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

Administration's response to issues raised by deputations and individuals

We noted the comments raised by deputations/individuals regarding the Pharmacy and Poisons (Amendment) Bill 2014 ("the Bill") at the meeting on 20 May 2014. Their views can be broadly summarized as follows:

(a) Requested to establish a separate statutory body to take over the existing function of the Pharmacy and Poisons Board ("the Board") for regulating registered pharmacists;

(b) Requested to include more representatives from the industry as members of the Board, so that the Codes of Practice ("COPs")/ Code of Conduct ("COC") issued by the Board for various licensed and listed traders as well as registered pharmacists will be more representative;

(c) Expressed concerns towards the proposal which allows a person, who is not a registered pharmacist, to become an authorized person if he/she holds a qualification awarded on completion of a course recognized by the Board;

(d) Expressed concerns towards the proposed amendments to the definition of "authorized seller of poisons";

(e) Expressed concern towards the proposed amendments to the definition of "pharmaceutical product" and "medicine";

(f) Opposed to the proposal of extending the validity of clinical trial certificates and medicinal test certificates from two years to five years; and

(g) Expressed concerns towards the proposed requirement of placing orders of pharmaceutical products in written form.

2. In the **LC Paper No. CB(2)1543/13-14(01)** issued on 16 May 2014, we have set out in detail the consultation work carried out by the

Administration for enhancing the regulation of the pharmaceutical industry in Hong Kong since March 2009. The said paper has elaborated on 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 for the majority of the views expressed by the deputations/individuals at the meeting on 20 May 2014, we have also in earlier time made a detailed written response. In order to facilitate the deliberation of the Bills Committee on the Pharmacy and Poisons (Amendment) Bill 2014 ("the Bills Committee"), the key points of relevant written responses and follow-up work are set out as below.

To establish a separate statutory body for regulating registered pharmacists

[Relevant written response by the Administration:

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

3. In view of the proposal raised by some deputations/individuals about establishing a separate statutory body to take over the existing function of the Board in terms of regulating registered pharmacists, we wrote to the Chairman of the Bills Committee on 26 May 2014 (**LC Paper No. CB(2)1629/13-14(01)**) to point out that the request would be followed up by the Pharmacists Sub-group under the Steering Committee on Strategic Review on Healthcare Manpower Planning and Professional Development ("Steering Committee"). The Sub-group will take into account the results of the consultancy study undertaken by the Chinese University of Hong Kong on the long term professional development of healthcare professionals, and discuss the subject before the end of this year.

4. We wish to reiterate that the main purpose of the Bill is to implement some of the recommendations put forth by the Review Committee on the Regulation of Pharmaceutical Products in Hong Kong ("Review Committee") for enhancing the drug safety and safeguarding

public health in Hong Kong. The current Bill will not only enhance the regulation of various aspects in the supply chain of pharmaceutical products, but also facilitate the research and development as well as registration of pharmaceutical products. All these are beneficial to the development of the pharmaceutical industry as a whole as well as the patient groups who can have more choices of pharmaceutical products in good quality. Since the establishment of a separate regulatory body for registered pharmacists is not one of the purposes of the Bill, it therefore should not be a consideration to delay the implementation of the Bill. We consider it more appropriate for the Pharmacists Sub-group under the Steering Committee to follow up with the issue of establishing a separate statutory body to regulate registered pharmacists.

Codes of Practice (COPs) / Code of Conduct (COC)

[Relevant written responses by the Administration:

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

5. Deputations/individuals have generally accepted the proposal of the Board to issue COPs/COC for various licensed traders, traders subject to registration requirement and registered pharmacists. However, some deputations/individuals are of the view that the representation of the membership of the Board is inadequate and more trade representatives should be recruited, and that the Board should be empowered to issue COPs/COC only after it has sufficient representatives from the trade. We wish to clarify that in order to fulfill its statutory duties to regulate the pharmaceutical industry, the Board must maintain its independence. At the same time, in order to ensure the effectiveness of its monitoring work in various aspects, the existing eleven members of the Board already include two members holding qualifications in pharmacology, each of whom is teaching at and nominated respectively by the University of Hong Kong and the Chinese University of Hong Kong. Besides, the membership of the Board also includes three registered pharmacists nominated by the industry.

6. As pointed out in Item 14 of the Annex to the **LC Paper No. CB(2)1522/13-14(01)** issued on 16 May 2014, and the **LC Paper No. CB(2)1584/13-14(02)** issued on 20 May 2014, the proposal to empower the Board to issue COPs/COC is similar to section 26 of the Supplementary Medical Professions Ordinance (Cap. 359). As a matter of fact, some existing Ordinances also empower relevant authorities to issue COPs, such as section 3 of the Broadcasting Ordinance (Cap. 562) and section 67 of the Insurance Companies Ordinance (Cap. 41).

