供各委員傳閱
Pharmacy and Poisons (Amendment) Bill 2014 Committee
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Dear President Prof. Lee,

Submission by College of Consultant Pharmacist on Pharmacy and Poisons (Amendment) Bill 2014

Replacing the term "Poison 毒 藥".

We suggest using more positive term to replace the wording "Poison 毒 藥". The Food and Health Bureau suggested to replace the wording "Poison 毒 藥", as required to be labeled on pharmaceutical products classified as poisons, with other terms to alleviate the unnecessary concern of consumers that the products might be harmful and unsuitable for use or consumption. The revised terms are *Prescription Dru Drug 處方藥物 and Drugs under Supervised Sales 監督售賣藥物*. However, these terms may cause confusion to general public. Firstly, the term *Drug* is widely used in advertising for prohibition use of illicit substances. Therefore, in order to prevention confusion, we suggested to use the term medicine, i.e. Prescription Only Medicine, this term is more clear, positive and this term is an international convention. Secondly, the term *Drugs under Supervised Sales* is ambiguous, which does not state under whose supervision. We suggest using the term *Pharmacist Only Medicine*, which clearly states that the medicine need to sell under Pharmacist's supervision and this term is an international convention. In summary, we suggest using clear and positive wording (Prescription Only Medicine and Pharmacist Only Medicine) to replace the wording "Poison 毒 藥".

Authorized Person at the local drug manufacturers

First of all, we disagree that the Food and Health Bureau has sneakily changed the requirement of the Authorized Person (AP) in the amendment bill. The Review Committee did not recommend non-registered pharmacist to be an Authorized Person in the report. The committee did recommended to strengthen the experience requirement for APs, the heads of production and quality control. The report recommended tightening up the qualification of the Authorized Person but not relaxing it.

Further, this change is contradicted to the requirement from the Review Committee. The Review Committee has recommended upgrading of Hong Kong's GMP licensing standards, including more stringent qualification requirements for the position of the authorized person who oversees the entire drug manufacturing process. Allowing non-registered pharmacist to assume the AP position is relaxing the requirement and not upgrading. Hong Kong's manufacturers are not in par with international manufacturing standard. The report has already recorded that our manufacturers are only adopting the GMP standard promulgated by the World Health Organization in 1995. Even now in 2014, the local manufacturers are not reached the Pharmaceutical Inspection Cooperation Scheme, i.e. the PIC/S standard. Therefore, in the substandard environment we need more stringent qualification requirements for the Authorized Person. Allowing non-registered pharmacist to assume the AP position is contradicted to the recommendation from the Review Committee.

Furthermore, the Bureau did not provide enough background and context about local manufacturers. The local pharmaceutical product manufacturers most are far deviated from international manufacturing practice. Firstly, most factories are located in industrial building instead of a stand-alone building. Secondly, each production line produces multiple products rather than produce single medicine at one plant or per line production line. You may imagine a chocolate factory producing different chocolate products (such as with and without peanut chocolate) in the same plant and there will be cross contamination within the plant. Thirdly, most local factories do not operate under Grade A or B clean room environment. Acknowledge the local manufacturers' situation is important before relaxing the AP's requirement. We urge the Bureau to provide more information about local manufacturers' operation environment and their products' quality compare with other EU companies.

Moreover, we agree the recommendations number 6 and 10 of the Review Committee on regulation of Pharmaceutical Products in Hong Kong which require legislative amendments. We agree to maintain an Authorized Person register and remove any AP from the register should the AP be found incompetent to perform the role of an AP. We also agree to introduce a code of practice to govern the conducts of the manufacturers and Aps. We disagree to allow non-registered pharmacist be an AP in Hong Kong, at least not at this moment while the local manufacturing has not reach the PIC/S' standards.

Revised Pharmaceutical Product definition

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 ambiguous. The amended definition has used a subjective and vague 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 what is *presented as* a pharmaceutical product? Using this unclear term is a regressive change 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 to judge whether a product is a pharmaceutical product. The existing definition is clear and objective. For example, as shown in appendix 1, there are two of food products and under current law they do not need to register as pharmaceutical products. However, according to the revised pharmaceutical product definition, it is not clear whether these product need registration?

Moreover, this amended definition 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.

Regulatory Impact Assessment (RIA)

The Regulatory Impact Assessment Report (RIAR) has never disclosed to stakeholder. Upon completion of discussion of the Review committee on regulation on pharmaceutical products in Hong Kong in 2009, with their 16 recommendations to be implemented via legislation, the administration commissioned a consultant (IBM) to conduct a Regulatory Impact Assessment. Many stakeholders provided their options to the consultant and the Bureau has mentioned the RIA many times. Some of our members were there and reported not so many neither frontline pharmacists nor medical professionals agreed to the to-be imposed recommendations because they contrast with the frontline operations which were originally designed to benefit patient drug safety.

However, the administration has never disclosed the RIA and there is no access for this document for stakeholders. The RIA assesses the positive and negative effects of proposed and existing regulations and non-regulatory alternative. The report provides important finding and recommendation. We urge the Bureau to disclose this important document.

If not for patients' drug safety sake, zero amendment should be carried out by the Government unless this only holy motive behind every law drafting in an open and just society is made clear.

Thank you for your kind attention.

Yours sincerely,

TAM Po Chun Patrick
Member
College of Consultant Pharmacist

Appendix 1