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

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16 September 2026

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

Dear Sirs or Madams,

Implementation of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Q7 Guideline on Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients

This letter serves to remind you that, as a registration requirement, pharmaceutical products and substances, including active pharmaceutical ingredients ("APIs"), manufactured in or outside Hong Kong are required to comply with the applicable Good Manufacturing Practice ("GMP") standards of the Pharmaceutical Inspection Co-operation Scheme ("PIC/S"). The Pharmacy and Poisons Board ("the Board") considers that compliance with Part II of the PIC/S GMP Guide, which applies to the manufacture of APIs, constitutes implementation in Hong Kong of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ("ICH") ***Q7 Guideline: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients,*** within the applicable scope of that Guideline.

The Board has adopted the PIC/S GMP Guide since 1 October 2015, and gained accession as PIC/S Participating Authority since 1 January 2016. The PIC/S GMP Guide (current version adopted being PE 009-17) includes Part II, which sets out GMP requirements for APIs used as starting materials. As part of the registration requirements, applicants are required to provide appropriate evidence that the relevant manufacturer(s) comply with the applicable PIC/S GMP standards.

The ICH Q7 Guideline provides GMP guidance for the manufacture of APIs. It was adopted by PIC/S in 2001 and subsequently integrated into the PIC/S GMP Guide as Part II in 2007. As part of the implementation of ICH Tier 1 Guidelines, the Board considered the matter at its meeting held on 13 March 2026 and noted that the Board's adoption and implementation of the PIC/S GMP Guide, including Part II, since 1 October 2015 constitutes implementation of ICH Q7 in Hong Kong, within the applicable scope of ICH Q7. Overall, Part II of the PIC/S GMP Guide has a broader stated scope than that of ICH Q7, whilst the technical contents and quality requirements for APIs set out therein are aligned. Information on the relevant requirements and direct links to the applicable guidelines, including ICH Q7, are available on the Board's website. The ICH Q7 Guideline is also available on the ICH website at www.ich.org/page/quality-guidelines.

Accordingly, this letter reiterates that for the registration of pharmaceutical products for human use under the Pharmacy and Poisons Ordinance (Cap. 138), compliance with both the applicable substantive GMP requirements for APIs under Part II of the PIC/S GMP Guide as well as ICH Q7 is required.

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