7. On the other hand, we have also reiterated on several occasions that the Board has carried out sufficient consultation with the trade when revising/formulating relevant COPs/COC. In **LC Paper No. CB(2)1543/13-14(01)** issued on 16 May 2014, we have listed out in detail the consultation work carried out by the Board and the participation of individual organisations/associations, including the memberships of the working groups on various COPs/COC, and the list of organisations/associations which have participated in relevant consultation meetings, public consultation and briefing sessions. Attending/participating parties included 40 organisations/enterprises from different sectors, all authorized sellers of poisons, all listed sellers of poisons, all licensed wholesalers of poisons and importers/exporters of pharmaceutical products as well as all licensed manufacturers. The above demonstrates that the Board has put in place a well-established mechanism to provide the trade and relevant stakeholders with various channels to participate in formulating, revising and issuing COPs/COC and to express their views on such codes.

<u>Qualification of Authorized Persons (APs)</u>

[Relevant written response by the Administration:

- *LC Paper No. CB(2)1584/13-14(01) (19 May 2014)]*

8. We have clarified in the **LC Paper No. CB(2)1584/13-14(01) i**ssued on 19 May 2014 that the new regulations 30A to 30F added to the Pharmacy and Poisons Regulations (Cap 138A) ("the Regulations") as proposed by the Bill specify that a licensed manufacturer is required to employ at least one AP to ensure and certify that each and every batch of pharmaceutical products manufactured by the manufacturer is in

compliance with the Good Manufacturing Practice (GMP) Guide, registered particulars and requirements of relevant legislation. The proposed regulation 30C provides that all applicants, regardless registered pharmacists or persons holding qualifications awarded on completion of the courses recognised by the Pharmacy and Poisons (Manufacturers Licensing) Committee, must have at least 3 years' experience in manufacturing pharmaceutical products in accordance with the GMP Guide.

9. As shown in the proposed regulation 30C, being a registered pharmacist remains to be the major qualification requirement for APs. Given the diversified and complicated nature of drug manufacturing, various scientific considerations are involved in the course of drug manufacturing. In this regard, the qualification requirements for APs also need to be diversified. As such, besides registered pharmacists, the proposed regulation 30C also allows any person who holds a qualification awarded on completion of a course recognised by the Pharmacy and Poisons (Manufacturers Licensing) Committee to act as an AP, which is also a common international practice. For example, Article 53(2) of the Directive 2001/82/EC of the European Union specifies that any person who possesses qualifications in scientific disciplines (for example experimental physics, organic chemistry, microbiology and toxicology) and relevant qualifications can also act as AP.

10. The Department of Health (DH) and the consultant are now drawing up the relevant requirements for APs, including, inter alia, holding recognised university qualifications and qualifications awarded on completion of recognized courses related to drug manufacturing. It is expected that details of the recognition system will be submitted to the Board for consideration and announced to the public within this year. We would like to reiterate that the proposed AP system as introduced by the Bill is made in accordance with one of the recommendations put forth by the Review Committee to upgrade Hong Kong's GMP standards in manufacturing pharmaceutical products. The Review Committee's recommendations have taken into account the study and recommendations on Hong Kong's GMP made by a consultancy study, which was commissioned by the DH and conducted by overseas GMP experts from Australia in May 2009, in the light of the latest practices

adopted by major drug regulatory authorities in the world. The objective of this proposal is to establish a registration and regulatory system for APs to ensure that they are capable of discharging their duties for strengthening the regulation of pharmaceutical profession and raising the standards of drug manufacturing and quality control of local manufacturers.

11.

Definition of Authorized Sellers of Poisons ("ASP")

[Relevant written responses 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)]*

12. As we clarified to Members in our letter to the Chairman of the Bills Committee (**LC Paper No. CB(2)1629/13-14(01)**) issued on 26 May 2014, under the revised definition of ASP as proposed by the Bill, a registered pharmacist who is an employee of an ASP and himself/herself not a holder of an ASP registration would not be liable for breaches of ASP registration conditions committed by the ASP.

13. We wish to reiterate that the amendment to the definition of ASP proposed by the Bill is purely a technical amendment. We have given detailed explanation in Item 1 of the Annex to **LC Paper No. CB(2)1522/13-14(01)** issued on 16 May 2014, and in Paragraphs 1 and 2 in **LC Paper No. CB(2)1584/13-14(02)** issued on 20 May 2014.

