



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

Your Ref. :
貴處檔號

Our Ref. : DH DO PRIE/1-55/1
本局檔號

Tel. No. : 3974 4175
電 話

Fax No. : 2803 4962
圖文傳真

Drug Office
Department of Health
Suites 2002-05, 20/F, AIA Kowloon Tower,
Landmark East, 100 How Ming Street,
Kwun Tong, Kowloon, Hong Kong
香港九龍觀塘巧明街100號
Landmark East 友邦九龍大樓
20樓2002-05室
衛生署藥物辦公室

31 March 2026

To: Applicants for registration of pharmaceutical products and
certificate holders of registered pharmaceutical products

Dear Sirs/Madams,

**Implementation of the International Council for Harmonisation of
Technical Requirements for Pharmaceuticals for Human Use (ICH)
Q1 Guidelines on Stability**

This letter serves to inform you that the Pharmacy and Poisons Board (“the Board”) has endorsed the implementation of ICH Q1 Guidelines in Hong Kong in the first quarter of 2026.

In June 2025, the Government announced the timetable¹ for the establishment of the Hong Kong Centre for Medical Products Regulation, 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 Q1 Guidelines on Stability, are one of the prerequisites to applying for the accession.

The ICH Q1 Guidelines establish the specific stability data requirements for registration applications concerning new molecular entities (defined as an active pharmaceutical substance that has not been previously approved in Hong Kong) and their associated drug products. This classification also includes new salts, esters, or non-covalent-bond derivatives of an existing drug, which are treated as new entities for stability testing purposes.

¹ For details, please refer to www.dh.gov.hk/english/main/main_pocmpr/files/cmpr_infobro202506_e_tc.pdf

Currently, the ICH Q1 Guidelines on Stability include Q1A-E which are listed below:

- **Q1A(R2)** Stability Testing of New Drug Substances and Products
- **Q1B** Stability Testing: Photostability Testing of New Drug Substances and Products
- **Q1C** Stability Testing for New Dosage Forms
- **Q1D** Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products
- **Q1E** Evaluation of Stability Data

With effect from **31 March 2026**, all initial applications for registration of the following product types must include evidence demonstrating compliance with the stability requirements of the current ICH Q1A-E guidelines:

- products containing new chemical or biological entity (NCE);
- products containing a new salt, ester or non-covalent-bond derivative of approved drug substance;
- products with a new dosage form.

Applications that do not meet this requirement will not be accepted for evaluation. For the updated Guidance Notes and the ICH Q1A-E Guidelines, please visit the website of the Board (www.ppbhk.org.hk/eng).

If you have any queries on the above, please contact the Drug Office at tel. no. 3974 4175.

Yours faithfully,



(Y. F. YEUNG)

Secretary,
Pharmacy and Poisons (Registration of
Pharmaceutical Products and Substances)
Committee