EMA/INS/GMP/426453/2024

Mandate, objectives and rules of procedure

GMP/GDP inspectors working group (GMDP IWG)

1. General considerations

In 1981 the European Commission established the Working Party on Control of Medicinal Products and Inspections. This working party established the groundwork for harmonisation of Good Manufacturing Practice (GMP) inspections in the European Community and practical implementation of Mutual Recognition Agreements (MRAs) with certain 3rd countries. The working party was also responsible for developing the first European Community GMP Guidance.

In 1996 the Ad Hoc GMP Inspection Services group was set up with the aim of developing specific aspects in relation to the centralised procedure and both groups worked in a parallel and complementary manner. Responsibility for MRAs was transferred to EMA in 1997 and in 1998 the Commission's working party was dissolved leaving the EMA group as the only forum for discussion of GMP-related topics at Community level. Given the need for such a forum and the tasks given to EMA in Regulation (EEC) No 2309/93 subsequently replaced by Regulation (EC) No 726/2004, to, inter alia, co-ordinate the verification of compliance with the principles of Good Manufacturing Practice, the tasks of the Commission's Working Party were assumed by the Ad Hoc GMP Inspections Services group. It also serves as the Telematics Implementation Group (TIG) for the EudraGMDP database.

The Ad Hoc group has met regularly since 1996, its 45th meeting taking place at the end of 2006 so therefore the term "Ad Hoc" was no longer appropriate.

The principles and guidelines of GMP apply systematically across the entire range of medicinal products whether for human or veterinary use and regardless as to whether the active substance used is chemical, biological or herbal in nature and therefore developments at EU level affect a wide range of different stakeholders.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

2. Mandate and objective

According to Directive 2001/83/EC and Regulation (EU) 2019/06 conclusions reached following a GMP inspection are valid throughout the EU. The GMP/GDP Inspectors Working Group provides input and recommendations on all matters relating directly or indirectly to Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) irrespective of the marketing authorisation procedure through different reporting lines as indicated below.

2.1. Co-operation with the European Commission

- Development and agreement by consensus of GMP/GDP related guidelines for submission to the European Commission for adoption;
- Development, agreement by consensus and maintenance of high-level procedures for the conduct of GMP and GDP inspections, dealing with suspected quality defects, taking regulatory action against manufacturers/distributors and exchange of information. Agreed procedures will be submitted for adoption by the European Commission and published in the Compilation of Community Procedures for Inspections and Exchange of Information;
- Discussion on practical implementation of GMP and GDP guidelines, common interpretation of guidelines and harmonisation of GMP/GDP inspection approaches in the EEA covering national, mutual recognition, decentralised and centralised procedures;
- Development, implementation and monitoring of plans for implementation/operation of MRAs (GMP sectoral annex) and other similar European Union arrangements;
- Formulating advice and comment on GMP/GDP related issues including draft legislation to the European Commission;
- Development and agreement by consensus of other documents within the framework of pharmaceutical guidelines and related documents in connection with GMP/GDP such as reflection papers and questions and answers to be published on the EMA website.

2.2. Co-operation with EMA

- Advising on procedures for the coordination of inspections requested by the scientific committees;
- To develop and operate integrated approaches for inspection and assessment with EMA scientific committees and in conjunction with the Scientific Coordination Board;
- Advising on the coordination of sampling and testing of medicinal products authorised by way of the centralised procedure;
- Formulating advice and comment on GMP/GDP related issues to the scientific committees and their working parties;
- Liaison with Good Clinical Practice Inspectors Working Group (GCP IWG), Phamacovigilance Inspectors Working Group (PhV IWG), Quality Working Party (QWP), Biologics Working Party

(BWP) and Immunologicals Working Party (IWP) and the Novel therapy and Technologies WP (NTWP on matters of mutual interest;

- Facilitating the introduction of new approaches to manufacturing and control methodologies through the Quality Innovation Group, the Innovation Task Force and through Scientific Advice Procedures..

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

- When requested, formulating advice and comment on GMP/GDP related issues to HMA and its working groups;
- Overseeing the Joint Audit Programme and providing annual reports to HMA;
- To contribute to the development of the Benchmarking of European Medicines Agencies with respect to those elements related to GMP/GDP inspections and related processes;
- Liaison and co-operation with the Working Group of Enforcement Officers (WGEO);
- Where necessary to establish the position of the EEA GMP inspectorates with respect to the management of crises arising from non-compliance;
- To develop ways of ensuring efficient use of EEA inspection resources.

2.4. Relationship with coordination groups

- When requested, formulating advice and comment on GMP/GDP related issues to the Coordination Groups for Mutual Recognition and De-centralised Procedures (CMD (h&v)).

2.5. Co-operation with other bodies

- Liaison and cooperation on matters of mutual interest with international bodies. In particular: The Pharmaceutical Inspection Cooperation Scheme (PIC/S), European Directorate for the Quality of Medicines and HealthCare (EDQM), World Health Organisation (WHO), and (Veterinary) International Conference on Harmonisation ((V)ICH) as well as MRA partners and key regulatory authorities;
- Liaison with interested parties (EFPIA, IFAH, AESGP, APIC, and other specific interested groups).

1.1. 2.6. Training

- To promote and actively contribute to training of GMDP inspectors and the development of harmonised procedures and practices supporting training programmes, workshops and joint observed inspections.

Communication with the public and external bodies

- GMP/GDP 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.

