EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 June 2012
EMA/INS/PhV/313103/2012
Compliance and Inspection

Work plan for the Pharmacovigilance Inspectors Working Group for 2012

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 mainly focus on the following areas:

- Preparation for the implementation of the new human pharmacovigilance legislation, including input into the development of guidance documents and processes (human). It is noted that the work in this area will need to continue after the new legislation becomes effective, in July 2012.
- 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 2012:

- 21-22 March 2012
- 24-25 May 2012
- 03-04 October 2012

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8595
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

- 13-14 December 2012

The following meetings will take place this year:

- Human medicinal products: Approximately monthly meetings (remote access provided) have been scheduled of the Audits/Inspections project team for the implementation of the new pharmacovigilance legislation, including PhV IWG and PhV WP delegates, to discuss draft documents and specific topics, in particular items to support the implementation of the new pharmacovigilance legislation.
- 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 possible.

3. Inspections conducted in support of the centralised procedure

- Implementation of the 2012 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

- Concerning human medicinal products, the group will focus on the preparation of the following documents in 2012:
  - In relation to the work on the implementation of the new pharmacovigilance legislation, preparation of community 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.
  - 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.
  - Distant/Virtual pharmacovigilance inspections of MAHs during a crisis situation – Points to consider.
  - Guidance on pharmacovigilance inspection of MAHs of pandemic influenza vaccines.
- The following documents, concerning veterinary medicinal products, will be developed and are expected to be finalized in 2012:
  - SOP on the follow-up of pharmacovigilance inspections by EMA for veterinary medicinal products.
  - Record-keeping and archiving of documents obtained or resulting from the pharmacovigilance inspections.

- Recommendations on the training and experience of inspectors performing pharmacovigilance inspections.
- 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 (PhV Inspection Training course – Copenhagen, 11-13 April 2012).
- Conduct a EudraVigilance and Eudravigilance Data Analysis System/Data Warehouse training for pharmacovigilance inspectors (Human and Veterinary).
- 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 preparation of the following Good Vigilance Practice Guideline modules.
    - GVP Module I - Pharmacovigilance systems and their quality systems.
    - GVP Module II - Pharmacovigilance System Master File.
    - GVP Module III – Pharmacovigilance Inspections.
    - GVP Module IV - Pharmacovigilance System Audits.
  - Contribution to the document describing the role of the Pharmacovigilance Risk Assessment Advisory Committee (PRAC), in relation to pharmacovigilance inspections.
  - 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.
- **Veterinary medicinal products:**
  - Inspections/Pharmacovigilance Systems.

6. Collaboration with the European Commission

- **Human medicinal products:**
  - Continue with the work in relation to the 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 respectively, dealing with topics including the selection of sites for inspection, the coordination, preparation, conduct and reporting of inspections as will 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 IWG,
  - CHMP, CVMP and respective Pharmacovigilance Working Parties,
  - Pharmacovigilance Risk Assessment Advisory Committee (PRAC), as of July 2012.
  - 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.