HONG KONG PHARMACISTS UNION

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Pharmacy and Poisons (Amendment) Bill 2014 Committee
Legislative Council, Hong Kong
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Dear President Prof Lee, Honorable Legco Members, Dr Ko,

Submission by Hong Kong Pharmacists Union on Pharmacy and Poisons (Amendment) Bill 2014

On behalf of the Hong Kong Pharmacists Union, we would like to request that the Pharmacy and Poisons Amendment Bill 2014 is withdrawn for further discussion and agreement with stakeholders:

We and many of our healthcare partners have concerns on the following issues which would require further time for discussions between the government and stakeholders:

(I) Authorized Person at the local drug manufacturers

1. Why is the proposed Bill relaxing the current requirement to mandate that a registered pharmacist MUST be the Authorized Person to ensure for the quality of the drugs produced by local drug manufacturers that hold a Good Manufacturing Practice (GMP) Certificate?

2. Why was it necessary to install the requirement that a Registered Pharmacist must be the Authorized Person when GMP was introduced to Hong Kong drug manufacturers since a decade ago?

3. What has changed in the local drug manufacturing environment to warrant this important change in key personnel of drug manufacturers?

4. Why are requirements to strengthen professionalism and regulation of local drug manufacturers in requiring more experienced pharmacists as key personnel not being increased despite the fact that a drug quality incident involving fungal contaminated medicines may have killed 8 hospital patients in 2009 in Hong Kong?

5. Why is the government following the European PIC/S standard of not requiring registered pharmacists as AP when NO local manufacturers have been able to achieve all the standards required for PIC/S?

6. Why is the government just following one element of PIC/S and not following all standards of PIC/S?

7. Does the government realize that the PIC/S standard can only assure for quality of drug ONLY when it is followed in total as a complete Quality Assurance system and will fall apart and fail to achieve its purpose if it is followed in fragments?

(II) Code of Practice

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1. Why is the Pharmacy and Poisons Board not being re-organized as promised and agreed by the Regulatory Review Committee at the last meeting before changing law to give the Board a new power to issue Codes of Practice?

2. How can the Pharmacy and Poisons Board be capable to issue and revise from time to time the Code of Practice if the minority or no representatives from pharmacy profession is on the Board?

3. What are the Checks and Balance system for the decisions of the Board?

4. How can the conflict of interests of the regulator be balanced if the government led Pharmacy and Poisons Board be both the issuer of the Codes and also the law enforcement at the same time?

5. Why can't the Board adopt and make reference to the Codes of Practice that is issued by the pharmacy and pharmaceutical profession associations themselves rather than take over the control of the professional practice which the government has no practical experience to do?

(III) Revise ASP Definition

1. How can the law enforcement agencies differentiate the first Registered Pharmacist from the second Registered Pharmacist that appears in the definition?

2. For what reason is the ASP definition being changed to be a person instead of the Business as in the original intent of the law and in the existing definition?

3. If the ASP already has a specific person called PIC (Person in charge) to take full responsibility of the ASP business then why does the ASP need to be a person?

4. If the law has inconsistency in the role of the ASP, then why can't other parts of the law be revised for ASP to be a business

(IV) Revised Pharmaceutical Product definition

Why is the definition of the Pharmaceutical Product so unclear to need the regulator to provide the answer to pharmacists and other stakeholders to know whether the product need government registration?

First of all, we disagree that the Food and Health Bureau has stealthily changed the definition of the Pharmaceutical Product (PP) in the amendment bill. The Review Committee did not recommend changing the definition of PP. The Bureau has sneakily changed the definition of PP in the amendment bill without consultation with stakeholder.

Further, the revised definition of the PP is very ambiguous. The revised definition has used a subjective and unclear term *presented as*. What is the definition of *presented as*? Who is going to define what is *presented as*? Is there an international guideline to help health professional to judge

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what is *presented as* a pharmaceutical product? Using this ambiguous term is a regressive movement for pharmaceutical industry and this definition is not an international practice.

On the other hand, the current definition of pharmaceutical product is clear. Currently, health profession judge whether or not a product is a *pharmaceutical product* is well-defined and objective. They based on the composition and the nature of the claims of the product. The existing definition is clear and objective.

Moreover, using this ambiguous term is not an international custom. International countries including China, America, Canada, New Zealand and more do not use the ambiguous wording *presented as*. Although some EU countries use *presented as* wording, however, their pharmaceutical product registration requirements and channels are different to Hong Kong. Firstly, they allow vitamins, herbal extract i.e. Gingko and food supplement to register. Secondly, these non-medical products may register through simplified registration scheme to shorten the registration duration. It is imprudent to copy the definition of pharmaceutical product from EU without considering the local situation in Hong Kong.

(V) Issues about the law amendment process

1. Why was the feedback given to the government briefing session on the Bill for Pharmacists on 10 April 2014 about the concerns mentioned above not being responded to?

2. Why is a qualified legal person not able to be provided by the Drug Office to meet with the Legal Advisor of the HK Pharmacists Union in June 2014 despite complaints had been repeatedly raised that the representatives of the Drug Office are not able to answer our questions about legal implications of the law amendments?

3. Why are members of the Government misrepresenting the views of the HK Pharmacists Union and other stakeholders that our objections to the law amendment is merely an attempt to fight for Separation of Prescribing and Dispensing without any facts and evidence that the allegation is the truth?

4. Why is the government not placing public interests as first priority and has been pushing forward the interests of wealthy drug manufacturers?

5. Was there any form of disclosed or undisclosed trade offs between the government and the commercial entities in the law amendment process?

6. Why are there so many new amendments above an beyond the original 16 amendments of the 75 recommendations of the Review Committee being out forth to the LegCo for approval and claiming that the whole Bill is only for the 16 recommendations of the Review Committee?

7. Why is the government rushing the whole amendment process without having enough time to agree the contents with key stakeholders?

8. Why is the government claiming to have consulted stakeholders on all the issues when they have only consulted on some or on entirely different issues?

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We believe the above mentioned set of questions need to be answered before the law amendment process is further progressed as the implications of inappropriate pharmacy law change in Hong Kong and in any other country will affect the health and lives of millions of citizens. For the interests of saving time and resources, we believe that the best option is to withdraw the Bill and remove the items in disagreement and which may not have been discussed as part of the Recommendations of the Review Committee and revise the Bill to contain only the amendments that are less debated. Otherwise, the entire Bill will not be able to be approved efficiently. The pharmacy profession around the world is observing the way Hong Kong is conducting the current change in pharmacy law and will make reference to the process and changes accordingly as part of the global development in pharmacy practice. We hope the government can withdraw the Bill so that a more proper and thorough discussion with concerned parties can be duly conducted.

Thank you for your kind attention to this matter.

Sincerely,

Kevin Cheung
Hong Kong Pharmacists Union