EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 April 2010
EMA/INS/GMP/714068/2009
Compliance and Inspection

Guidance for Rapporteurs of documents developed by the GMP/GDP Inspectors Working Group

Background

According to the mandate of the GMP/GDP Inspectors Working Group, among its tasks is the development and agreement, by consensus, of GMP/GDP related guidelines and high-level procedures on GMP and GDP inspection related activities. Normally the lead for the development of any document is undertaken by a rapporteur appointed from within the Group.

The purpose of this document is to provide guidance on the responsibilities of rapporteurs and applies to the development of the following documents:

- Concept Papers
- New or amended text for the EU GMP or GDP Guide
- New or amended documents forming the Compilation of Community Procedures
- Reflection Papers
- Questions and Answers

The Agency recognises and appreciates that National Competent Authorities are making a significant commitment in terms of resources when undertaking the role of rapporteur, and to a lesser extent when contributing to drafting groups. All Member States are therefore encouraged to share resources by contributing to this work, which is done for the benefit of the Community as a whole.

Appointment of Rapporteurs

All members of the Group are actively encouraged to accept rapporteurships in order to share the Group's workload in a fair way and to promote the active engagement of all National Competent Authorities in the Group's activities. Acceptance of a rapporteurship is on a voluntary basis and is normally agreed during plenary meetings of the Group. The rapporteur is a member of the Group although he may choose to delegate the detailed tasks to a suitable expert within his own National Competent Authority. A member of the Group's secretariat at the European Medicines Agency may act as a rapporteur where this is considered appropriate and agreed by the Group.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8595
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

Responsibilities

Rapporteur

The rapporteur should immediately establish whether the Group wishes to form a drafting group for the activity in question, identify the experts to be involved and inform the Agency of the names and contact details of those experts.

In cases where there is to be an amendment to a chapter or Annex of the EU GMP Guide the rapporteur should review the entire chapter or Annex and seek input from the Group on other changes that might be necessary to maintain the currency of the guidance. The relevant Concept Paper should also request input from other stakeholders on this aspect.

In the case of amendments to, or new texts for inclusion in, the EU GMP Guide a Concept Paper will be necessary. Upon appointment of the rapporteur the European Medicines Agency will provide him with the appropriate guidance for drafting a Concept Paper.

The rapporteur should take account of comments received on the Concept Paper from the public when drafting the relevant guidance and provide an explanation to the Group if any such comment is to be disregarded and the Group should agree to this.

The rapporteur may ask the Agency to set up a face-to-face meeting of the drafting group if required. Normally this should be restricted to a kick-off meeting but additional meetings may be agreed where justified and depending on availability of funds. The majority of drafting group interactions is expected to take place through the exchange of Emails, teleconferences or the use of web conferencing tools. To promote and facilitate a more even distribution of work between Member States and to minimise travelling the rapporteur, in agreement with the drafting group, may choose to organise a meeting outside of the offices of the European Medicines Agency in London and may request the Agency to reimburse travel and accommodation expenses. In such cases a written request for authorisation must be forwarded well in advance of the proposed meeting to ADM-GMDP@ema.europa.eu with supporting evidence that the costs will be no more than those that would be incurred by having the meeting in London.

The rapporteur will draft documents taking into account comments expressed by the drafting group, comments expressed during plenary meetings of the GMP/GDP IWG, unless it is already clear that the Group does not support the comment in question, and any written comments received. He should treat all comments in a balanced way and avoid bias towards his personal views or those expressed by his own National Competent Authority.

The rapporteur will provide drafts to the European Medicines Agency sufficiently in advance of plenary meetings of the Group in order that they can be distributed to the Group in time to allow for consultation within each National Competent Authority prior to the meeting. The deadlines provided on agenda and summary records of the Group's meetings should therefore be respected.

The rapporteur should report on progress at each plenary meeting of the Group, either verbally or in writing as necessary. This report should include an overview of any significant comments received since the last meeting and the outcome of the consideration of those comments. The report should also indicate any areas of difficulty, any specific requests for feedback from the Group and should in particular highlight cases where the timelines expressed in Concept Papers or published Work Plans, as relevant, cannot be met.

Draft documents tabled at plenary meetings of the Group should include the letterhead of the European Medicines Agency and be marked as confidential.

Unless otherwise instructed the following documents should be in Microsoft Word format and the body text should use Verdana font size 9 (justified). Templates will be provided by EMA secretariat:

- Concept Papers
- Reflection Papers
- Questions and Answers
- Documents for the Compilation of Community Procedures

For new or amended text for the EU GMP or GDP Guide i.e. which will ultimately be published by the European Commission, Times New Roman font size 12 (justified) should be used for body text in addition the general layout and formatting of these documents should be in accordance with the relevant existing Chapter or Annex when appropriate.

In the case of amendments to, or new texts for inclusion in, the EU GMP or GDP Guide a public consultation phase will normally be necessary. The rapporteur should take account of comments received from the public and provide a tabulated summary of the major comments together with the outcome following consideration of each comment, and this should be tabled at a plenary meeting of GMP/GDP IWG before final agreement of the text. The European Medicines Agency will provide the rapporteur with the template document for this purpose.

Secretariat (European Medicines Agency) for GMP/GDP IWG

The secretariat will check the status of experts involved in drafting groups and request relevant documentation from experts as needed.

The secretariat will provide the rapporteur with the appropriate guidance and formats as relevant to the documents in question.

The secretariat will give proper consideration to all requests from rapporteurs for face-to-face meetings of drafting groups in London and where appropriate will send invitations, provide a meeting room in London and any further support as agreed. When requested in writing the secretariat will seek Agency authorisation for reimbursement of travel and accommodation expenses for drafting group meetings outside of its London offices and will inform the rapporteur of the outcome.

The secretariat will, upon request, set up teleconference calls for drafting groups using its own teleconferencing facilities or set up web conferences, using its *Vitero* system and arrange for the supply of relevant software and training when needed.

The secretariat will review final drafts for consistency with other relevant guidelines, and in particular in the case of an amendment to the GMP or GDP Guide, consistency within the Guide itself, and where necessary will suggest amendments to the text to the rapporteur. Where possible it may also suggest linguistic corrections where the rapporteur is not a native English speaker.

The secretariat will provide advice on other Groups or Working Parties that should be consulted prior to the finalisation of drafts.

The secretariat will if necessary convert final drafts into the correct format for publication or transmission to the European Commission and will publish or transmit final documents to the European Commission as appropriate. The European Medicines Agency publishes Concept Papers, Reflection Papers, Questions & Answers and the Compilation of Community Procedures on Inspections and Exchange of Information. The European Commission publishes draft GMP and GDP guidance for public consultation, adopted amendments and additions to the GMP or Guide and the summary of public comments.

GMP/GDP IWG

The group will provide all necessary scientific support to the rapporteur.

Each member of the Group will ensure that all relevant experts within his own National Competent Authority are consulted on each draft tabled at meetings and provide the resulting feedback to the rapporteur at the plenary meetings or in writing.

The group will ensure that comments received during external consultations have been satisfactorily addressed by the rapporteur.

European Commission

The European Commission performs a legal review of documents for the GMP Guide or Compilation of Community procedures before these are adopted.

Further Information

Documents produced in accordance with this guidance are subject to the Procedure for European Union Guidelines and Related Documents within the Pharmaceutical Legislative Framework:

http://www.emea.europa.eu/pdfs/human/regaffair/2414304en.pdf