European Medicines Agency
Inspections

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EC – Switzerland MRA
Sectoral Annex on GMP medicinal products GMP inspection and batch certification

Update on the operation of the Annex with respect to active pharmaceutical ingredients

Joint Common Statement
Final

Background

The Mutual Recognition Agreement (MRA) between the European Community (EC) and Swiss Confederation, in its Annex on medicinal products GMP inspection and batch certification includes the provision to cover manufacture of active pharmaceuticals. At the time of implementing the Sectoral Annex, only Switzerland had legal requirements for GMP for Active Pharmaceutical Ingredients (API) in place. Following the review of the EC legislation introducing GMP requirements for APIs discussion between EC and Switzerland have taken place to include APIs in the operational phase under the current scope of the MRA.

Requirements for API in the European Community

With new Community legislation, obligations have been established for finished medicinal product manufacturers to use only active substances (active pharmaceutical ingredients), which have been manufactured in accordance with GMP (Article 46 (f) of Directive 2001/83/EC and Article 50 (f) of Directive 2001/82/EC; as amended). To fulfill their obligations, manufacturers of medicinal products are expected to audit their API suppliers. The principles of GMP for APIs are published as Part II of the European Union's GMP Guide, which is based on the international provisions laid down in the ICH Q7 guide for active substances. Regulatory authorities in the EC will carry out inspections of API manufacturers in the EC and in third countries in line with Community legislation and procedures. While there is no harmonised requirement for a manufacturing authorisation of API manufacturers, Community legislation includes specific provisions for inspections. Inspections are carried out by competent authorities at the specific request of the manufacturer or when it considers that there are grounds for suspecting non-compliance with GMP. Member States had to implement these provisions by October 2005.

Requirements for API in Switzerland

The Swiss federal legislation for therapeutic products came into force in January 2002. It took up the former legislation for APIs through its Ordinance on Establishment Licences GMP requirements for APIs based on ICH Q7, the PIC/S and EU Guide for Good Manufacturing Practice for Medicinal Products. The legislation requires licensing for all Swiss manufacturers of medicinal products including manufacturers of APIs. Swiss authorities carry out inspections of API manufacturers located in Switzerland on a routine basis.

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Conclusion

GMP requirements for active substances were deemed to be equivalent in the EC and in Switzerland. Inspections may be requested by the active substance manufacturer or, whenever considered necessary, by the competent authority. Conclusions of such inspections by the relevant inspection services in the EC and Switzerland on their respective territories should be exchanged and mutually recognised. Such an exchange of information may take place at the request of an exporter, importer or the competent authority of the other party. Technical arrangement for the exchange of GMP certificates will be similar to those established for finished medicinal products in line with provisions of Chapter 15 of the Agreement.

In accordance with the general provisions of the Agreement, both EC and Switzerland shall continue to exchange any information necessary for the mutual recognition of inspections and endeavor to proceed towards their approximation.