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.: FHB/H/23/6 Pt.29 *Tel. No.:* 3509 8956
Your ref.: *Fax No.:* 2840 0467

15 January 2014

Dr Hon LEUNG Ka-lau
Chairman, Legislative Council Panel on Health Services
Legislative Council Complex
1 Legislative Council Road
Central, Hong Kong

Dear Dr Hon LEUNG,

Legislative Council Panel on Health Services

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

We noted that Hon Vincent FANG sent a letter to the Chairman of the Legislative Council Panel on Health Services ("the Panel") on 27 December 2013 which states his views on the Administration's legislative proposals to enhance the regulation of pharmaceutical products in Hong Kong. In this connection, we would like to provide the Chairman and Members of the Panel with supplementary information in relation to the assessment and consultation work carried out by the Administration when drafting the above legislative proposals and the Administration's response to the concerns raised by the trade and stakeholders.

2. The main objective of the Administration's current legislative proposals is to implement some of the recommendations put forth by the Review Committee on the Regulation of Pharmaceutical Products in Hong Kong ("the

Review Committee"), which seek to enhance the safety of pharmaceutical products in Hong Kong and protect public health. In early 2009, a series of incidents relating to the safety of pharmaceutical products caused widespread concern in the community. In response, the Government set up in March 2009 the Review Committee to conduct a comprehensive review on the existing regulatory regime for pharmaceutical products. The Review Committee was chaired by the Permanent Secretary for Food and Health (Health) and comprised of members from various representative sectors, including the pharmaceutical sector, medical profession, academia, patient groups and consumer representatives. In consideration of the wide range and complexity of the issues to be examined, the Review Committee set up two Subcommittees, one on quality management of drug manufacturing and another on drug distribution and procurement, to conduct in-depth study on various issues. Moreover, the Department of Health set up two task forces to provide expert advice for the Review Committee. The memberships of the Review Committee and the above Subcommittees/task forces are set out at **Annex 1**.

3. The Review Committee issued its report with 75 recommendations in December 2009 and submitted it to the Panel in January 2010. Among these recommendations, the Administration is required to amend the existing Pharmacy and Poisons Ordinance (Cap. 138) and its subsidiary legislation in order to implement 16 recommendations. To assess the impacts of the proposed legislative amendments on various stakeholders and to ensure transparency of the legislative process, the Administration commissioned a consultant in January 2011 to conduct a Regulatory Impact Assessment ("RIA"). The assessment methods included (i) soliciting stakeholders' views in consultation meetings and workshops and (ii) gauging public sentiments towards the proposed legislative amendments through a public opinion survey carried out by the University of Hong Kong. During the period from February to March 2011, the consultant held a total of 24 in-depth consultation meetings and 12 interactive workshops with major stakeholders (the list is in **Annex 2**). Subsequently, the consultant completed the RIA report in January 2013.

4. Apart from amending the Pharmacy and Poisons Ordinance and its subsidiary legislation for the purpose of implementing some recommendations of the Review Committee, the Administration has planned to revise or formulate Codes of Practice ("COPs") for relevant licensed drug traders in order to implement the other recommendations of the Review Committee. Since January 2012, the Pharmacy and Poisons Board ("PPB") has set up different working groups, with trade representatives and stakeholders as members, to

provide comments on the revision/formulation of COPs for the relevant licensed drug traders. In addition, during the process of revising/formulating the 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 3**.

5. At the Panel meeting held on 18 November 2013, the Administration tabled a paper (LC Paper No. CB(2)254/13-14(03)) on the legislative proposals to enhance the regulation of pharmaceutical products in Hong Kong. The paper provides Members with information on the background, objective and proposed modus operandi of the suggested requirements. Subsequently, the Administration also submitted supplementary information regarding the proposed requirement of written order of drugs (LC Paper No. CB(2)414/13-14(01)) to the Panel on 2 December 2013, and attended the special meeting of the Panel held on 10 December 2013 to listen to views and concerns of the relevant stakeholders on the legislative proposals.

