The Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014

Administration's Responses to Issues raised by Pharmacy Groups/Individual Pharmacies

We noted the written submissions made by pharmacy groups/individual pharmacies to the Chairman of the Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014 ("the Bill") (vide LC Paper CB(2)57/14-15(02)), in which objections were raised to the following proposals of the Bill:

(1) amendment to the definition of "authorized sellers of poisons" ("ASPs");

(2) regulation of ASPs; and

(3) recovery of conviction-related expenses.

2. In the LC Paper No. CB(2)1543/13-14(01) issued on 16 May 2014, we set out in detail the consultation work that the Administration has carried out since March 2009 to enhance the regulation of the pharmaceutical industry in Hong Kong. The paper gave a detailed explanation of the proposals and implementation details for enhancing the regulation of pharmaceutical products in Hong Kong, which were formulated after extensive discussions and studies by organisations and individuals from various sectors over the years, with appropriate adjustments in response to the concerns raised by the trade, stakeholders and the public expressed through various channels. As regards the concerns expressed by pharmacy groups/individual pharmacies in the aforementioned submissions, we have already made a number of written or verbal explanations during earlier scrutiny of the Bill by the Bills Committee, setting out in detail the justifications for the relevant proposals of the Bill. The relevant justifications are now set out in the ensuing paragraphs again for reference by the Bills Committee.

Definition of ASPs

[Relevant written response by the Administration:

- *LC Paper No. CB(2)1522/13-14(01) (16 May 2014)*
- *LC Paper No. CB(2)1584/13-14(02) (20 May 2014)*

- *LC Paper No. CB(2)1629/13-14(01)(26 May 2014)*
- *LC Paper No. CB(2)1735/13-14(02)(6 June 2014)]*

3. We propose to revise the definition of ASPs to reflect the usage of the term in the legislation which refers to 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 ASPs adopted by the existing Pharmacy and Poisons Ordinance (Cap. 138) ("PPO"). That is, an ASP should be a registered pharmacist, a body corporate or an unincorporated body of persons who 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. In the meeting with the Hong Kong General Chamber of Pharmacy Ltd. ("HKGCP") on 29 April 2014, the Administration has clarified that the revision is purely a technical amendment and it would not lead to the imposition of extra legal liabilities.

4. Subsequently, the HKGCP raised 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 would have an impact on the liabilities of ASPs. We immediately made clarifications in LC Paper No. CB(2)1584/13-14(02) issued on 20 May 2014 and pointed out clearly that the amendment of "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) ("IGCO") stipulates that "person" includes any public body and any body of persons, corporate or unincorporated.

Regulation of ASPs

[Relevant written response by the Administration:

- *LC Paper No. CB (2)1522/13-14(01) (on 16 May 2014)*
- *LC Paper No. CB (2)1543/13-14(01) (on 16 May 2014)*
- *LC Paper No. CB (2)1584/13-14(02) (on 20 May 2014)*
- *LC Paper No. CB (2)1735/13-14(02) (on 6 June 2014)]*

Code of Conduct ("COC") and Code of Practice ("COP")

5. We have reiterated for many times that in drafting and revising COPs or COCs, the Pharmacy and Poisons Board ("PPB") would conduct consultation and invite representatives from the trade and stakeholders to

raise their opinions. Since January 2012, the PPB has established different working groups and invited representatives of the trade and relevant stakeholders to join the groups with a view to advising on the formulation and amendment of relevant COPs/COCs. In amending the COP for ASPs, the PPB established a working group in January 2012, which was comprised of members from HKGCP, pharmacy groups, individual pharmacies and pharmacist representatives. A public consultation was also conducted from July to December 2012 to collect opinions from registered pharmacists, doctors, dentists, pharmaceutical associations, other stakeholders and consumers. In August and September 2012, the Administration also held consultation sessions with stakeholders and members of the HKGCP. The Administration will analyse the opinions collected and make amendments to the draft COPs/COCs based on those opinions. The whole process is open and transparent. Relevant legislative proposals also stipulate that if a COC or COP is issued/revised, the PPB must, by notice published in the Gazette, identify the code/the revised code or part revised and specify the date on which the code/revision is to take effect.