Definition of "Pharmaceutical Product" and "Medicine"

[Relevant written responses 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)]*

14. As we pointed out in Item 3 of the Annex to **LC Paper No. CB(2)1522/13-14(01)** issued on 16 May 2014 and Paragraph 3 in **LC Paper No. CB(2)1584/13-14(02)** issued on 20 May 2014, the revised definition of "pharmaceutical product" and "medicine" as proposed by the Bill to include "presented as having properties for treating or preventing disease in human beings or animals" is in line with the current

guidance note on registration of pharmaceutical product published by the DH. The guidance note specifies that a product may fall within the definition of pharmaceutical product under the Pharmacy and Poisons Ordinance (Cap. 138) 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. In other words, the revised definition of "pharmaceutical product" and "medicine" as proposed by the Bill only aims to codify the current registration requirement. After the revision, the definition of "pharmaceutical product" and "medicine" will still cover products which have not proven their efficacy but claim to be able for treating or preventing disease, so as to offer protection for consumers.

The validity of clinical trial certificates and medicinal test certificates

[Relevant written response by the Administration:

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

15. As we explained in Item 25 of the Annex to **LC Paper No. CB(2)1522/13-14(01)** dated 16 May 2014, in view of the Review Committee's concern that the current two-year validity of the clinical trial certificate and medicinal test certificate is often too short for the completion of a clinical trial / medicinal test, the Bill therefore proposes to extend the validity of clinical trial certificate / medicinal test certificate to not more than five years, so that the applicant does not need to apply for a certificate again if a trial/test lasts more than two years. This proposal will also help enhance the capacity of drug research and development in Hong Kong.

The requirement to place drug orders in written form

[Relevant written responses by the Administration:

- *LC Paper No. CB(2)414/13-14(01) (3 December 2013)*
- *LC Paper No. CB(2)541/13-14(01) (16 December 2013)*
- *LC Paper No. CB(2)1522/13-14(01) (16 May 2014)*
- *LC Paper No. CB(2)1584/13-14(02) (20 May 2014)]*

16. We have explained to the Panel on Health Services of the Legislative Council ("the Panel") and the deputations attending the

special meeting of the Panel, as well as in the **LC Paper No. CB(2)414/13-14(01)** issued on 3 December 2013, Paragraphs 2 to 4 in the **LC Paper No. CB(2)541/13-14(01)** issued on 16 December 2013, Item 35 of the Annex to **LC Paper No. CB(2)1522/13-14(01)** issued on 16 May 2014 and **LC Paper No. CB(2)1584/13-14(02)** issued on 20 May 2014, that according to the recommendation by the Review Committee, the purpose of requiring licensed drug traders to place drug orders in written form is to build up a complete set of drug transaction records, thus facilitating the tracing of source of drugs and minimizing errors in the placing/accepting order, delivery and receipt of drugs so as to offer the best protection for the general public. Besides, placing drug orders in written form can also help combat the illegal sale of drugs. For example, when law enforcement officer finds that a retailer commits in sale of illegal drugs, if the retailer has not retained written records of drug orders, he/she can attempt to evade responsibility by claiming that the illegal drugs have been provided by a supplier without his/her knowledge. Having considered the regulation of the drug supply system and the concerns of the industry, we propose to implement the requirement of placing drug orders in written form by administrative means whereby the Board would incorporate the requirement in the COP for the relevant licenced drug traders. To help the industry adapt to the requirement, the Board will accept drug orders by electronic means (e.g. e-mails), fax and mail, etc.. Such requirement will also be implemented by phases according to the risk levels of drugs.

Conclusion

17. The proposals put forth by the Bill will not only enhance the regulation of various aspects in the supply chain of pharmaceutical products, but also facilitate the research and development as well as registration of pharmaceutical products. All these are beneficial to the development of the pharmaceutical industry as a whole as well as the patient groups who can have more choices of pharmaceutical products in good quality. We noted that various organisations, including –

- the Patients' Alliance on Healthcare Reform, which represents patients and concerns about patients' rights;

- the Hong Kong Association of the Pharmaceutical Industry, which is formed by various enterprises engaged in the research and development of drugs ;
- the Hong Kong Pharmaceutical Manufacturers Association, which represents various pharmaceutical manufacturers;
- the Department of Pharmacology and Pharmacy of the University of Hong Kong;
- the Faculty of Medicine of the Chinese University of Hong Kong; and
- the School of Pharmacy of the Chinese University of Hong Kong

have separately written to the Chairman of the Bills Committee recently to show support to the Bill. We therefore hope that the Bills Committee can support the Bill and endorse our legislative proposals.

Food and Health Bureau
6 June 2014