**PHARMACY AND POISONS BOARD**
**HONG KONG**
**香港藥劑業及毒藥管理局**

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10 April 2014

Professor Juliana CHAN
Clinical Research Management Office
The Chinese University of Hong Kong
8/F, Lui Che Woo Clinical Sciences Building
Prince of Wales Hospital
Shatin
New Territories

Dear Professor CHAN,

**Applications for Clinical Trial/Medicinal Test Certificate**
**New Application Forms and Guidance Notes**

I write to inform you that the Pharmacy and Poisons Board of Hong Kong (the Board) has recently endorsed the new application forms and guidance notes regarding the applications for Clinical Trial/Medicinal Test Certificate (CTC).

To facilitate the processing of applications for CTC and the adoption of a risk assessment approach, the Board endorsed the following three proposals in late 2012:

(a) adopting the definition of "clinical trial" given in the International Conference on Harmonization Guideline for Good Clinical Practice;

(b) adopting a risk assessment approach, i.e. three-risk-level categorization, similar to that of the United Kingdom in which the medicine used in the trial forms the backing for the risk level of the various categorization; and

(c) introducing a simplified mechanism, i.e. a Listed Scheme, to facilitate the processing of CTC applications for the low risk clinical trials.

Three consultation sessions with the relevant stakeholders on the above-mentioned proposals were conducted from May to July 2013. Besides, the proposals were posted on the website of the Drug Office of the Department of Health (DH) in July 2013. In general, all participating parties supported the proposals which would streamline and facilitate the processing of applications for CTC.

Based on the comments received, the following new application forms and guidance notes were finalized, and subsequently endorsed by the Board at its recent meeting:

(a) application form for a clinical trial submitted under the Listed Scheme (**Annex Ia**);

(b) application form for a clinical trial submitted under the Standard Scheme or for a medicinal test (**Annex Ib**); and

(c) guidance notes on the applications for CTC (**Annex II**).

A set of Frequently Asked Questions (FAQs) (**Annex III**) and a general workflow chart for processing the applications (**Annex IV**) are also attached to facilitate better understanding of the application procedures and related matters.

Please note that **with effect from 1 May 2014**, all applications for CTC should be submitted using the new application forms according to the guidelines as set out in the new guidance notes. The new application forms, guidance notes, FAQs and workflow chart can be downloaded at the following website of the Drug Office of the DH starting from 1 May 2014:

http://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/guidelines_forms/clinicaltrial.html

If you have any enquiries, please feel free to contact Ms Eva FUNG at 2319 8454.

Yours sincerely,

(Miss Maggie CHOW)
Secretary, Pharmacy and Poisons Board