EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Compliance and Inspections

Mandate, objectives and rules of procedure

Good Clinical Practice Inspectors Working Group (GCP IWG)

1. General considerations

In 1997, the Ad Hoc Meeting of GCP Inspection Services was established by the European Medicines Agency (EMA), within the scope of article 51(e) of Regulation (EC) No. 2303/93, subsequently amended as article 57(1)(i) of Regulation (EC) No. 726/2004.

In recognition that its meetings are regular and no longer "Ad Hoc" the group agreed to adopt the name of "GCP Inspection Services Group" at its meeting of December 2005.

In 2004, the GCP Inspection Services Group published its mission statement and objectives and these are now incorporated in the appropriate sections of the present mandate.

In 2006, the European Commission published Volume 10 "Clinical Trials" of the Rules governing medicinal products in the European Union and Chapter IV describes the GCP Inspection Services Group as follows:

"Good Clinical Practice Inspection Services Group: This group provides expert advice and support to the Union, its members, the European Commission, the European Medicines Agency and its scientific committees and other parties as required on matters related to good clinical practice and inspections. It draws its membership from representatives of the good clinical practice inspectorates of the Member States and the European Medicines Agency Inspection Sector."

At the Heads of Medicines Agencies (HMA) meeting in Lisbon in July 2007, it was decided that the names of the GMP/GDP and the GCP Inspectors groups should be harmonised and it was agreed that this group should therefore be called the GCP Inspectors Working Group (GCP IWG).

Key to its role is the development and implementation of procedures and processes to ensure harmonisation and mutual recognition, within the EU, of a high standard of GCP inspection and harmonisation with the wider membership of the group.

The clinical trial legislation and marketing authorisation legislation in the EU covers the full range of interventional clinical trials of medicinal products for human use, including both commercially and non-commercially sponsored trials and regardless of whether the active substance used is chemical, biological or herbal in nature. Developments concerning GCP at Union level affect a wide range of different stakeholders.

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This group has developed interactions with the former Pharmacovigilance Working Party, has developed procedures for inspection of pharmacovigilance systems in both pre and post authorisation scenarios and has worked on Chapter 2 of Volume 9A of the Rules governing medicinal products in the European Union. From September 2006 to September 2007 a dedicated one day meeting on pharmacovigilance inspection was conducted as a twice yearly addition to two of the quarterly GCP inspection meetings. However, in 2008 an ad hoc Pharmacovigilance Inspections Working Group (PhV IWG) was formed and in 2009 the PhV IWG was formally established in order to address all matters relating directly or indirectly to PhV inspections.

The group will address GCP issues for veterinary products on an ad hoc basis as requested by CVMP and in conjunction with the CMD(v).

2. Mandate and objectives

According to Directive 2001/20/EC an inspection of GCP compliance carried out by one Member State is carried out on behalf of the Union and the results are recognised by all the Member States. The GCP Inspectors Working Group provides input and recommendations on all matters relating directly or indirectly to GCP in the context of clinical trials and/or any marketing authorisation procedures, through different reporting lines as indicated below.

2.1. Co-operation with the European Commission

- Development and agreement by consensus of GCP related guidelines for submission to the European Commission for adoption or the Agency's Executive Director.
- Development, agreement by consensus and maintenance of high-level procedures for the conduct of GCP inspections as set out in Chapter IV of Volume 10 "Clinical trials" of the Rules governing medicinal products in the European Union, dealing with topics including the selection of sites for inspection, and the coordination, preparation, conduct and reporting of inspections as well as their follow-up. Agreed procedures will be submitted for adoption by the European Commission or the Agency's Executive Director.
- Discussion on practical implementation of GCP guidelines, common interpretation of guidelines and harmonisation of GCP inspection approaches in the EEA covering clinical trial procedures and marketing authorisation via national, mutual recognition, decentralised and centralised procedures.
- Development, implementation and monitoring of plans for implementation/operation of MRAs (GCP sectoral Annex) and other similar Union arrangements.
- Formulating advice and comment on GCP related issues including draft legislation to the European Commission.
- Providing advice to and liaising with the European Commission's ad hoc group for the development of implementing texts for Directive 2001/20/EC on matters relating to GCP.
- Development and agreement by consensus of other documents within the framework of pharmaceutical guidelines and related documents in connection with GCP such as reflection papers and questions and answers to be published on the EMA website.

2.2. Co-operation with the European Medicines Agency (EMA)

- To develop and operate integrated approaches for inspection and assessment with EMA scientific committees and in conjunction with the Scientific Coordination Board (SciCoBo).

- Advising on and developing procedures for the coordination of inspections requested by the scientific committees – these procedures are published by the EMA.
- Formulating advice and comment on GCP related issues to the scientific committees and their working parties.
- Liaison with the Good Manufacturing Practice/ Good Distribution Practice Inspectors' Working Group (GMP/GDP IWG), with the Pharmacovigilance Inspectors' Working Group (PhV IWG), the Paediatric Committee (PDCO), the Scientific Advice Working Party (SAWP) and other EMA or scientific committee working parties as applicable on matters of mutual interest.

