23rd May 2014

Prof The Hon Lee Kok Long, Joseph
Chairman, Bills Committee
Pharmacy & Poisons (Amendment) Bill 2014
Legislative Council Complex
1 Legislative Council Road
Central
Hong Kong

Dear Prof Hon Joseph Lee & Members of the Bills Committee,

Re: Pharmacy and Poisons (Amendment) Bill 2014

Asia Regulatory Professional Association (ARPA) is an organization of Healthcare Regulatory Affairs professionals in Asia.

ARPA supports the amendment of the Pharmacy and Poisons (Amendment) Bill 2014 ("the Bill") and has submitted a document to express our views on 12th May 2014.

After the deputation meeting on 20th May 2014, ARPA would like to provide the following information to further support the Bill.

1. Extend the validity of clinical trial certificate from 2 years to 5 years

   At the May 20th deputation meeting, a pharmacist association has expressed concerns on extending the validity of clinical trial certificate as this may pose increased risk of patient safety. This comment is quite misleading. There are international guidelines, for example, Good Clinical Practices (GCP) which provide clear guidance to clinical trial sponsors, investigators and trial subjects regarding their obligations and responsibilities. These guidelines set a very clear governance framework to ensure patients' rights and safety are being carefully looked after whenever they participate in such important and meaningful scientific research activities.

   Besides, in Hong Kong, all certificate holders of clinical trial are required to report any serious and unexpected adverse drug reactions to the Drug Office as well as to submit their study progress report on a yearly basis. If there are any new

safety signals identified from the investigational products, drug companies have to inform and to provide an update of such safety signals to their investigators, ethics committee and the health authority. As such, extending the duration of a clinical trial certificate should not have any direct impact on patient safety. In fact, most developed countries do not impose a valid "shelf-life" on their clinical trial certificates. Once a clinical trial study is granted, its certificate will be valid until the study is completed.

2. Written Orders

Plenty pharmaceutical literatures have documented that a lot of drug errors were resulted due to the problem that some medicines and vaccines have very similar trade names or generic names as well as they may have very similar presentation format.

Untoward incident happened from time to time when wrong medicines were delivered to clinic and subsequently be dispensed to patients because clinic staff has spoken the wrong name and the receiving staff of wholesaler wrongly interpreted the drug name subsequently. On the contrary, written orders are more reliable and more precise. These also allow a permanent record of communications between the two parties. Any profession who puts patient safety first should support the introduction of such good practice in the territory as it can bring additional measures and checking to reduce unnecessary drug errors.

Written orders can also reduce unnecessary drug wastage. In Hong Kong, each day, there are orders that are being wrongly placed to the wholesalers because of poor verbal communications. Medicines and vaccines have very specific storage conditions. Once the medications or vaccines have left the warehouse, they cannot be re-entered into the distribution chain nor be re-used again due to good distribution practice. Wrong orders will be written off and disposed. It is therefore important to capture the name of the medicine or vaccine, its strength and quantity correctly before the delivery. Written orders can allow pharmaceutical wholesaler staff to get ordering information clearly and directly. As a result, the proposal to introduce written orders in the code of practice is a good intention to protect public health and a clear improvement on ordering or distribution practices. It is difficult to understand why professional bodies or individuals do not support the proposal.

3. Code of Practice

ARPA supports any changes in the existing ordinance or regulations that can bring benefits to public and/or improve pharmaceutical products' safety and quality. Introducing Code of Conduct or Code of Practice to manufacturer, wholesaler, retailer and distributor can certainly drive operational excellence and best practices among these key stakeholders in the pharmaceutical industry.

Thank you for your attention.

Yours sincerely,

Chiu Pik Kam
On Behalf of Asia Regulatory Professional Association