Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014

Major issues of concern raised by the Bills Committee and the Administration's response

Major issues of concern	Response given by the Administration in writing and/or at the meeting	Relevant LC Paper No. of the Administration's response in writing
Proposed amendments under the Pharmacy and Poisons (Amendment) Bill 2014		
(a) The legal liability of a registered pharmacist who was an employee of an authorized seller of poisons ("ASP") under the proposed amended definition of ASP	• The proposed amendment which defined ASP as "a registered pharmacist, body corporate or unincorporated body of persons that is authorized to carry on a business of retail sale of poisons under section 11" was purely a technical amendment. • The existing provisions of the Pharmacy and Poisons Ordinance (Cap. 138) provided that if a natural person wanted to carry on a business as an ASP, such person had to be a registered pharmacist. • Under the revised definition, a registered pharmacist who was an employee of an ASP and not a holder of an ASP registration would not be liable for breaches of the ASP registration conditions committed by that ASP.	• CB(2)1522/13-14(01) ~ item 1 • CB(2)1584/13-14(02) ~ paragraphs 1-2 • CB(2)1629/13-14(01) ~ paragraph 5 • CB(2)1735/13-14(02) ~ paragraphs 12-13
(b) The scope of products that would be covered under the proposed amended definition of pharmaceutical product and medicine	• The aim to amend the definition of pharmaceutical product and medicine to include the limb of "combination of substances presented as having properties for treating or preventing disease in human beings or animals" was	• CB(2)1522/13-14(01) ~ item 3 • CB(2)1584/13-14(02) ~ paragraph 3

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	to codify the current registration requirement set out in the Department of Health's guidance note on registration of pharmaceutical product. • The amendment would make the definition of pharmaceutical product and medicine more closely aligned with the definition of medicinal product adopted by the European Commission and similar definitions adopted by Australia and the United Kingdom.	• CB(2)1735/13-14(02) ~ paragraph 14
(c) The appropriateness to empower the Pharmacy and Poisons Board ("PPB") to issue corresponding codes of practice ("COPs") for traders subject to the registration requirement and licensed traders, and a code of conduct ("COC") for registered pharmacists; and whether PPB was obliged to consult the trade and relevant stakeholders when formulating, revising and issuing any COPs and COC	• The proposal of empowering PPB to issue COPs and COC was similar to the arrangement under other existing ordinances which empowered the relevant authorities to issue COPs. • Since January 2012, PPB had set up different working groups, with trade representatives and stakeholders as members, to provide comments on the revision or formulation of relevant COPs and COC. • Public consultation exercises were conducted to gauge the views from stakeholders on the various draft COPs. A number of briefing sessions had also been organized for the traders. As of 16 May 2014, a total of 213 representatives from ASPs, 27 representatives from the listed sellers of poisons, 204 representatives from the licensed wholesalers of poisons and importers and exporters of pharmaceutical products, and 206 representatives	• CB(2)1522/13-14(01) ~ item 14 • CB(2)1543/13-14(01) ~ paragraphs 6-7 • CB(2)1584/13-14(02) ~ paragraphs 6-13 • CB(2)1735/13-14(02) ~ paragraphs 5-7

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	from the licensed pharmaceutical manufacturers had attended the briefing sessions.	
(d) The appropriateness to allow a non-registered pharmacist to act as an authorized person ("AP") for a licensed manufacturer provided that the person held a qualification awarded on completion of course recognized by the Pharmacy and Poisons (Manufacturers Licensing) Committee and had at least three years' experience in the pharmaceutical product manufacturing or quality control in compliance with the Good Manufacturing Practice Guide ("the GMP Guide")	• According to the proposed new regulation 30A of the Pharmacy and Poisons Regulations (Cap. 138A) ("the Regulations"), a licensed manufacturer had to employ at least one AP to ensure and certify that the pharmaceutical products were manufactured and checked in accordance with the GMP Guide. • Given the diversified and complicated nature of the manufacturing of pharmaceutical products, various scientific considerations were involved in the course of manufacturing. The qualification requirements for APs also needed to be diversified, with being a registered pharmacist remained to be the major requirement. The proposed requirement was in line with international practice, such as the European Union where the holders of manufacturing authorization were required to, among others, comply with the principles and guidelines of good manufacturing practices ("GMP") for medicinal products. • At present, all 24 licensed manufacturers engaged in the preparation of pharmaceutical products, from purchase or acquisition of materials, through processing and packaging, to their completion as finished products for sale or distribution were in compliance with the Hong	• CB(2)1522/13-14(01) ~ items 2 and 4 • CB(2)1584/13-14(01) • CB(2)1735/13-14(02) ~ paragraphs 8-10