2.3. Co-operation with Heads of Medicines Agencies (HMA)

- When requested, formulating advice and comment on GCP related issues to HMA and its working groups.
- When requested, formulating advice and comment on GCP related issues to the Clinical Trial Facilitation Group (CTFG).
- To contribute to the development of the benchmarking of European Medicines Agencies with respect to those elements related to GCP inspections and related processes.
- Liaison and co-operation with the Working Group of Enforcement Officers (WG EO) on specific issues.

2.4. Relationship with coordination groups

- Establish a platform for cooperation with coordination groups for example through the creation of common subgroups
- When requested, formulating advice and comment on GCP related issues to the CMD (h).

2.5. Training

- To promote and actively contribute to training of inspectors and the development of harmonised procedures and practices through training programmes, workshops and joint inspections. Increase shared experience through review of (anonymised) inspection reports and findings. Discussion of problem issues/case reports.

2.6. Co-operation with other bodies

- Promote international cooperation in the inspection of clinical trials and capacity building in this area though workshops, training course and conferences with other international bodies and regulatory authorities.
- Liaison and cooperation on matters of mutual interest with international bodies. In particular: The World Health Organisation (WHO) and International Conference on Harmonisation (ICH), as well as MRA partners and key regulatory authorities.
- Share information on inspections and GCP related documents of common interest and conduct collaborative inspections under the framework of confidentiality arrangements established between the European Commission, the EMA and regulatory authorities such as the US Food and Drug Administration (FDA) (EMA-FDA GCP initiative).

- Liaison with interested parties (EFPIA, EuropaBio, EGA, AESGP, ESF, EFGCP, CDISC, EUCROF and other specific interested groups).

2.7. Communication with the public and external bodies

GCP Inspectors Working Group will regularly communicate details of its work to external organisations and the general public using appropriate vehicles including in particular the EMA and HMA websites. Appropriate opportunities will be taken through international training courses and conferences to communicate on GCP requirements and inspections.

3. Composition and rules of participation

3.1. Chairmanship

Meetings will be chaired by a representative of EMA Compliance and Inspection sector or delegate. Members may request, for specific topics coming under the heading of cooperation with HMA that a co-chair is appointed from within the members. Appointment of the co-chair will be by consensus of the members or, if necessary, using the voting rules described in section 6.4.

3.2. Membership

Membership is composed of experts nominated by their relevant authority with senior responsibility for and broad experience in the area of GCP inspections. A replacement to participate in those exceptional cases where the nominated member is unable to attend a meeting, may also be nominated.

Meeting documentation will be distributed by EMA to members and any nominated replacements.

There will be one member from each of the EEA Member States. Members from EU Member States will be reimbursed for attendance at meetings. Additional staff of the authorities may attend with the chairman's agreement, in particular where their participation is needed for a specific topic. The European Commission – DG Health and Consumers will also be invited to send a representative to meetings.

The Executive Director of the Agency and members of EMA secretariat may attend all meetings.

3.3. Observers

Observers may include representatives of:

EU accession countries.

MRA partners (operational).

Specific confidentiality rules will apply to observers. Observers attend at the discretion of the chairman, in line with EMA policy on observers, and may not be involved when particular items of concern to EU/EEA member states are discussed, product specific matters or other confidential matters.

Observers are encouraged to participate freely in discussions but shall not take part in any decision-making process.

Other observers may participate with the agreement of the chairperson in consultation with the group where possible, in line with EMA policy on observers.

4. Meeting frequency

GCP Inspectors Working Group shall meet at least 4 times per year. Additional meetings may be held when planned for specific reasons such as training. The dates of the meetings shall be included in the work plan. Some meetings or part of meetings may involve joint activities with other working groups. Drafting groups will conduct the majority of their business by correspondence and teleconference but upon reasoned request meetings will be organised by EMA usually in the margins of the plenary meeting of GCP Inspectors Working Group.

5. Duration of activity

Not applicable.

6. Rules of procedure

6.1. Responsibilities of chairperson

The chairperson is responsible for the efficient conduct of the business of GCP Inspectors Working Group and shall in particular:

- plan the work of GCP Inspectors Working Group;
- monitor that the rules of procedure are respected;
- ensure that at the beginning of each meeting that any potential conflict of interest is declared regarding any particular item to be discussed;
- aim to achieve consensus on issues discussed;
- decide in exceptional cases, when a vote is necessary;
- ensure the regulatory and scientific consistency of recommendations;
- co-ordinate the work of GCP Inspectors Working Group with that of the Agency's scientific committees, working parties and other relevant groups of EMA, Heads of Medicines Agency or European Commission;
- report on the activities of GCP Inspectors Working Group to the Agency's scientific committees, working parties and other relevant groups of EMA, Heads of Medicines Agency or European Commission as appropriate.

