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Inspections

Compliance Group Mandate

Joint Audit Programme for EEA GMP Inspectorates

1. Introduction

The role of the Compliance Group in the Joint Audit Programme (JAP) of EEA GMP Inspectorates is to oversee the audit programme, plan the audits, review the outcome and coordinate follow up of any corrective and preventive actions, in liaison with the concerned audit team. The Compliance Group will report to the GMDP Inspectors Working Group (GMDP IWG) and prepare upon request reports to the Heads of Medicines Agencies (HMA).

2. Responsibilities

The responsibilities of the Compliance Group are as follows:

- to plan and co-ordinate audits as outlined in the Joint Audit Programme;
- to monitor the audits timelines;
- to review the outcome of the audits including the quality of the report and the conclusion on the assessment of the equivalence of the audited competent authority with the compilation of Union procedures;
- to conclude on equivalence if requested by the audit team in the audit report;
- to adopt JAP audit reports as delegated by the GMP/GDP Inspectors Working Group (GMDP IWG);
- to coordinate follow up of any corrective and preventive actions and to follow-up on actions if requested by the audit team;
- to discuss and resolve where possible any major problems that occur and to present to the GMDP IWG any issues which cannot be resolved;
- to ensure that documentation of the Joint Audit Programme is relevant and up-to-date;
- to regularly report at the meetings of the GMDP IWG;
- to prepare annual reports to the HMA for adoption by the GMDP IWG;
- to define and monitor training courses for auditors;

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- to liaise with Pharmaceutical Inspection Co-operation Scheme (PIC/S) on the Joint Re-assessment Programme (JRP) procedures and planning, exchange of audit results and maintenance of mutual recognition of audits;
- to exchange information with other regulatory bodies involved in audits concerning GMP inspectorates;
- to provide technical advice to the GMDP IWG and the European Commission on equivalence and/or on specific topics from audit reports of Mutual Recognition Agreement (MRA) partners;
- to review annual reports under the MRA maintenance programme and provide input to the planning of JAP audits;
- to reply to queries on the Joint Audit Programme, after consultation with experts from the National Competent Authorities if necessary;
- to provide suggestions for continuous improvement of the Joint Audit Programme.

3. Composition of the Compliance Group

The Compliance Group will be composed as follows:

- members of the Compliance Group shall be members or alternates of the GMDP IWG;
- the number of the members is 6-8, it may be higher depending on workload;
- the GMDP IWG nominates the members of the Compliance Group for a term of three years which may be renewed;
- resource estimation for members is expected to be 8-16 working days per year;
- the Compliance Group elects its Chair and Vice-Chair from among its members. The Chair and Vice-Chair are elected for a term of three years which may be renewed;
- European Medicines Agency (EMA) staff provide secretarial assistance.

Members of the Compliance Group can appoint one alternate from their agency in case they cannot attend a meeting or participate in an activity. The participation of alternates complies with the following conditions:

- alternates are experts included in the EMA Experts database;
- alternates are familiar with the Compliance Group activities and have knowledge and/or experience with the Joint Audit Programme;
- the member informs the Compliance Group secretariat well in advance of the involvement of the alternate;
- alternates who are not nominated members or alternates of the GMDP IWG will not be reimbursed by the EMA for their attendance;
- the minutes of the meeting reflect when an alternate participated on behalf of the member;
- the alternates can vote on behalf of the members.

Representatives of the European Commission may attend all meetings of the Compliance Group.

Participation of Member State and/or external participants (e.g. non-EU PIC/S participating authorities, MRA partners) requires approval of the GMDP IWG.

4. Responsibilities of the Chair and Vice-Chair

The Chair, and in his absence the Vice-Chair, is responsible for the efficient conduct of the business of the Compliance Group and shall in particular:

- monitor that the mandate is respected;
- ensure that at the beginning of each meeting any potential competing 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 consistency of recommendations and conclusions;
- report on the activities of the Compliance Group to the GMDP IWG and HMA.

The Vice-Chair will deputise for the Chair when the latter is unable to chair either all or part of the Compliance Group meeting. On such occasions the Chair will seek the agreement of the Vice-Chair as early as possible, prior to the meeting and the EMA secretariat shall be informed immediately.

