



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

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貴處檔號

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31 March 2026

To: All holders/applicants of Certificate for Clinical Trial/Medicinal Test

Dear Sir/Madam,

**Implementation Plan of the International Council for Harmonisation  
of Technical Requirements for Pharmaceuticals for Human Use (ICH) E6  
Guideline for Good Clinical Practice in Hong Kong**

This letter serves to inform you that the Pharmacy and Poisons Board of Hong Kong (“the Board”) has endorsed the implementation plan for the ICH E6(R3) Guideline for Good Clinical Practice (“ICH Guideline for GCP”) as the Good Clinical Practice (“GCP”) requirements for clinical trials to be conducted in Hong Kong.

In October 2023, the Board officially became an observer of the ICH. In June 2025, the Government announced the timetable for the establishment of the Hong Kong Centre for Medical Products Regulation (“CMPR”) (“the Timetable”)<sup>1</sup>, which sets out steps to prepare for Hong Kong’s accession to the ICH as a regulatory member with the target of submitting application by **Q2 2027**. Implementation of ICH Tier 1 Guidelines, including ICH Guideline for GCP, are required before applying for the accession.

The ICH Guideline for GCP establishes an international standard for the planning, initiating, performing, recording, oversight, evaluation, analysis and reporting activities of clinical trials involving human participants. It outlines the responsibilities of sponsors, investigators, and other stakeholders to protect the rights, safety, and well-being of trial participants, while ensuring the integrity and credibility of clinical trial data. Considering

<sup>1</sup> For details, please refer to [https://www.dh.gov.hk/english/main/main\\_pocmpr/files/cmpr\\_infobro202506\\_e\\_tc.pdf](https://www.dh.gov.hk/english/main/main_pocmpr/files/cmpr_infobro202506_e_tc.pdf)

the local situation and requirements, the implementation plan for ICH Guideline for GCP is summarised as below.

**(1) Formal Implementation and Communication**

- With effect from 30 June 2026, the Board will implement the ICH Guideline for GCP in Hong Kong that provides principles and guidelines in respect of the conduct clinical trials. The ICH Guideline for GCP will be made publicly accessible on the website of the Board and Drug Office as a document link.
- Guidance Notes on the Application for Certificate for Clinical Trial/Medicinal Test will be updated to reflect the new GCP requirements.
- Applicants of any new applications of Certificate for Clinical Trial (“CCT”) submitted on and after the implementation date (30 June 2026) would be required to declare the respective clinical trial follow the ICH Guideline for GCP, and whether the clinical trial under application is intended to be submitted to regulatory authorities to support marketing authorisation.

**(2) Enhancement of electronic Clinical Trial System (“e-CTS”) (by Q2 of 2026)**

- e-CTS will be updated for applicant to declare whether the interventional clinical trial is intended to be submitted to regulatory authorities to support marketing authorisation (i.e. to support registration of the investigational drug, either locally or overseas), and corresponding conditions (as stipulated in (3)) below would be imposed to the CCT issued by the Board based on the declaration of the applicant.

**(3) Imposing New Conditions to all Newly Issued CCT: (by Q4 of 2026)**

- (a) For interventional clinical trials of investigational products that are **intended** to be submitted to regulatory authorities to support marketing authorisation:
- The clinical trial is required to be conducted in full compliance with ICH Guideline for GCP; and
  - Certificate holders should allow and facilitate GCP inspection to be conducted by inspectors of the Drug Office at all relevant premises related to the trial.
- (b) For interventional clinical trials of investigational products that are declared **not intended** to be submitted to regulatory authorities:
- The conduct of the clinical trial should adhere to the principles as stated in ICH Guideline for GCP.

Please refer to the updated Guidance Notes on the Application for Certificate for Clinical Trial/Medicinal Test and Guidance for Industry – Implementing ICH Guideline

for Good Clinical Practice E6(R3) in Hong Kong that would be released on the implementation date 30 June 2026 for details of implementation of ICH Guideline for GCP in Hong Kong.

If you have any queries on the above, please contact the Drug Office at tel. no. 3974 4180.

Yours faithfully,



(P. Y. TSE)

Secretary, Pharmacy and Poisons  
(Certification of Clinical Trial/  
Medicinal Test) Committee

c.c. DH DO PRIE/7-15/5