Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014
Administration's Responses to Concerns of the Trade

(1) Definition of Authorised Seller of Poisons

As stated in item 1 of the Annex to LC Paper No. CB(2)1522/13-14(01) issued on 16 May 2014, the purpose of our proposal to revise the definition of authorised seller of poisons (ASP) is to reflect the usage of the term in the legislation as an entity that carries on a business of retail sales of poisons. Hence, the proposed revision is purely a technical amendment which seeks to accurately reflect the meaning of an ASP already adopted by the Pharmacy and Poisons Ordinance (PPO). That is, an ASP should be a registered pharmacist, a body corporate or an unincorporated body of persons that carries on a business of retail sales of poisons. It should be noted that according to the existing PPO, if a natural person wants to carry on a business as an ASP, such person must be a registered pharmacist. If we adopted the written suggestion of the Pharmaceutical Society of Hong Kong (PSHK) (LC Paper No. CB(2)1522/13-14(04)) in revising the definition of ASP, a registered pharmacist would no longer be able to carry on the business of an ASP. This would bring about substantive changes to the definition of ASP.

2. On the other hand, the Hong Kong General Chamber of Pharmacy Limited (HKGCPL) indicated in its written submission (LC Paper No. CB(2)1522/13-14 (02)) that the amendments to be made to section 16 of the PPO as proposed by Clause 15 of the Bill will have an impact on the liabilities of the ASP. We must clarify that the proposal of amending "person or body" to "person" in section 16 of PPO, as proposed by Clause 15 of the Bill, is purely a technical amendment. The reason for such amendment is that section 3 of the Interpretation and General Clauses Ordinance (Cap. 1) already stipulates that "person" includes any public body and any body of persons, corporate or unincorporate.

(2) Definition of "pharmaceutical product" and "medicine"

3. As mentioned in item 3 of the Annex to LC paper No. CB(2)1522/13-14(01), we propose to revise the definition of "pharmaceutical product" in accordance with

the definition of the European Commission and to put it on a par with similar definition adopted by countries such as Australia and the United Kingdom, so as to keep Hong Kong's situation aligned with the international practice. The Guidance Notes on Registration of Pharmaceutical Products/Substances currently published by the Department of Health (DH) specifies that a product may fall within the definition of pharmaceutical product under the PPO if it contains a drug substance in its composition, or if it carries "medicinal" claims in its label, leaflet, brochure, wrapper, advertisements and other promotional materials. Therefore, the revised definition of "pharmaceutical product" to include "presented as having properties for treating or preventing disease", as proposed by the Bill, solely aims to codify the current registration requirement.

(3) Repackaging activities

4. In response to the concerns raised by the PSHK about the repackaging of pharmaceutical products by the ASPs (LC Paper No. CB(2)1522/13-14(04)), we have already pointed out in items 2 and 8 of the Annex to LC Paper No. CB(2)1522/13-14(01) that under the existing PPO, the definition of "manufacture" does not include individual dispensing on a prescription or otherwise of any pharmaceutical product (section 2 of the PPO refers). As such, even if regulation 29(2) of the Pharmacy and Poisons Regulations (PPR) is repealed, the ASPs can still carry out the above dispensing activities without the manufacturer's licence. If the repackaging activities mentioned in the letter of the PSHK solely refer to the above dispensing activities, such repackaging activities will not be regarded as manufacture and hence can be carried out without the manufacturer's licence.

(4) Recovery of conviction-related expenses

5. As explained in item 30 of the Annex to LC Paper No. CB(2)1522/13-14(01), in order to implement the recommendations of the Review Committee on Regulation of Pharmaceutical Products in Hong Kong (the Review Committee) to increase the deterrent effect, we propose to empower the court to order recovery from the defendant of all expenses incidental to the taking, examination and analyses of any sample of pharmaceutical products incurred by the Administration in respect of which

the conviction is based. In line with the concept of recovery of costs, the amount to be granted would be compensatory in nature. To reflect this intention more accurately, the Administration will propose Committee stage amendments to rectify that the sum ordered to be paid under this provision is recoverable in the same manner as a "civil debt" (rather than a "fine"). We would like to emphasise that the proposed legislation would only be applicable to convicted traders. Moreover, currently section 11 of the Costs in Criminal Cases Ordinance (Cap. 492) already empowers a magistrate to recover costs, which could include the expenses referred to in this clause, from a convicted defendant. In order to provide a clearer message to the trade and increase the deterrent effect, we propose to add a specific provision for the recovery of investigation-related cost in the PPO. Indeed, there are precedent cases in which specific provisions are made on recovering investigation-related expenses. Examples of such provisions include:

- section 74 of the Public Health and Municipal Services Ordinance (Cap. 132);
- section 184(5) of the Securities and Futures Ordinance (Cap. 571);
- section 43 of the Unsolicited Electronic Messages Ordinance (Cap. 593).