6. After numerous consultations and exchanges with different trade parties and relevant stakeholders through various channels, we have concluded that the trade and stakeholders are supportive of the Administration's legislative amendments to enhance the regulation of pharmaceutical products in Hong Kong, so as to provide better protection for the public. Nevertheless, we have also gathered from these consultations and exchanges the trade's concerns. After carefully considering views of different parties, we have adjusted the legislative proposals as appropriate on the condition that such adjustments will not affect the overall effectiveness of the proposed regulation. In conclusion, the trade is mainly concerned about two proposed requirements. The first one is the legislative proposal which requires the presence of a registered pharmacist whenever an authorised seller of poisons ("ASP") is open for business. The second one is the proposed requirement that licensed wholesalers of poisons should only accept orders of drugs made in writing. In formulating the first legislative proposal, the Administration has already taken into account the current manpower supply of registered pharmacists. Therefore, we have stated in LC Paper No. CB(2)254/13-14(03) submitted on 18 November 2013 that the relevant provision for this proposal would be implemented at a later stage. Since the Administration's original intention is to implement the above proposed provision when the supply of registered pharmaceutical is sufficient, after further considering the concerns of stakeholders and some Members of the Panel about the above proposal as expressed at the Panel's special meeting held on 10

December 2013, the Administration has decided to remove the proposed provision from the legislative proposals. In other words, the existing statutory requirement that the registered premises of an ASP must be under the personal control of a registered pharmacist for not less than two-thirds of the opening hours will remain unchanged. As regards the second proposed requirement, we have also repeatedly pointed out that the proposed requirement of placing drug orders in writing aims to build up a complete set of drug movement record to facilitate tracking of drug sources, so as to reduce errors in drug delivery and receipt and to combat illegal sale of drugs. The relevant requirement will be incorporated into the COPs respectively for drug manufacturers, wholesalers and retailers as revised/formulated by the PPB after consulting the trade and stakeholders. The requirement will become one of the compliance codes for the licensed drug traders. In other words, the requirement will not be regulated by law. As pointed out in paragraph 4 above, the PPB has set up working groups comprising trade representatives to work on the revision and formulation of the abovementioned COPs, and public consultation and briefing sessions for the trade have been/would be conducted. On 16 December 2013, the Administration submitted an information paper (LC Paper No. CB(2)541/13-14(01)) to the Panel to explain the above two requirements and the latest updates.

7. The above information shows that the processes of drafting the legislative proposals and revising/formulating the relevant COPs are both open and transparent. Apart from engaging trade representatives and stakeholders in the drafting work, the Administration has also conducted extensive consultation and reported to the relevant parties from time to time the latest updates and progress of these proposals. The Administration has also responded actively to the concerns raised by Members and the trade, and made appropriate adjustments to the legislative proposals.

8. We are thankful for Members' support and views for our legislative exercise. We also appreciate that the Panel has invited deputations to express their views, which allowed us to further exchange views with the trade about the enhancement of the regulation of pharmaceutical products in Hong Kong. As mentioned above, since March 2009, the proposals and implementation details for enhancing the regulation of pharmaceutical products in Hong Kong have been formulated after extensive discussions and studies by organisations and individuals from various sectors since March 2009, with appropriate adjustments in response to the concerns raised by the trade, stakeholders and the public expressed through various channels. We consider that the current legislative

proposals have suitably addressed the urgent need of enhancing the regulation of pharmaceutical products in Hong Kong, and have also taken account of and responded as appropriate to concerns of the trade, stakeholders and the public. We hope to introduce the legislative proposals and the amendment bill to the Legislative Council in the first half of 2014. We are also willing to explain in greater details on the provisions and implementation details of the amendment bill to the Members and stakeholders at the meetings of the relevant Bills Committee so that appropriate legislative amendments for implementing the recommendations of the Review Committee could be made as earlier as possible, with a view to perfecting the regulatory regime of pharmaceutical products in Hong Kong and providing better protection to the general public.