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	Kong GMP Guidelines for Pharmaceutical Products. Existing licensees were required to comply with the Guide to GMP for Medicinal Products and its annexes (where applicable) published by the Pharmaceutical Inspection Cooperation Scheme by 2015. • Under the revised definition of "manufacture", secondary packaging activities would also be required to be carried out by a licensed manufacturer who had complied with the relevant GMP requirements.	
(e) Whether the validity of clinical trial certificate and medicinal test certificates should be extended from two years to not more than five years	• The extension of the validity period of clinical trial certificate and medicinal test certificate was proposed in response to the concern of the Review Committee on Regulation of Pharmaceutical Products in Hong Kong that the current two-year validity was often too short for the completion of a clinical trial or medicinal test. Under the proposal, the applicant did not need to apply for a certificate again if a trial or test last more than two years. • The proposal would also help enhancing the capacity of drug research and development in Hong Kong.	• CB(2)1522/13-14(01) ~ item 25 • CB(2)1735/13-14(02) ~ paragraph 15

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(f) The appropriateness 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	• The proposed requirement would only be applicable to convicted traders. • 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 would propose Committee Stage Amendments to rectify that the sum ordered to be paid under the legislative amendment was recoverable in the same manner as a "civil debt" rather than a "fine". • It was estimated that the analytical cost for one exhibit would be around $1,200.	• CB(2)1522/13-14(01) ~ item 30 • CB(2)1584/13-14(02) ~ paragraph 5
Issues not covered in the current legislative exercise		
(a) The implementation of the requirement of placing orders of pharmaceutical products in written form	• The purpose of requiring licensed drug traders to place drug orders in written form, which would be set out in the corresponding COPs for the drug traders, was 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 provide the best protection to the public. It should also be noted that verbal order was prone to errors, as many drug names were similar and misunderstanding would easily arise.	• CB(2)1522/13-14(01) ~ item 35 • CB(2)1584/13-14(02) ~ paragraph 8 • CB(2)1735/13-14(02) ~ paragraph 16

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	• The requirement would also help combat the illegal sale of pharmaceutical products. For example, when law enforcement officer found that a retailer committed in sale of illegal pharmaceutical products, if the retailer had not retained written records of the orders, he/she could attempt to evade responsibility by claiming that the illegal pharmaceutical products had been provided by a supplier without his/her knowledge. • The proposal was welcomed by the manufacturers of pharmaceutical products as any products returned due to errors in delivery had to be destroyed. Many of them had already designed standard procurement forms for use by their clients in order to save their efforts. • At present, ASPs could only supply the poisons listed in the First Schedule to the Regulations by way of wholesale dealing to a purchaser for the purpose of their trade, business or profession if a written order signed by the purchaser was obtained before the completion of the sale. It was proposed that in future, the supply of poisons listed in Part I of the Poisons List Regulations (Cap. 138B) (which would be merged in the Regulations under the current legislative proposal) would also be subject to the same requirement. In addition, the acquisition of controlled medicines by ASPs from manufacturers, wholesalers or other retailers had to be by way of a written order.	

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	• The written order practice was already recommended in the Good Dispensing Practice Manual issued by the Hong Kong Medical Association. • To help the industry adapted to the requirement, PPB considered that drug orders placed by electronic means, fax and mail could be accepted. The traders had to retain the written order for each transaction in either electronic or paper mode. The requirement would also be implemented by phases in accordance with the risk levels of pharmaceutical products.	
(b) Whether the Administration would review the composition of PPB and include more representatives from the industry as members of PPB	• The existing eleven members of PPB already included two members holding qualifications in pharmacology, each of whom was teaching at and nominated by The University of Hong Kong and The Chinese University of Hong Kong, as well as three registered pharmacists nominated by the industry. • The current composition of PPB was effective in delivering its various statutory functions. The Administration would keep in view the development of the pharmaceutical industry and, if necessary, consider if it merited a review on the composition of PPB in future.	• CB(2)1522/13-14(01) ~ item 31 • CB(2)1735/13-14(02) ~ paragraphs 5

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(c) Whether a separate statutory body would be established to take over the existing function of PPB for regulating registered pharmacists	• The Pharmacists Sub-group under the Steering Committee on the Strategic Review on Healthcare Manpower Planning and Professional Development would discuss the regulatory framework for registered pharmacists before the end of 2014 taking into account the results of the consultancy undertaken by the Chinese University of Hong Kong on the long term professional development of healthcare professionals.	• CB(2)1629/13-14(01) • CB(2)1735/13-14(02) ~ paragraphs 3-4

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