EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Compliance and Inspection

# Work plan for the Pharmacovigilance Inspectors Working Group for 2013

## 1. Introduction

The Pharmacovigilance Inspectors Working Group (PhV IWG) was established by the European Medicines Agency 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 mainly focus on the following areas:

- the implementation of the new human pharmacovigilance legislation, including input into the development of guidance documents and processes (human);
- development of processes for risk-based inspection planning and follow-up (veterinary);
- inspectors and assessors collaboration and training.

## 2. Meetings

Due to the implementation of the new human pharmacovigilance legislation, the group agreed to re-organise the meetings to accommodate a joint session and two separate sessions, one dedicated to human and one to veterinary medicinal products only.

The following meetings are scheduled in 2013:

- 21-22 March 2013;
- 13-14 June 2013;
- 19-20 September 2013;

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- 05-06 December 2013.

The following virtual meetings will take place this year, using teleconference or equivalent:

- human medicinal products: ad-hoc teleconferences/meetings, including PhV IWG and PRAC delegates, when applicable, have been scheduled (remote access provided) in relation to the implementation of the new pharmacovigilance legislation, and specifically to support the development of the Union procedures on pharmacovigilance inspections, to be published as appendices to good vigilance practice guideline (GVP) module III on pharmacovigilance inspections;
- veterinary medicinal products: a number of subgroup teleconferences/meetings (e.g. PhV IWG - PhV WP) to discuss topics of interest and draft documents will be organised in the margins of the plenary meetings, when necessary.

# 3. Inspections conducted in support of the centralised procedure

- Implementation of the 2013 risk-based programme for routine pharmacovigilance inspections of marketing authorisation holders 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

- Concerning human medicinal products, the group will focus on the preparation of the following documents in 2013:
  - in relation to the work on the implementation of the new pharmacovigilance legislation, preparation of Union pharmacovigilance inspection procedures on the planning, coordination, conduct, reporting, follow-up and documentation of pharmacovigilance inspections, to support further harmonisation for the mutual recognition of pharmacovigilance inspections within the EU in liaison with PRAC and CMDh as appropriate;
  - the group will also review, as applicable, existing inspection procedures and guidance for pharmacovigilance inspections for medicinal products for human use conducted in the context of the centralised procedure, in particular to support the implementation of the new pharmacovigilance legislation;
  - the document on the guidance on pharmacovigilance inspection of marketing authorisation holders of pandemic influenza vaccines will be further developed and is expected to be finalised in 2013.
- The following documents, concerning veterinary medicinal products, will be developed and are expected to be finalized in 2013:
  - triggers and risk factors for selection of sites/prioritisation for pharmacovigilance inspection;
  - the group will also review existing inspection procedures and guidance for pharmacovigilance inspections for medicinal products for veterinary use conducted in the context of the

centralised procedure and revise those, as applicable. In addition the group will focus on further harmonisation in the grading of pharmacovigilance inspection findings between member states;

- the group, in relation to human and veterinary medicinal products, will 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 (pharmacovigilance inspection training course in 2013).
- Conduct a eudraVigilance and eudravigilance data analysis system/data warehouse training for pharmacovigilance inspectors (human and veterinary).
- Interact with the pharmacovigilance risk assessment committee (PRAC) members for the implementation of the Union procedures on pharmacovigilance inspections and specifically for the topic of pharmacovigilance inspection follow up.
- Conduct training on the extended eudravigilance medicinal product dictionary (XEVMPD) and the generation and use of XEVMPD reports for human medicinal products pharmacovigilance inspectors.
- Conduct pharmacovigilance inspectors training in good vigilance practice and new processes, within the scheduled PhV IWG meetings for 2013.
- Peer review of case studies, sharing and discussion of inspection reports, including grading of anonymised findings.
- 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

- **Human medicinal products:** continue the work in relation to the implementation of the new human pharmacovigilance legislation:
  - contribution and feedback during the finalisation or revision of good vigilance practice guideline modules, as applicable;
  - contribution to the development of question and answers (Q&A) and other guidance documents in relation to the ongoing implementation of the new pharmacovigilance legislation;
  - contribution to the preparation of specific guidance on the use of EMA databases and IT systems in relation to the pharmacovigilance system master file location, the contact details of the qualified person responsible for pharmacovigilance and inspection information sharing;
  - preparation of the Union procedures, appendices to GVP module III on pharmacovigilance inspections, on the planning, coordination, conduct, reporting, follow-up, sharing of inspection information and documentation of pharmacovigilance inspections.
- **Veterinary medicinal products:**
  - inspections/pharmacovigilance systems.

# 6. Collaboration with the European Commission

- **Human medicinal products:**
  - continue with the work in relation to the ongoing implementation of the new pharmacovigilance legislation (please refer to sections 4 and 5 for further information).
- **Veterinary medicinal products:**
  - preparation of high-level guidance for the conduct of pharmacovigilance inspections as set out in section 2.5 of Volume 9B of the rules governing medicinal products in the European Union for veterinary medicinal products, dealing with topics including the selection of sites for inspection, the coordination, preparation, conduct and reporting of inspections as well as their follow-up and sharing of inspection information.

# 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 GMDP Inspectors Working Group;
  - Committee for Medicinal Products for Veterinary Use (CVMP) and its pharmacovigilance working party (PhV WP);
  - Committee for Medicinal Products for Human Use (CHMP);
  - Pharmacovigilance Risk Assessment Committee (PRAC);
  - Heads of Medicines Agencies;
  - other regulatory agencies;
  - Co-ordination Group for Mutual Recognition and Decentralised Procedures – human and veterinary (CMDh and CMDv);
  - Clinical Trial Facilitation Group (CTFG);
  - external bodies.

# 8. International Cooperation

- Development of contacts between EU and non-EU/EEA agencies on pharmacovigilance matters.