Application for registration of premises of ASPs

6. In considering the applications for registration of premises of ASP, according to section 13(4) of the existing PPO, the PPB shall not register premises unless it is satisfied, in relation to the retail sale of poisons at such premises, with the four conditions specified in that section, including the condition that ASP is a fit and proper person to conduct the retail sale of poisons. The Bill has made no amendments to those four conditions. The proposed amendment merely specifies more clearly that any person who is disqualified as an ASP by the Disciplinary Committee under section 16(2)(b)(i) of the PPO is not a fit and proper person to conduct the retail sale of poisons during the disqualification period. Accordingly, during the disqualification period, the seller's application for registration of other premises of ASP with the PPB will not be granted under section 13 of the PPO. The amendment aims to clarify the application for registration of premises for retail sale of poisons and to specify the type of person, among others, with whom the PPB would not regard as a fit and proper person to conduct the retail sale of poisons.

Appointment of Disciplinary Committee

7. Currently, section 15 of the PPO prescribes the circumstances in which a Disciplinary Committee may be appointed, such as when a

complaint is received by the PPB regarding the conduct of the person concerned, or when any such person or body is convicted of an offence under the PPO, 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 relevant amendment put forth by the Bill is mainly to expand the circumstances in which a Disciplinary Committee may be appointed by the PPB to inquire into the conduct of registered pharmacists and the ASPs. The additional circumstances include contraventions of COCs or COPs, or conviction of an offence in contravention of certain provisions of the Public Health and Municipal Services Ordinance (Cap. 132) or the Trade Descriptions Ordinance (Cap. 362). In other countries like the United Kingdom, there is also a similar mechanism on the appointment of a disciplinary committee as prescribed in the relevant legislative provisions on the regulation of pharmacies and pharmacists to ensure the conduct of pharmacies and pharmacists for safeguarding public health. The power conferred to the PPB to appoint a Disciplinary Committee under section 15(1) of the existing PPO is also retained in the Bill.

8. We would like to stress that the PPB has a well-established mechanism, which is open and transparent, to appoint a Disciplinary Committee. It will conduct preliminary assessment of a complaint/claim and initiate investigation if necessary. PPB will appoint a Disciplinary Committee to inquire into any misconduct only if it considers that there are sufficient grounds. Registered pharmacists or ASPs convicted of any misconduct will be subject to disciplinary action. The person or body may, within 28 days after receipt of a direction or notice from the PPB, appeal to the Court of First Instance. According to the Bill, the disciplinary action will become effective after the expiry of the period for lodging an appeal under normal circumstances. The PPB may have the right to order a disciplinary award to take immediate effect only if it is for the "protection of public interest". Moreover, a mechanism of suspension period has also been included in the Bill to allow the PPB or its executive committee to suspend (for a maximum period of 3 years) the operation of a disciplinary award according to individual circumstances, resulting in a more comprehensive and flexible disciplinary mechanism.

Listed sellers of poisons

9. Clause 20 of the Bill proposes to add section 25(2A) after section 25(2) of the PPO to provide that the PPB may impose any conditions subject to which a person's name is entered on the list of listed sellers of poisons. The PPB and its executive committees have already been empowered under the existing IGCO to impose/vary licensing or

registration conditions and the relevant proposed amendment merely aims to expressively spell out such power in the PPO.

Separation of prescribing from dispensing of drugs

10. As the separation of prescribing from dispensing of drugs could have far-reaching implications on, among others, the current role of doctors, manpower demand for pharmacists and medical expenditure of the public, and may involve a major change of patient behaviour, the matter would require a thorough discussion by the community as a whole. We consider that any changes to be introduced should be conducive to the cooperation between doctors and pharmacists and the well-being of patients should prevail. A consensus should be reached by members of the community before any major changes are made. We will continue to listen to the views of various stakeholders.

Recovery of conviction-related expenses

[Relevant written response by the Administration:

- *LC Paper No. CB(2)1522/13-14(01)(16 May 2014)*
- *LC Paper No. CB(2)1584/13-14(02) (20 May 2014)]*

11. We have already provided detailed explanation in the written documents submitted to the Bills Committee earlier. The Bill proposes to add a specific provision for the recovery of investigation-related cost in the PPO in order to implement the recommendations of the Review Committee on Regulation of Pharmaceutical Products in Hong Kong to increase the deterrent effect. In fact, section 11 of Costs in Criminal Cases Ordinance (Cap. 492) currently empowers a magistrate to recover costs, which could include the expenses that the Bill proposes to recover, from a convicted defendant. In order to provide a clearer message to the trade and increase the deterrent effect, the Bill proposes to add provisions in the PPO to specify clearly that the Court has already been empowered 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 onwhich the conviction is based. In line with the concept on recovery of costs, the amount to be granted would be compensatory in nature. To reflect the correct intention, 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 provisions for the recovery of cost would only be applicable to convicted traders. 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).

Food and Health Bureau
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