



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Compliance and Inspection

Work plan for the Pharmacovigilance Inspectors Working Group for 2011

1. Introduction

The Pharmacovigilance Inspectors Working Group (PhV IWG) was established by the EMA within the scope of article 57(1)(i) of Regulation (EC) No. 726/2004 and its mandate was endorsed by the Heads of Medicines Agencies and the EMA Management Board in 2009, thereby formally establishing the PhV IWG. It is a joint meeting made up of pharmacovigilance inspectors dealing with human products and pharmacovigilance inspectors dealing with veterinary medicinal products.

The PhV IWG focuses on harmonisation and co-ordination of pharmacovigilance related activities at community level. The group activities for this year are outlined in this document and the priorities of the group will be mainly focus on the following areas:

- Preparation for the implementation of the new human pharmacovigilance legislation, including input on the development of guidance documents and processes.
- Inspectors and assessors training.

2. Meetings

The following meetings are scheduled in 2011:

- 24 March 2011
- 16 June 2011
- 29-30 September 2011
- 08-09 December 2011

The following joint meetings will take place this year:

- Joint meeting with the human and veterinary Pharmacovigilance Working Party (PhV WP) assessors (29 September 2011).



A number of subgroup meetings (e.g. PhV IWG - PhV WP) to discuss draft documents and specific topics, in particular items for the development of the new pharmacovigilance legislation will be organised to coincide with the main meetings when possible but if needed a limited number of additional teleconferences or meetings will be scheduled.

3. Inspections conducted in support of the centralised procedure

- Implementation of the 2011 risk-based programme for routine pharmacovigilance inspections of MAHs connected with human and veterinary centrally authorised products (CAPs).
- Targeted inspections at the request of the Scientific Committees for Human and/or Veterinary Medicinal Products (CHMP and/or CVMP).

4. Harmonisation topics

Procedures and guidance documents

- The following documents, concerning human and veterinary medicinal products, are under preparation and expected to be finalized in the second quarter of 2011:
 - Guideline on communication of scheduled pharmacovigilance inspections and information sharing of inspection outcomes.
 - Guideline on document retention and record keeping for pharmacovigilance inspections.
 - Procedure on coordination of post-approval pharmacovigilance inspections for the centralised procedure.
 - Procedure on the follow-up of pharmacovigilance inspections.
 - Triggers and risk factors for selection of sites/prioritisation for pharmacovigilance inspection: points to consider for assessors.
- The group will also review, as applicable, inspection procedures and guidance for pharmacovigilance inspections for medicinal products for human use conducted in the context of the centralised procedure.
- The following documents, concerning veterinary medicinal products, are under preparation and expected to be finalized in the third quarter 2011:
 - Pre-submission instructions and template for the "Detailed Description of the Pharmacovigilance System" (DDPS) document for veterinary medicinal products.

Joint Inspections

- To develop and monitor opportunities for joint inspections of sites involving inspectorates from more than one National Competent Authority.

Training and development

- Conduct a PhV IWG Training Course.

- Conduct a EudraVigilance and Eudravigilance Data Analysis System training for pharmacovigilance inspectors.
- Develop peer review of case studies.
- Sharing and discussion of inspection reports, including grading of anonymised findings.
- Development of training guidance.
- Develop opportunities for lectures/workshops at the time of PhV IWG meetings, on special topics, by members of the group and by invited guests.

5. Pharmacovigilance topics

- To prepare for the work in relation to the implementation of the new human pharmacovigilance legislation by identifying and initiating the preparation of guidance and procedures to be developed to facilitate its implementation and in particular in the following areas addressed by the new legislation:
 - Inspections/Pharmacovigilance Systems
 - Cooperation between Member States and the EMA on pharmacovigilance inspection, including on planning of third country inspections.
 - Increased pharmacovigilance inspection coordination in the European Union and widened programme of inspection of pharmacovigilance systems.
 - Communication of cases of non-compliance between Member States, the EMA and the Commission (and follow-up of this).
 - Content and maintenance of the pharmacovigilance system master file.
 - Quality systems for the performance of pharmacovigilance activities by Marketing Authorisation Holders, National Competent Authorities and the EMA.
 - Electronic circulation of inspection reports on reasoned request to another member state or the agency.
 - Contribution to the preparation of a Good Vigilance Practice Guideline.
 - Interaction with the future Pharmacovigilance Risk Assessment Advisory Committee (PRAC).
- Provide recommendation to the Pharmacovigilance Working Party and pharmacovigilance inspectors in relation to pharmacovigilance inspection or related assessment issues.
- Contribution to the preparation of a procedure to trigger the use of the Infringement Regulation.

6. Collaboration with the European Commission

- Implementation of the new pharmacovigilance legislation.
- Preparation of high-level guidance for the conduct of pharmacovigilance inspections as set out in section 2.4 of revised Volume 9A and section 5 of Volume 9B of the Rules Governing Medicinal Products in the European Union for human and veterinary products respectively, dealing with topics including the selection of sites for inspection, 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.

7. Liaison with other groups

- The PhV IWG will liaise, as appropriate, with the following groups on pharmacovigilance areas identified of common interest as indicated in its [Mandate](#):
 - GCP and GMP IWG
 - CHMP, CVMP and respective Pharmacovigilance Working Parties
 - Heads of Medicines Agencies
 - Other Regulatory Agencies
 - CMD(h) and CMD(v)
 - External bodies

8. International Cooperation

- Development of contacts between EU and 3rd country agencies on pharmacovigilance matters.