

衛生署藥物辦公室
藥物註冊及進出口管制部
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DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION AND
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本署檔案 OUR REF: DH DO PRIE/7-15/5

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9 February 2015

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, NT

Dear Professor CHAN,

**Re: Legislative Amendments to the Pharmacy and Poisons Ordinance
and Its Subsidiary Legislation - Clinical Trials and Medicinal Tests**

Please be informed that the Pharmacy and Poisons (Amendment) Bill 2014 was passed by the Legislative Council on 21 January 2015 and published in Gazette (Number 5, Volume 19, Legal Supplement No. 1 (No.2)) as the Pharmacy and Poisons (Amendment) Ordinance 2015 ("Amendment Ordinance") on 30 January 2015. All the amendments have come into operation on **6 February 2015** except the labelling requirement for prescription and pharmacy only medicines which shall commence 18 months later.

According to the Amendment Ordinance, the following amendments to the Regulation 36B of the Pharmacy and Poisons Regulation (Cap.138A) on clinical trials and medicinal tests, which have come into operation on 6 February 2015, are highlighted for you and your colleagues attention:-

1. A person must not conduct a clinical trial on human beings/medicinal test on animals, or cause or permit such a trial/test to be conducted, except in accordance with a Clinical Trial/Medicinal Test Certificate

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(CTC) issued to the person. Any person who contravenes the above commits an offence and is liable to a fine at level 2 (currently HK\$5,000);

2. Provision of a sample of the product or substance is no longer required for the application;
3. The Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee (the Committee) may, subject to any conditions it thinks fit to impose, issue a CTC which is valid for a period not exceeding 5 years; and
4. The Committee may vary the condition imposed if it thinks fit to do so, and may also cancel a CTC, suspend it for a period specified by the Committee, or issue a warning letter to the holder of the certificate if it is of the opinion that the holder of the certificate has contravened a condition of the certificate or it considers it to be in the public interest to do so.

The updated application form and guidance notes for the CTC are available at the website of the Drug Office at:

http://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/guidelines_for_ms/clinicalTrial.html.

For more details of the Amendment Ordinance, you may refer to the following website of the Government of the Hong Kong Special Administrative Region:

<http://www.gld.gov.hk/egazette/pdf/20151905/es1201519052.pdf>

Should you have any questions, please contact Ms. Arkie LO at 2319 8452.

Yours sincerely,



(W Y CHOW)

for Director of Health