

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

1. What are the arrangements for applications for registration of pharmaceutical products submitted before 1st January 2016?

For all the new applications for registration of pharmaceutical products received before 1st January 2016, but have not been submitted with the completed set of documents for processing for registration before 1st 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 1st January 2016?

With effect from 1st 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 1st 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 inspectors, to conduct inspection of the manufacturing facilities of the overseas manufacturer.

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 inspectors to conduct the inspection, the applicant will need to provide the following information about the manufacturing facilities and their products:

- the current site master file of the manufacturer,
- history of GMP inspections by other drug regulatory authorities,
- master formula, manufacturing and testing methods of the product, and
- process validation reports of the product.

The above information and supporting documents must be in-line with the PIC/S standards as the prerequisite to conduct overseas inspections by the DH GMP inspectors, and/or to renew the registration of the pharmaceutical products.

Upon receipt of the above mentioned documents and after review, the DH Drug Office GMP inspectors will contact the applicant for any additional information, and/or to make arrangement to conduct the inspection. For further assistance on the arrangement for DH Drug Office GMP inspectors to conduct overseas inspections and the above supporting documents, applicants could contact DH Drug Office Manufacturers Regulatory Unit at 2961 8162.

Note: In light of the potential demand and limited resources for the DH Drug Office GMP inspectors to conduct inspections of overseas 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 overseas inspection 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.drugoffice.gov.hk/eps/do/en/doc/guidelines_forms/copGuide.pdf?v=ro8an

5. Will there be any cost required to invite DH Drug Office GMP inspectors to conduct an overseas inspection of the manufacturer?

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 overseas inspection 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 overseas 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.