppliers.com

January 2, 2014

To: Dr. Hon Leung Ka-lau
Chairman of Panel on Health Service
Legislative Council, HKSAR

cc: Hon. Vincent Fang Kang, SBS, JP
Dr. Ko Wing-man, BBS, JP, Secretary for Bureau of Food and Health
Dr. Chan Hon-yee, Constance, JP, Director for Department of Health

Re: Legislative Proposal to enhance the regulation of pharmaceutical products (Petition to exempt hair dye and vitamins/minerals dietary supplements from additional, unnecessary regulatory control)

Dear Dr. Hon Leung,

Thank you inviting our Association to the special meeting with deputation and the Administration on December 10, 2013 and providing us the opportunity to express our concern on the Legislative Proposal to enhance the regulation of pharmaceutical products.

We are greatly disappointed the views we expressed on December 10, 2013 were not addressed or even mentioned in the Administration's report, L/C Paper No. CB(2)541/13-14(01), on latest development of the said proposal after our meeting on December 10, 2013. There were no follow-up on our views directly or indirectly from the Administration. Our view and the presence of our trade association in the special meeting appeared to have been completely ignored.

We sincerely hope that you would follow up with the Administration on the view we expressed on December 10, 2013.

We strongly object to Recommendation No. 18 and 19 under the Recommendations of the Review Committee on Regulations of Pharmaceutical Products. No. 18 requires all wholesalers of non-poisons to be subjected to inspection and licensing control and No. 19 requires all wholesalers to keep transaction records of all products, including Part II poison and non-poison in THE SAME MANNER as Part I poison.

As I mentioned in the meeting on December 10, 2013, our membership mainly composed of suppliers from the Fast Moving Consumer Goods (FMCG) business. We truly have no place in such a meeting involving the regulation of high risk product, DRUGS, that the targeted client are PATIENTS requiring medical attention and doctor care. The topics of drug safety and patients care were the only subject for discussion by the professional associations, the Administration and the Legislators. The products our members supplying are neither drugs nor targeted at patients with illness. We are bewildered and frustrated that we, somehow, got entangled into such a regulation involved highly sophisticated pharmaceutical products.

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It is unfortunate that the Administration proposed to place our FMCG, such as hair dye for salon and home uses and the low risk vitamins/minerals dietary supplements under the same stringent regulation of drugs that one administered by mistake to a patient could means life and death.

RECOMMENDATION No. 19

Recommendation No. 19 requires wholesalers of Part II poison and non-poison to keep transaction records of all products in THE SAME MANNER as Part I poison. Cosmetic products such as Hair Dye happened to fall into Part II poison. The suppliers of hair dye are traders of everyday consumer products. They do not possess the same sophisticated inventory control system as the suppliers of pharmaceutical products. It is almost unheard of in our business that a SME supplier would have an inventory system that is capable of keeping transaction record by lot numbers. It is our understanding that, amongst many requirements, this is one of the requirements of record keeping in Part I poison. We dared to say that even multi-national or large suppliers in the FMCG suppliers business may not have such lot number monitoring inventory system. FMCG suppliers generally carry large number of stock keeping units (SKU) and Part II poison and non-poison, if they supply them, generally accounted for a very small % of their SKU. The implementation of a transaction tracking system as Part I poison will be extremely expensive relative to the small % of SKU in question for the FMCG suppliers. It will force some of the law abiding suppliers out of the business because of compliant cost. A handful of large suppliers may be fortunate enough to be able to adopt such a lot number keeping procedure into their system. The remaining small suppliers will be the invisible law breaking suppliers that do not comply with the new regulation and probably will be difficult for the Administration to prosecute. The same argument applies to suppliers of low risk vitamins/minerals dietary supplements.

To put it another way, Recommendation 19 will force law abiding SME to give up the business; if to comply, price of products will have to increase substantially; it will inhibit business and encourage business domination; there will still be large number of parallel goods importers and suppliers invisible to the Administration continuing the business without complying.

WE RESPECTFULLY ASK THE ADMINISTRATION THE REASON IN REGULATING SUCH LOW RISK NON-DRUG PRODUCTS SUCH AS HAIR DYE AND VITAMINS/MINERALS DIETARY SUPPLEMENT **IN THE SAME MANNER** AS THE HIGH RISK PART I POISON.

We urge the Administration to exempt hair dye and Vitamins/minerals dietary supplements form Recommendation no. 19.

RECOMMENDATION No. 18

Our association supports those recommendations which protect patients by better control of pharmaceutical products for treatment of diseases.

Recommendation No. 18 requires wholesaler of non-poison to be subjected to inspections and licensing control. We would support Recommendation No. 18 for non-poison products that are pharmaceuticals. Vitamins and minerals dietary supplements are classified under non-poison drugs; but they are not drugs, they are for provision of nutrients. Vitamins and minerals dietary supplement are for the fortification of daily nutrients. These dietary supplements are mainly for health conscious individuals, not for patients.

We strongly object to place vitamins/minerals dietary supplements under the inspections and licensing control as pharmaceuticals. Such low risk products should not be placed under the same requirement as high risk pharmaceutical products. It will only add unwarranted cost to the suppliers.

We urge the Administration to exempt vitamins and minerals dietary supplements from Recommendation no. 18.

REMOVE HAIR DYE FROM THE POISON LIST AND VITAMINS/MINERALS SUPPLEMENT FROM THE NON-POISON LIST

The administration proposed to revise the definition of the word "pharmaceutical products" in accordance with the definition adopted by the European Union (EU). EU classified phenylene diamines and toluene diamines as hair colorants under European Cosmetic Regulation 1223/2009, not as Poison or pharmaceutical products. These two hair colorants are also permitted in ASEAN countries (10 countries) under ASEAN Cosmetic Directive. In fact, these two ingredients are also considered as hair colorant, not pharmaceutical, in U.S.A., Japan and many parts of the world. Why Hong Kong has to be different by placing such cosmetic products under the tight control of the Department of Health?

Vitamins and minerals without treatment claims are classified as foods by our major trading partners, such as, U.S.A., Mainland China, EU, Japan, Korea, Taiwan, etc. They are not regulated as pharmaceutical products in almost all over the established world according to our understanding. Vitamins and minerals are helpful in health maintenance, but they are much more expensive in Hong Kong than other established markets. Almost all vitamins and minerals sold in Hong Kong are imported. The current regulation on these products are already so stringent and probably one of the causes for the high prices. Could we consider adopting policies of our trustworthy trading partners to lessen the tight control that could be the cause of high prices and limiting choices?

We urge the Administration to remove hair dye with ingredients of Phenylene Diamines and Toluene Diamines for coloration of hair from the Poison List and Vitamins/minerals dietary supplements from the Non-poison list.

Thank you for your attention.

Yours truly,

Albert Tang
Chairman
Hong Kong Suppliers Association

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