EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Cooperation between the Pharmaceutical Inspection Co-operation Scheme and the European Medicines Agency

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Cooperation between the Pharmaceutical Inspection Co-operation Scheme and the European Medicines Agency

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) and the European Medicines Agency (the Agency), in particular, the Agency's Compliance and Inspection Sector have agreed to strengthen their cooperation in the field of Good Manufacturing and Distribution Practice (GMDP) in areas of common interest with a view to the sharing of resources and avoidance of duplication of activities. This cooperation does not constitute any legal obligation or financial liability on either side.

The cooperation shall focus on:

Training of inspectors in the field of GMDP

In the field of GMDP, PIC/S and the Agency shall cooperate in the development of training for EU and PIC/S inspectors. This may include participation at each other's training events, providing material for training, providing speakers for training and if possible hosting of training events.

Participation at each other's meeting

A representative of PIC/S may participate at meetings of the GMP/GDP Inspectors Working Group (GMDP IWG). The PIC/S representative shall be appointed by the PIC/S Committee from one of the EEA PIC/S participating authorities and be a regular member of the GMDP IWG. The PIC/S representative is bound by the terms of reference and mandate for this group.

A representative of the Agency may participate at PIC/S Committee meetings in the capacity of PIC/S partner. The Agency's representative is bound by the Rules of Procedure of the PIC/S Committee.

Neither party shall charge the other party for participation at meetings, provided that the meeting takes place at the organisers' headquarters.

Exchange of information

The exchange of information[1] between PIC/S and the Agency may include but is not limited to:

1. All legislation and guidance documents available under the rules and regulations governing medicinal products in the EU in the field of GMDP. This includes GMDP guidance and procedures in the Compilation of Community Procedures; concept papers and guidelines either finalised or released for public consultation.

2. All GMDP guidance documents developed by PIC/S at Committee meetings, Expert Circles and Seminars.

[1] Regulation EC/1049/2001 and the Agency's implementing rules on access to documents (EMEA/MB/203359/2006) apply

3. For specific topics of interest the exchange may include advance drafts of guidance documents providing for the opportunity for early comments or contributions to guidance development and the participation in drafting groups on the development of guidance documents. Participation in drafting groups is subject to the Agency's policy and procedures for handling conflicts of interest for experts participating in the Agency's activities.

4. Timings of public consultation and publication of documents.

5. Information exchanged under this co-operation may include confidential / restricted information exempt from public disclosure which will only be shared according to the procedures and policies of the parties as permitted by their respective laws and regulations. None of the parties will divulge confidential / restricted information, including, but not limited to, trade secret information or personal information, without the consent of the provider of such information.

6. This co-operation also covers confidential / restricted information shared (or received) during (or in-between) official meetings, whether orally or in writing.

Auditing of GMP inspectorates

PIC/S and the Agency shall cooperate in exchanging information in the context of the EEA Joint Audit Programme of GMP inspectorates and the PIC/S Joint Assessment Programme and evaluation of applicants and reassessment of participating authorities. This includes an exchange of auditing schedules with a view to avoid any duplication with international QA activities in the framework of BEMA, MRAs, and WHO Vaccines Programme. To foster mutual acceptance of audit outcomes between the two programmes, the Agency and PIC/S shall endeavour to maintain equivalent auditing tools and programmes and exchange reports upon request by either party subject to the agreement of the authority audited.

Nothing in this agreement should be considered as precluding co-operation in other areas that may arise and mutually agreed.

This cooperation is concluded for a period of two years after which its effectiveness shall be assessed and if positive be renewed tacitly.

Date and signatures:

28 December 2010 Tor Gråberg	
Mr. Tor Gråberg Chairman FOR THE PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME (PIC/S)	Dr. Thomas Lönngren Executive Director FOR THE EUROPEAN MEDICINES AGENCY (EMA)