(5) <u>Code of Conduct (COC) and Code of Practice (COP)</u>

6. The Administration's responses to the proposal of empowering the Pharmacy and Poisons Board (PPB) to issue relevant COC and COPs have been set out in item 14 of the Annex to LC Paper No. CB(2)1522/13-14(01). The proposal of empowering the PPB to issue the COC and COPs is similar to section 26 of the Supplementary Medical Professions Ordinance (Cap. 359). In fact, some existing Ordinances, such as section 3 of the Broadcasting Ordinance (Cap. 562) and section 67 of the Insurance Companies Ordinance (Cap. 41), also empower the relevant authorities to issue COPs. The Administration reassured the trade that the PPB has put in place a well-established mechanism for consultation with the trade and relevant stakeholders in drafting, issuing and revising any COPs or COCs. The consultation work carried out by the Administration on the COPs and COC was set out in item 14 of LC Paper No. CB(2)1522/13-14(01).

7. Moreover, we have to clarify that the Bill has proposed to empower the PPB to promulgate the corresponding COC and COPs for registered pharmacists, licensed traders and traders subject to the registration requirement (including manufacturers, wholesalers and retailers). The Bill does not, as indicated in the written submission of the Hong Kong Doctors Union (LC Paper No. CB(2)1560/13-14(01)), propose to empower the PPB to issue the COP for medical practitioners. On the contrary, according to our understanding, the Hong Kong Medical Association already recommended in the Good Dispensing Practice Manual (GDP Manual) issued in 2007 that ordering of drugs should be made in writing. All practising doctors should comply with the GDP Manual.

8. As regards the proposal of requiring the relevant licensed traders of pharmaceutical products to place orders of pharmaceutical products in written form, we have explained to the Panel on Health Services of the Legislative Council (the Panel) as well as representatives of organisations attending the special meeting of the Panel that the requirement aims to implement the recommendation of the Review Committee to develop a complete set of movement records of pharmaceutical products, thus facilitating the tracing of the sources of pharmaceutical products, minimising errors upon delivery and receipt of pharmaceutical products and combating illegal sale of pharmaceutical products. All these strive to provide the best protection for the public. Having considered the regulation of the supply system of pharmaceutical products and the concerns of the pharmaceutical industry, we will implement the requirement by administrative means whereby the PPB will incorporate the requirement into the COPs for the relevant licensed traders of pharmaceutical products. To help the industry adapt to the requirement, the PPB considers that orders of pharmaceutical products placed by electronic means (e.g. emails), fax and mail etc. could be accepted. The requirement will also be implemented by phases in accordance with the risk levels of pharmaceutical products.

(6) <u>The COP for ASPs</u>

9. <u>Page 2 – Introduction</u> : Regarding the remark of the HKGCPL on how to define misconduct in the COP for ASPs, we would like to clarify that according to the

existing section 15 of the PPO, when a complaint is received by the PPB regarding the conduct of a body which is an ASP or an officer or employer of or partner in such body, or when it otherwise appears necessary or desirable to the PPB that the conduct of any such person or body should be inquired into, the PPB may, for the purpose of such inquiry, appoint a Disciplinary Committee. It is explicitly stated in the introduction of the COP for ASPs that non-compliance with the COP may constitute misconduct.

10. Page 8 - Section 1.3c : Some ASPs with long history are permitted to maintain the lockable receptacles for storage of specific poisons outside the dispensing area. These are special approvals granted by the PPB having regard to exceptional circumstances and such special approvals will not be revoked in the COP for ASPs. As the PPB will not issue any new special approvals to permit the lockable receptacles for storage of specific poisons to be maintained outside the dispensing area, we consider that it is not necessary to incorporate such exceptional circumstances into the COP for ASPs.

11. Page 10 - Section 1.4a : We have clearly explained in item 13 of the Annex to LC paper No. CB(2)1522/13-14(01) that all along the retention of the key by registered pharmacist has been one of the requirements stipulated by the PPR. Our legislative proposal does not introduce any change to such requirement, and the revised regulation 19(2)(a) does not carry the phrase "the only key". The proposed change is rather to expand the types of poisons to be kept in such locked receptacle (from First Schedule poisons to all Part I poisons). One of the objectives of regulation 19 of the PPR is to limit the access to the poisons if they are stored in the retail shop, and according to existing section 12 of the PPO, each set of premises of an ASP where poisons are kept for the purpose of retail sale shall be under the personal control of a registered pharmacist. On the other hand, it is the legal obligation of the ASPs under the existing PPO to ensure that all Part I poisons could only be sold by registered pharmacists or in their presence and under their supervision.

12. Page 12 – Section 2c and 2d : Section 13(4)(a) of the existing PPO stipulates that an ASP must be a fit and proper person to conduct the retail sale of

poisons. In enforcing this provision, the PPB will consider the previous conduct of the persons or entities concerned, as well as the assessment on their capability and experience as an ASP conducted by the DH's pharmacist inspectors.

13. Page 15 – Section 3: This section seeks to enforce regulation 5 of the existing PPR, which states that in the supply of pharmaceutical products included in the First Schedule, the ASP shall obtain before the completion of the sale an order in writing signed by the purchaser stating his name and address, trade, business or profession, the name and quantity of the article to be purchased, and the purpose for which it is required.

Food and Health Bureau
20 May 2014