

**Questions and Answers on Pharmaceutical Inspection Co-operation Scheme (PIC/S)  
Good Manufacturing Practice (GMP) Requirements for  
Registration of Imported Pharmaceutical Products  
(Revised as of 6 February 2025)**

**1. What are the arrangements for applications for registration of pharmaceutical products submitted before 1<sup>st</sup> January 2016?**

For all the new applications for registration of pharmaceutical products received before 1<sup>st</sup> January 2016, but have not been submitted with the completed set of documents for processing for registration before 1<sup>st</sup> January 2017, the applicants will be required to provide evidence that the manufacturers comply with the PIC/S GMP standards before the approval of the applications, e.g. certified true copy of the GMP certificate of the manufacturer issued by a PIC/S member authority.

For the list of the PIC/S member authorities, please visit the PIC/S website at:

- <http://www.picscheme.org/en/members>.

**2. What will be the GMP requirements of the manufacturer if I submit a new application for registration of pharmaceutical product or change of registered particulars on or after 1<sup>st</sup> January 2016?**

With effect from 1<sup>st</sup> January 2016, all the new applications for registration of pharmaceutical products or change of registered particulars must include evidence that the manufacturers comply with the PIC/S GMP standards. Otherwise, the applications will not be accepted for evaluation.

**3. How will the new requirements of PIC/S GMP standards affect the registered pharmaceutical products on the market?**

With effect from 1<sup>st</sup> January 2017, all the renewal applications for registration of pharmaceutical products must include evidence that the manufacturers comply with the PIC/S GMP standards. Otherwise, the products will not be renewed for registration.

**4. What are the available options if the manufacturer of the pharmaceutical product applying for new product registration, change of registered particulars or renewal of product registration is not subject to inspection by any PIC/S member authority, e.g. the product is not manufactured in a place in the list of the PIC/S member authorities?**

**Option 1**

The applicant may invite any PIC/S member authority, including the Hong Kong Department of Health (DH) Drug Office GMP inspectorate, to conduct inspection of the manufacturing facilities of the manufacturer outside Hong Kong.

If the applicant decides to invite a PIC/S member authority to conduct the inspection, the applicant should contact the PIC/S member authority direct for the requirements and arrangement.

For the list of the PIC/S member authorities, please visit the PIC/S website at:

- <https://picscheme.org/en/members>

If the applicant decides to invite the DH Drug Office GMP inspectorate to conduct the inspection if the facility has not been inspected by other PIC/S member authority, the applicant will need to complete the “Request Form for Assessment of GMP Compliance for Manufacturer Outside Hong Kong by the Drug Office” and provide the required documents and information as specified in the Request Form

Upon receipt of the above mentioned documents and after review, the DH Drug Office GMP inspectorate will conduct assessment of the GMP status of the manufacturer concerned. They will contact the applicant for any additional documents, and/or to make arrangement to conduct the inspection if deemed applicable. For further assistance on the arrangement for Drug Office GMP inspectorate to conduct inspections outside Hong Kong and the request submission, applicants could contact DH Drug Office Manufacturers Regulatory Unit at 2594 7647.

Note: In light of the potential demand and limited resources for the DH Drug Office GMP inspectorate to conduct GMP assessment (which may include inspection) of manufacturers outside Hong Kong, the DH Drug Office would only arrange inspections only if it will not affect the schedule for inspections of local manufacturers. Certificate holders of registered pharmaceutical products should decide their plans to renew the registration of their products as early as possible. Certificate holders are required to submit the application for GMP assessment of manufacturer outside Hong Kong at least

32 weeks before the expiry date of the product registration.

## **Option 2**

The certificate holder of the registered pharmaceutical product can make an application to the Pharmacy and Poisons Board for approval to change the registered manufacturer of the product to a new manufacturer which is subject to inspection by a PIC/S member authority, e.g. the product will be manufactured in a place in the list of the PIC/S member authorities.

Please refer to the following website for the requirements on the change of registered particulars of a registered pharmaceutical product:

[https://www.ppbhk.org.hk/eng/doc/guidelines\\_forms/copGuide\\_en.pdf](https://www.ppbhk.org.hk/eng/doc/guidelines_forms/copGuide_en.pdf)

### **5. Will there be any cost required to invite DH Drug Office GMP inspectorate to conduct an inspection of the manufacturer outside Hong Kong for GMP assessment?**

Yes. The whole inspection process includes preparation work, on-site inspection, report writing and review. The cost of inspection will depend on a lot of factors including the location of the manufacturer, type of the manufacturing facilities, etc.; and will be calculated on full recovery basis to include all cost relating to the inspection outside Hong Kong such as staff cost, travelling expense on case-by-case basis. The charges are non-refundable.

In general, the estimated cost of inspection per manufacturer within South East Asia will range between HK\$200,000 and HK\$250,000 which may be higher for certain products or manufacturing facilities.

### **6. What will be the GMP requirements for pharmaceutical products of Active Pharmaceutical Ingredients (APIs)?**

Pharmaceutical products of APIs will be subject to the same PIC/S GMP requirements for registration of pharmaceutical products.

Please refer to the above Questions & Answers on arrangement and implementation timeline for new and renewal applications for registration of APIs as pharmaceutical products.

**7. What will be the GMP requirements for veterinary pharmaceutical products?**

DH has considered the situations in different regions and decided that the above PIC/S GMP requirements for registration of pharmaceutical products will not be applicable to veterinary products at this stage.