6.2. Responsibilities of EMA secretariat

The EMA secretariat shall provide technical, scientific, legal, regulatory and administrative support to GCP Inspectors Working Group. This includes the following:

- prepare for and co-ordinate the work of GCP Inspectors Working Group;
- organise meetings and ensure timely circulation of meeting documents;
- facilitate the necessary contacts between GCP Inspectors Working Group and other bodies;
- ensure adequate co-ordination of the work carried out by GCP Inspectors Working Group and other concerned groups;

- contribute to the overall quality assurance and assurance of scientific and regulatory consistency of the documents/recommendations of GCP Inspectors Working Group;
- prepare the agenda, table of actions and summary records of meetings;
- communicate, in a pro-active manner, any output of GCP Inspectors Working Group to interested parties;
- transmit any recommendations of GCP Inspectors Working Group to the relevant body for adoption and/or publication as appropriate.

6.3. Responsibilities of members

Membership implies a commitment to participate actively in the work of GCP Inspectors Working Group and to attend meetings regularly.

- Members shall ensure that they communicate the views of the Member State, which they represent when contributing to discussions and agreements.
- Members shall ensure that all agreements are communicated within their Member State and should ensure that necessary steps are taken to act upon those agreements as appropriate.
- Members may identify and propose topics for consideration by GCP Inspectors Working Group. Any proposal should be supported by a problem statement or other adequate justification.
- Members tabling documents for discussion at meetings of the GCP Inspectors Working Group shall respect any guidelines prepared by the group for this purpose or relevant Union guidelines.
- Members shall observe deadlines for submission of documents to EMA in order that documents can be distributed to the other members in time to enable them to establish the position of the Member State that they represent.

6.4. Organisation of meetings

- The meetings will be held and minutes will be taken in English.
- The draft agenda for every meeting shall be circulated, together with the relating documents, by the EMA Secretariat, in consultation with the chairperson, at least 14 calendar days before the meeting.
- When a Member of GCP Inspectors Working Group is unable to participate in a meeting or part of a meeting, or discussion topic due to a conflict of interest, he/she must inform the Secretariat in advance in writing.
- GCP Inspectors Working Group shall prepare and agree on an annual work plan. The work plan shall be regularly reviewed and updated as necessary.
- A quorum is required for all internal decisions or recommendations of GCP Inspectors Working Group. This shall be reached when two thirds of the total members of the GCP Inspectors Working Group are present.
- Whenever possible, internal decisions or recommendations of the group shall be made by consensus. If such a consensus cannot be reached, the chair or any member may propose a vote. Each member state shall have one vote. An absolute majority (i.e. favourable votes by at least half of the total number of members eligible to vote plus one) shall be required. Divergent positions shall be mentioned in the summary record of the meeting.

- Prior to any vote the group will agree, depending on the nature of the topic, whether any members should not participate in the vote.

6.5. Drafting groups

When further consideration is required in order to prepare proposals on specific topics drafting groups may be convened constituted of members of GCP Inspectors Working Group or other experts, as appropriate.

The drafting group will report to GCP Inspectors Working Group.

Rules of procedure for drafting groups will be developed.

6.6. Guarantees of independence

The members of GCP Inspectors Working Group and experts referred to above shall not have any direct interests in the pharmaceutical industry that could affect their impartiality. They shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of interest which will be publicly available on the Agency's website.

Members and experts attending meetings shall declare at the beginning of each meeting any specific interests, which could be considered to be prejudicial to their independence with respect to the points of the agenda. These declarations shall be made available to the public.

The specific provisions for handling declarations of interests and confidentiality undertakings as defined in the EMA Policy on the handling of conflicts of interests for committee members and experts, adopted by the Management Board (EMA/513078/2010) are applicable to members of GCP Inspectors Working Group and experts participating in the activities of GCP Inspectors Working Group.

6.7. Code of Conduct

Members of GCP Inspectors Working Group and experts participating in EMA's activities shall abide by the principles set out in the EMA Code of Conduct.

6.8. Contacts with interested parties

- Where relevant, GCP Inspectors Working Group will establish contacts, on an advisory basis, with parties concerned with the manufacture and control of medicinal products.
- The pharmaceutical industry, health care professionals, patients/consumers or other interested parties have the opportunity to comment in writing on draft guidelines and general regulatory developments during the public consultation of the documents.
- When considered appropriate by GCP Inspectors Working Group, oral or written presentations by interested parties can be made during meetings at earlier stages of development of guidelines. GCP Inspectors Working Group may also meet with interested parties to discuss general matters or specific issues.
- In any case, GCP Inspectors Working Group shall neither conduct any deliberations nor reach any formal agreements in the presence of members of interested parties.
- Before any consultation session, interested party representatives and GCP Inspectors Working Group members will communicate to the EMA secretariat the points they would like to be

discussed, so that an agenda of the session can be prepared for agreement by the chairperson and circulation by the EMA secretariat.

6.9. General provisions

Members of GCP Inspectors Working Group as well as observers and all experts shall be bound, even after the cessation of their duties, not to disclose any information, which, by its nature, must be covered by individual professional secrecy. When participating in international or other fora on behalf of GCP Inspectors Working Group, members shall ensure that the views expressed are those of GCP Inspectors Working Group. When participating in international or other fora not specifically on behalf of GCP Inspectors Working Group, members shall make clear that the views expressed are their own views, or those of the National Competent Authority (NCA), and not those of GCP Inspectors Working Group.