EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The European Medicines Agency

Pharmaceutical Inspection Convention
Pharmaceutical Inspection Co-operation Scheme

London, 8 May 2012
EMA/352642/2012

Geneva, 8 May 2012
PS/W 2/2012

Addendum No. 1 to the Cooperation between the Pharmaceutical Inspection Co-operation Scheme PIC/S and the European Medicines Agency of 28 December 2010

Harmonisation of PIC/S and GMDP IWG Consultation Procedure

Whereas the Co-operation between the PIC/S and the EMA of 28 December 2010 foresees an exchange of information, a harmonisation of the drafts developed should be achieved prior to and after public consultation in a procedure based manner described in this document.

1. Scope of co-operation

The GMP Guide and related documents should be harmonised between PIC/S and the GMDP IWG (although they need not be identical) to keep the regulatory environment equivalent between the different regions and thus enable a better exchange and use of information concerning the manufacture of medicinal products.

To reach this goal, there should be an effective and co-operative exchange of information, including drafts and proposals, between both parties on all on-going revisions of existing documents or on the adoption of new documents, and this without delay.

A list of documents subject to harmonisation will be established and contain regularly up-dated information on their status.

2. Information on proposals to issue a new GMP document / revision of harmonised GMP documents

A liaison officer appointed by each party should inform regularly the other party about proposals influencing harmonised documents, which were made during a meeting of his party. A short report should be sent via e-mail within 2 weeks after the relevant meeting to PIC/S Secretariat and GMDP IWG Secretariat.

3. Exchange of concept papers

A concept paper should be the first step in the development of a new GMP document or the overall revision of a harmonised GMP document. Proposed / approved concept papers should be shared between the parties prior to publication.

4. Participation in drafting groups

If one party establishes a drafting group for the development of a new document or the overall revision of a harmonised document, the other party should be given the

opportunity to participate in this drafting group. In most cases PIC/S participation is already present in EU drafting groups and this clause is intended to offer the opportunity to non-EEA PIC/S participating authorities to participate in addition.

Participation related expenses will be borne by the participants.

Participation shall be approved by the proposing party (PIC/S Secretariat, GMDP IWG) and participating members of the drafting group should comply with rules for participation (e.g. the individuals concerned must at least fulfil requirements related to confidentiality and absence of conflicts of interest of the other party).

5. Exchange of draft documents

To enable appropriate involvement of the other party in the drafting process drafts of documents should be shared.

Once a draft document, which should be kept harmonised between the parties, is tabled for the meeting of one party and has reached a sufficient level of maturity, it should be shared with the other party without delay. The other party should respect the agreed timeframe for comments which should be no less than 2 months from receipt.

As a minimum, draft documents that should be harmonised should be provided to the other party for comments prior to public consultation so that major document revisions and additional public consultations can be avoided through the timely input of the other party.

6. Public/industry consultation

A harmonised timing for public/industry consultations should be aimed for. Consultations are managed by each party independently. The results of the consultations should be exchanged between the parties as soon as possible in a consolidated form.

7. Preparation of final draft

Any comments concerning the draft documents should be reviewed by the proposing party. All comments should be assessed and decisions (approval or refusal of the proposed change) should be justified.

The proposed final draft should be discussed in relevant meetings of both parties or – if necessary – by written procedures.

8. Approval of final documents

A harmonised date of implementation should be agreed upon, if possible, prior to publication.

9. Maintenance of a list of harmonised GMP related documents

A list of all GMP related documents which are considered by both parties as to be harmonised will be maintained by PIC/S. Any proposed change in this document should be supported by both parties.

Date and signature:

Ms. Helena Baião Chairperson 30 May 2012 FOR THE PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME (PIC/S)	Dr. Guido Rasi Executive Director FOR THE EUROPEAN MEDICINES AGENCY (EMA)