3. Composition and rules of participation

3.1. Chairmanship

Meetings will be chaired by a representative of EMA, normally the Head of the Quality and Safety Department 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 GMP/GDP inspections. A replacement (alternate), 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 with one additional member from each Member State where there is a separate GMP inspectorate for veterinary medicinal products. 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, Unit D6, Medicinal Products Safety, Quality and Efficacy, will also be invited to send a representative to meetings.

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

3.3. Observers

Observers may include representatives of:

- The European Directorate for Quality of Medicines, Council of Europe (EDQM);
- EU accession countries;
- MRA partners (operational).
- World Health Organisation.

All topics discussed by the GMDP IWG are considered confidential. 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 EEA Member States are discussed, product specific matters or other sensitive matters.

EDQM participates systematically as an observer in GMDP IWG meetings. However, despite its official status as observer to the IWG, considering EDQM's status in the European regulatory system and the input to the GMDP IWG meeting, EDQM participants may be considered as having an expert status. As such, they may be invited by the Chair to attend the discussion of sensitive topics where they have an active role and be provided with the relevant meeting documents.

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.

4. Meeting frequency

GMP/GDP Inspectors Working Group shall meet at least 4 times per year. The dates of the meetings shall be included in the work plan. Drafting groups will conduct the majority of their business by correspondence, teleconference or videoconference but upon reasoned request meetings will be organised by EMA, usually in the margins of the plenary meeting of GMP/GDP 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 the GMP/GDP Inspectors Working Group and shall in particular:

- Plan the work of GMP/GDP Inspectors Working Group;
- Monitor that the rules of procedure are respected;
- Ensure that at the beginning of each meeting 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 GMP/GDP Inspection Services with that of the Agency's Scientific Committees, Working Parties and other relevant groups of EEA, Heads of Medicines Agency or European Commission;
- Report on the activities of GMP/GDP 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 GMP/GDP Inspectors Working Group. This includes the following:

- Prepare for and co-ordinate the work of GMP/GDP Inspectors Working Group;
- Organise meetings and ensure timely circulation of meeting documents;
- Facilitate the necessary contacts between GMP/GDP Inspectors Working Group and other bodies;
- Ensure adequate co-ordination of the work carried out by GMP/GDP 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 GMP/GDP Inspectors Working Group;
- Prepare the agenda, table of actions and summary records of meetings;
- Communicate, in a pro-active manner, any output of GMP/GDP Inspectors Working Group to interested parties;
- Transmit any recommendations of GMP/GDP 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 GMP/GDP 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 GMP/GDP 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 GMP/GDP Inspectors Working Group shall respect any guidelines prepared by the group for this purpose or relevant EU 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 they represent.

6.4. Organisation of meetings

- Meetings may take place in person or they may be held remotely via teleconference.
- The meetings will be held and summaries 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 GMP/GDP 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;
- GMP/GDP Inspectors Working Group shall prepare and agree 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 GMP/GDP Inspectors Working Group. This shall be reached when two thirds of the total members of the GMP/GDP Inspectors Working 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. Each Member State shall have 2 votes, 1 on behalf of the veterinary medicinal products sector and 1 on behalf of the human medicinal products sector unless the subject of the vote affects only one of these sectors, in which case only one vote per member state shall be permitted. 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;
- Where there are 2 separate agencies representing the human and veterinary sectors in the same Member State, delegation between them is possible subject to advance notification to the secretariat;
- Prior to any vote the group will agree, depending on the nature of the topic, whether any members should not participate in the vote (e.g., due to a conflict of interests).

6.5. Written procedures

- Documents can, after approval of the chairperson, be submitted by the EMA secretariat to the GMDP IWG for adoption by written procedure. However, such written procedures should be restricted to measures and decisions required to be taken between scheduled meetings;

- Members may raise objections to the document within a specified time period, to be established in agreement with the chairperson. Adoptions by written procedures shall be achieved by consensus in line with principles set out for meetings in section 6.4 above.
- The secretariat shall report on the outcome of the written procedure at the next meeting.
- In the case of serious objections, the chairperson reserves the right to suspend the written procedure and postpone the discussion to the next meeting.

6.6. Drafting groups

When further consideration is required in order to prepare proposals on specific topics drafting groups may be convened constituted of members of GMP/GDP Inspectors Working Group or other experts, as appropriate. The drafting group will report to GMP/GDP Inspectors Working Group. Rules of procedure for drafting groups exist.

Drafting groups will conduct their activities by correspondence, teleconference or videoconference. Upon reasoned request, meetings may be organised by EMA, usually in the margins of the plenary meeting of GMP/GDP IWP.

6.7. Guarantees of independence

The members of GMP/GDP 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 their financial interests. All indirect interests, which could relate to the pharmaceutical industry, shall be entered in a register held by the Agency, which is accessible to the public.

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 (Policy 0044) are applicable to members of GMP/GDP Inspectors Working Group and experts participating in the activities of GMP/GDP Inspectors Working Group.

6.8. Code of conduct

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

6.9. Contacts with interested parties

- Where relevant, GMP/GDP 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 GMP/GDP Inspectors Working Group, oral or written presentations by interested parties can be made during meetings at earlier stages of development of guidelines. GMP/GDP Inspectors Working Group may also meet with interested parties to discuss general matters or specific issues;
- In any case, GMP/GDP 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 GMP/GDP Inspectors Working Group members will communicate to the EMA secretariat 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.

6.10. General provisions

Members of GMP/GDP 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 GMP/GDP Inspectors Working Group, members shall ensure that the views expressed are those of GMP/GDP Inspectors Working Group. When participating in international or other fora not specifically on behalf of GMP/GDP Inspectors Working Group, members shall make clear that the views expressed are their own views, or those of the national competent authority, and not those of GMP/GDP Inspectors Working Group.