DRUG SAFETY CONSORTIUM

供各委員傳閱

Pharmacy and Poisons (Amendment) Bill 2014 Committee

Legislative Council, Hong Kong

F 2185 7845

E bc_54_13@legco.gov.hk

Dear Dr Ko,

Submission by Drug Safety Consortium on Pharmacy and Poisons (Amendment) Bill 2014

On behalf of the Drug Safety Consortium, comprising of members including doctors, pharmacists, and patients, we would like to express our concerns on the Pharmacy and Poisons Amendment Bill 2014.

1. The validity of the clinical trial certificate should not be extended to 5 years from 2 years. As there is no other mechanism to check that studies are conducted within the context of the CTC application during the entire course of the study, investigators may change the details of the study without notifying the Dept of Health within the study period. At his moment, the investigator will be required to renew the CTC if the study continues for longer than the expiry date of the certificate which gives the regulator a chance to review the details of the study for the interests and safety of patients.
If the expiry period is 5 years, many of the details of the study may be changed without the knowledge o f the regulator.

For example, the AVIHA (Avastin in HA) clinical trial was issued a CTC clinical trial certificate last year by the Department of Health but the trial never commenced. All the important elements of the study is know to have changed including the study design and principle investigator but the trial is able to started with the CTC that was issued until the expiry of the certificate next year. Only upon the need for the investigator to renew the CTC for the AVIHA trial

would the regulator have the opportunity to conduct a review and may find out many important details have been changed. If the period of expiry is extended to 5 years, the regulator would never know that the details of the trial had been changed as the study is likely to be completed on half a decade time.

2. We believe the government should patient safety as the top consideration when considering what types of persons should be the Authorized Person at local manufacturers. We realize that the size, operating systems , and production volumes of world class manufacturers differ vastly with the small medium enterprises (SME) local manufacturers and as such, the types of persons required to assume the key personnel positions including the Authorized Person is also different.
According to the WHO (World Health Organization) recommendations, the key personnel in charge of quality assurance should be licensed pharmacists if the scale of the manufacturer is small to medium size where resources in insufficient to hire many quality assurance staff to oversee production workers which is the case in many countries like HK. It is hardly convincing reason to change the law to relax the requirements for the position of Authorized Person because HK want to follow European Standards when in fact; no local manufacturer has been able to fulfill all the other requirements needed to follow the European Standards of PIC/S as of today. We would conjuncture that the real reason for relaxing the requirements are strictly commercial and would facilitate businessmen to have more options to hire non-professionals to save costs for the Authorized Person position in the long term.

3. We would not support the Pharmacy and Poisons Board to be given new powers to issue Codes of Practices for pharmacists and trade as they do not have the proper capability to perform the role to setting professional standards. For example, the Pharmacy and Poisons Board has recently endorsed a Code of Practice for Authorized sellers of poisons and included a requirement to have drugs to be ordered in writing with no exceptions. We believe the Board is not aware of the technical and practical implications of the requirement and is unable to anticipate the chaotic scenarios that will lead to patients in the community not being able to obtain the necessary drugs on time. We are astonished at the fact the Food and Health Bureau suggests patients to visit the Accident and Emergency Dept if they are not able to purchase drugs on time at the community level as no other government would suggest the public to abuse and misuse the Accident and Emergency Dept just to obtain

medications to treat long term diseases. Therefore, the government officials are not in the best position to set professional practice standards due to their lack of understanding of the needs of front line professional practice.

If the government is unable to negotiate effectively with stakeholders and the public to align views on the future directions of pharmacy law and practice, we would request the government to withdraw the Bill first and discuss again with the profession and the users of the system.

Thank you for your kind attention.

Yours sincerely,

Law Chun Cheong
External Affairs Head
Drug Safety Consortium