Yours sincerely,

(Professor Sophia CHAN)
Under Secretary for Food and Health

Membership of the Review Committee on Regulation of Pharmaceutical Products in Hong Kong

Chairman:

- Ms Sandra LEE, Permanent Secretary for Health

Vice Chairman:

- Dr LAM Ping-yan, Director of Health

Official Members:

- Dr Gloria TAM, Deputy Director of Health
- Mr Anthony CHAN, Chief Pharmacist, Department of Health
- Dr CHEUNG Wai Lun, Director (Cluster Services), Hospital Authority
- Ms Anna LEE, Chief Pharmacist, Hospital Authority

Non-official Members:

- Ms Sabrina CHAN, Executive Director, Hong Kong Association of the Pharmaceutical Industry
- Ms Iris CHANG, President, The Practising Pharmacists Association of Hong Kong
- Ms Celine CHENG, President, The Hong Kong Pharmaceutical Manufacturers Association Ltd.
- Ms Sandra CHOW, Chairperson, Care for your Heart – Cardiac Patients Mutual Support Association (up to late December 2009)
- Mr William CHUI, Vice President, The Society of Hospital Pharmacists of Hong Kong
- Mr Benjamin KWONG, President, The Pharmaceutical Society of Hong Kong
- Dr Alan LAU, Chairman, Hong Kong Private Hospitals Association
- Mr Andy LAU, Chairman, Alliance for Renal Patients Mutual Help Association
- Ms Connie LAU, Chief Executive, Consumer Council
- Mr LAU Oi Kwok, Chairman, Hong Kong General Chamber of Pharmacy Ltd.
- Professor Kenneth LEE, Professor, School of Pharmacy The Chinese University of Hong Kong
- Dr TSE Hung Hing, President, Hong Kong Medical Association
- Ms Tina YAP, Chairman, The Pharmaceutical Distributors Association of Hong Kong

- Dr YEUNG Chiu Fat, President, Hong Kong Doctors Union

Secretary:

- Ms Shirley LAM, Principal Assistant Secretary for Health, Food and Health Bureau

Memberships of the two Subcommittees under the Review Committee on Regulation of Pharmaceutical Products in Hong Kong

(1) Subcommittee on Drug Manufacturing

Chairman:

- Dr Gloria TAM, Deputy Director of Health

Official Members:

- Mr Anthony CHAN, Chief Pharmacist, Department of Health
- Ms Anna LEE, Chief Pharmacist, Hospital Authority

Non-official Members:

- Ms Sabrina CHAN, Executive Director, Hong Kong Association of the Pharmaceutical Industry
- Ms Iris CHANG, President, The Practising Pharmacists Association of Hong Kong
- Ms Celine CHENG, President, The Hong Kong Pharmaceutical Manufacturers Association
- Ms Sandra CHOW, Chairperson, Care for your Heart – Cardiac Patients Mutual Support Association (up to late December 2009)
- Mr William CHUI, Vice President, The Society of Hospital Pharmacists of Hong Kong
- Mr Benjamin KWONG, President, The Pharmaceutical Society of Hong Kong
- Mr Andy LAU, Chairman, Alliance for Renal Patients Mutual Help Association
- Prof Kenneth LEE, Professor, School of Pharmacy The Chinese University of Hong Kong
- Dr TSE Hung Hing, President, Hong Kong Medical Association
- Ms Tina YAP, Chairman, The Pharmaceutical Distributors Association of Hong Kong
- Dr YEUNG Chiu Fat, President, Hong Kong Doctors Union

Secretary:

- Ms Linda WOO, Chief Pharmacist (Health) Special Duties, Food and Health Bureau

(2) Subcommittee on Drug Distribution and Procurement

Chairman:

- Mrs Susan MAK, Deputy Secretary for Food and Health (Health)

Official Members:

- Mr Anthony CHAN, Chief Pharmacist, Department of Health
- Dr CHEUNG Wai Lun, Director (Cluster Services), Hospital Authority
- Ms Anna LEE, Chief Pharmacist, Hospital Authority

Non-official Members:

- Ms Sabrina CHAN, Executive Director, Hong Kong Association of the Pharmaceutical Industry
- Ms Iris CHANG, President, The Practising Pharmacists Association of Hong Kong
- Ms Celine CHENG, President, The Hong Kong Pharmaceutical Manufacturers Association
- Ms Sandra CHOW, Chairperson, Care for your Heart – Cardiac Patients Mutual Support Association (up to late December 2009)
- Mr William CHUI, Vice President, The Society of Hospital Pharmacists of Hong Kong
- Mr Benjamin KWONG, President, The Pharmaceutical Society of Hong Kong
- Dr Alan LAU, Chairman, Hong Kong Private Hospitals Association
- Mr Andy LAU, Chairman, Alliance for Renal Patients Mutual Help Association
- Ms Connie LAU, Chief Executive, Consumer Council
- Mr LAU Oi Kwok, Chairman, Hong Kong General Chamber of Pharmacy
- Prof Kenneth LEE, Professor, School of Pharmacy The Chinese University of Hong Kong
- Dr TSE Hung Hing, President, Hong Kong Medical Association
- Ms Tina YAP, Chairman, The Pharmaceutical Distributors Association of Hong Kong
- Dr YEUNG Chiu Fat, President, Hong Kong Doctors Union

Secretary:

- Ms Shirley LAM, Principal Assistant Secretary for Health, Food and Health Bureau

Memberships of the two Task Forces under the Review Committee on Regulation of Pharmaceutical Products in Hong Kong

(1) Task Force on Enhancement of Regulation of Pharmaceutical Products in Hong Kong

Chairman:

- Dr LAM Ping-yan, Director of Health

Members:

- Dr TING Tai Lun, Government Chemist
- Dr Gloria TAM, Deputy Director of Health
- Dr Heston KWONG, Assistant Director of Health (Special Health Services)
- Dr KAM Kai Man, Consultant Medical Microbiologist, Department of Health
- Mr Anthony CHAN, Chief Pharmacist, Department of Health

Secretary:

- Ms Linda WOO, Chief Pharmacist (Health) Special Duties, Food and Health Bureau

(2) Expert Group on the Microbiological Hazards on Drug Manufacturing

Convener:

- Dr Heston KWONG, Assistant Director of Health (Special Health Services)

Expert Advisor:

- Professor YUEN Kwok Yung, Head, Department of Microbiology, University of Hong Kong

Members:

- Dr LIM Wei Ling Wilina, Head, Public Health Laboratory Services Branch, Department of Health
- Mr Joseph LEE, Pharmacist (Inspection & Licensing), Department of Health

List of stakeholders participating in Consultation Meetings conducted under the Regulatory Impact Assessment

Group of stakeholders		**Stakeholder interviewed**
1	Pharmaceutical manufacturers	Hong Kong Pharmaceutical Manufacturers Association
2	Pharmaceutical importer & exporters/ wholesalers/ distributors	Hong Kong Suppliers Association
		Major distributor – DKSH
		Major distributor – LF Asia
		Major distributor – Zuellig Pharma
		The Hong Kong Association of the Pharmaceutical Industry
		The Hong Kong Medicine Dealers Guild *
		The Pharmaceutical Distributors Association of Hong Kong
3	Pharmaceutical retailers	Hong Kong General Chamber of Pharmacy Limited
		The Direct Selling Association of Hong Kong
		The Hong Kong Health Food Association
		The Cosmetic and Perfumery Association of Hong Kong
		Federation of Beauty Industry Hong Kong
4	Pharmacists	The Practising Pharmacists Association of Hong Kong
		The Society of Hospital Pharmacists of Hong Kong
		The Pharmaceutical Society of Hong Kong
5	Medical / veterinary professionals	Hong Kong Academy of Medicine *
		Hong Kong Doctors Union
		Hong Kong Medical Association
		China (Hong Kong) Veterinary Association *
		Hong Kong Veterinary Association *
6	Hospital groups	Hospital Authority
		The Hong Kong Private Hospitals Association
7	Government department	Customs and Excise Department *
		Government Laboratory
8	Academics	The School of Pharmacy, The Chinese University of Hong Kong

Group of stakeholders		Stakeholder interviewed
		Faculty of Medicine, The Chinese University of Hong Kong *
		Li Ka Shing Faculty of Medicine, University of Hong Kong *
9	Patients/ consumers	Alliance for Renal Patients Mutual Help Association
		Care of your Heart – Cardiac Patients Mutual Support Association
		Consumer Council

* Through written consultation

Annex 3

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

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.

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
- 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- 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.