LC Paper No. CB(2)1757/13-14(02)

For Bill Committee Honourable Members circulation Pharmacy and Poisons (Amendment) Bill 2014 Committee Legislative Council, Hong Kong

Dear President Prof. LEE,

Re: Submission from Alliance of Safe and Quality Use of Medicines 20 May 2014.

Thank you Mr Chairman. Honourable Members.

We have two major issues with the Amendment Bill.

First, letting a non-pharmacist person, as proposed by the Government, to become an authorized person in the manufacturing process of pharmaceutical products will gravely compromise the safety of patients.

The government says we should keep up with foreign countries like EU. We think the Government is working the opposite.

Pharmaceutical Manufacturing plants in EU are well developed and fully operates under PIC/S - The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S). Hong Kong strives to keep up with this system – our manufacturing plants are working hard to upgrade from current cGMP system to PIC/S – yet until now we are not yet full gear operates under PIC/S.

As the profession agrees that PIC/S is higher standard than the current cGMP, and we have not yet achieved this system -- no matter logical wise or professional wise -- any loosen control should never be implemented before improvement of the system. Overlooking the reality would bring unnecessary harm to this life-and-death profession.

We believe that an authorized person of a pharmaceutical manufacturing facility should be a registered pharmacist with the appropriate experience. In the designation of the Pharmacy program, it has been taken through consideration that a pharmacist-to-be would be well equipped with all sort of knowledge that one would be equipped with hard and soft skills, as a healthcare professional, to safeguard patients' safety, no matter what one would do in the pharmacy sector, including pharmaceutical manufacturing position, when one graduates.

The Pharmacy program is therefore an integration of Pharmacodynamics, Pharmacokinetics, Biochemistry, Microbiology, Medicinal Chemistry, Dosage Formulation Science, Pharmacology and so on – such program is diverse, provides complete coverage and good preparation for one to take up the position as gatekeeper for release of pharmaceutical products to the community.

This role is not merely a technical position, this role requires a person whom really cares the whole process from drug design to drug reaching the hospital and taken by patients – this is a mission. And to ensure patients' drug safety is Pharmacists' mission.

We are totally against the Government's idea of allowing a non-pharmacist person, who merely needs some experience and to take a short course in manufacturing as a requirement, to become an authorized person.

It requires Pharmacist to uphold professional standards, not layman.

Second, too much power is being given to the Pharmacy and Poisons Board under the proposed amendment.

We do not agree with the part of amendment which will give the Board new power to issue and subsequently revise the Code of Practice and the Code of Conducts. There is not much voice from frontline pharmacists in the composition of the Board – only three representatives out of eleven are from professional Association – nominated by the Pharmaceutical Society of Hong Kong – the rest come from the Government, or academic sectors. With this imbalanced composition, opinion from frontline pharmacists is easily overheard. Such would be an impeding factor in future policy making and development for the profession.

The Board needs to be reformed and restructured in such a way that it reflects the proper representation of today's stakeholders in the pharmacy profession, only then it will have the capability and legitimacy to carry out such an important task.

Last but not least, we hope that the government could be open and honest with sector at all times so that there would be efficient communication and mutual respect with public or sector at any stage of policy making in future times.

Sincerely, Joseph CHEUNG Alliance of Safe and Quality Use of Medicines