5. Responsibilities of members

Membership implies a commitment to participate actively in the work of the Compliance Group and to attend meetings, including by teleconference, regularly:

- members may identify and propose topics for consideration by the Compliance Group. Any proposal should be supported by a problem statement or other adequate justification;
- members shall observe deadlines for submission of documents to EMA in order that documents can be distributed to the other members in time.

Members can be assigned to act as a "sponsor" for the adoption process of audit reports. The tasks of the sponsor include:

- performing the full detailed review of the JAP audit report he/she is sponsoring to facilitate the other Compliance Group members to focus on the key aspects of the audit report;
- contacting directly the lead auditor for technical clarifications on the report, as necessary;
- acting as topic technical leader for the audit report at the Compliance Group meeting;
- enabling a timely adoption of the audit report by the Compliance Group.

Criteria for assigning and accepting sponsorships include: knowledge of the language in the audited agency, (lead) auditor is not from the same agency as the Compliance Group member, workload of the Compliance Group members, equal distribution among Compliance Group members and Compliance Group member's acceptance of the assignment. The member can delegate the sponsorship to an alternate, who should be a qualified auditor.

6. Responsibilities of EMA secretariat

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

- prepare for and co-ordinate the work of the Compliance Group;

- organise meetings and ensure timely circulation of meeting documents;
- prepare the agenda and minutes of meetings;
- co-ordinate the planning and monitoring of the JAP audits timelines;
- ensure adequate co-ordination of the work carried out by the Compliance Group and the GMDP IWG;
- contribute to the overall quality assurance and consistency of the documents/recommendations of the Compliance Group, especially in the field of coherence with MRA and PIC/S JRP processes;
- transmit any recommendations of the Compliance Group to the GMDP IWG or other relevant body for adoption and/or publication as appropriate.

7. Procedures of meetings

- The Compliance Group will meet at least 4 times per year in person or by teleconference.
- The dates of the prospective meetings will be preferably in conjunction with the meetings of the GMDP IWG.
- The draft agenda for each meeting will be prepared by the Chair and circulated to the participants in advance of the meeting.
- The Compliance Group will hold ad hoc meetings as requested by the GMDP IWG, e.g. due to increased workload.
- The meetings will be held and minuted in English.
- A quorum is required for all internal decisions or recommendations of the Compliance Group. This shall be reached when two thirds of the total members of the Compliance Group is present.
- Whenever possible, internal decisions or recommendations of the group shall be achieved by consensus. If such a consensus cannot be reached, the Chair or any member may propose a vote. The vote shall include the Chair. 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 minutes of the meeting.
- For the adoption of audit reports, a quorum of two thirds of the total members of the Compliance Group is required and no objections should have been raised by any member of the Compliance Group to progress with the adoption. Audit reports can be adopted by written procedure.
- Prior to any vote, the Compliance Group will agree, depending on the nature of the topic, whether any members should not participate in the vote, e.g. due to competing interests.

8. Documents

The Compliance Group will:

- maintain and revise if necessary the documents of the Joint Audit Programme;
- maintain and update the list of audits carried out in the EEA;
- maintain and update the list of auditors and audit training records;
- prepare and agree all documents to be submitted to the GMDP IWG.

9. Reporting arrangements

The Compliance Group will:

- report at the meetings of the GMDP IWG on the audit plan and outcomes of the audits and any other matter relating to the Joint Audit Programme such as proposals for improvement of JAP audit documents and quality system for GMP inspectorates;
- prepare annual reports or reports upon request to the HMA for adoption by the GMDP IWG.

10. General provisions

- The members of the Compliance Group as well as alternates shall not have any direct or indirect 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 their financial interests.
- Members attending meetings as well as alternates 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.
- The specific provisions for handling competing interests and confidentiality undertakings as defined in the EMA Policy on the handling of competing interests of scientific committees' members and experts (Policy 0044) are applicable to members of the Compliance Group as well as alternates.
- Members of the Compliance Group as well as alternates shall abide by the principles set out in the EMA Code of Conduct.
- Members of the Compliance Group as well as alternates 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.