EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 January 2014
EMA/INS/PhV/555137/2013
Compliance and Inspection

Work plan for the Pharmacovigilance Inspectors Working Group for 2014

1. Introduction

The Pharmacovigilance Inspectors Working Group (PhV IWG) was established by the European Medicines Agency (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 medicinal 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:

- continue with the implementation of the new human pharmacovigilance legislation, including the finalisation and publication of the Union procedures on pharmacovigilance inspections, implementation of the pre-authorisation inspections new requirement and input into the development of other guidance documents and processes (human);
- initiate the work on the implementation of the new legislation for veterinary medicines (veterinary);
- 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 2014:

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
An agency of the European Union

- 20-21 March 2014;
- 05-06 June 2014;
- 25-26 September 2014;
- 04-05 December 2014.

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

- human medicinal products:
  - *ad-hoc* teleconferences/meetings of the subgroups working on the finalisation of the Union procedures on pharmacovigilance inspections that complement the good vigilance practice guideline (GVP) module III on pharmacovigilance inspections,
  - *ad-hoc* teleconferences/meetings with PRAC delegates/assessors will be scheduled (remote access provided), when necessary, in relation to the implementation of the new pharmacovigilance legislation and specifically to discuss practical aspects of the new legislation (i.e. pre-authorisation inspections) and familiarise assessors with the Union procedures on pharmacovigilance inspections,
  - *ad-hoc* participation in PRAC meetings (remote access available) to discuss the outcome and follow up of specific PhV inspections, as necessary;
- veterinary medicinal products: a number of subgroup teleconferences/meetings (e.g. PhV IWG - Pharmacovigilance Working Party (PhV WP)) to discuss topics of interest and draft documents will be organised in the margins of the plenary meetings, when necessary.

3. Sharing of information and coordination of pharmacovigilance inspections

- Implementation of the 2014 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 (PRAC, CHMP and CVMP).
- Implementation of the proposal to use the Agency's managing meeting documents system (MMD) to improve the process for sharing of pharmacovigilance inspections information (planned and conducted inspections, third country inspections and inspection outcome) between the Agency, the Members States (inspectors and assessors) and the European Commission.

4. Harmonisation topics

Procedures and guidance documents

- Concerning human medicinal products, the group will focus on the preparation and/or completion of the following documents in 2014:
  - in relation to the work on the implementation of the new pharmacovigilance legislation, finalisation and publication of Union pharmacovigilance inspection procedures as listed below:
    - Union procedure on the coordination of EU pharmacovigilance inspections

        - Union procedure on the preparation, conduct and reporting of EU pharmacovigilance inspections
        - Union procedure on the sharing of information on EU pharmacovigilance inspections
        - Union procedure on the management of pharmacovigilance inspection findings which may significantly impact the benefit/risk profile of the concerned medicinal products
        - Union guidance on document retention and record keeping for PhV inspections
        - Union recommendations on the training and experience of inspectors performing pharmacovigilance inspections,
    - finalisation of the guidance on pharmacovigilance inspections of marketing authorisation holders of pandemic influenza vaccines;
- Concerning veterinary medicinal products, the group will focus on:
    - finalisation of the guidance on triggers and risk factors for selection of sites/prioritisation for pharmacovigilance inspection,
    - further harmonisation of pharmacovigilance inspections between member states, including revision of the classification of inspection findings,
    - revision of existing inspection procedures and guidance for pharmacovigilance inspections for medicinal products for veterinary use conducted in the context of the centralised procedure to include the latest developments, as applicable;
- 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.
- Conduct eudravigilance and eudravigilance data analysis system/data warehouse training for pharmacovigilance inspectors (human and veterinary).
- Conduct data analysis workshop(s) (pharmacovigilance data in excel) for pharmacovigilance inspectors (human and veterinary), as necessary.
- Familiarise the Pharmacovigilance Risk Assessment Committee (PRAC) members with 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.
- Continue with the conduct of pharmacovigilance inspectors training in good vigilance practice and new processes, within the scheduled PhV IWG meetings for 2014.
- 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, including interaction with industry on topics of common interest.
- Follow up on the proposals for training within the PIC/S Working Group(s) ("WG") on good clinical practice & pharmacovigilance ("GVP") in accordance with the agreed mandate.

5. Pharmacovigilance topics

- **Human medicinal products:** continue the work in relation to the implementation of the new human pharmacovigilance legislation:
  - finalisation and publication of the Union pharmacovigilance inspection procedures listed in section 4 above,
  - 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 and the contact details of the qualified person responsible for pharmacovigilance *(entry and maintenance of information within the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD)*
    - pharmacovigilance inspection information sharing
    - categorisation of pharmacovigilance inspection findings identified in CHMP/PRAC requested inspections coordinated by EMA for entry into the EMA Corporate GxP database,
  - contribution to the preparation of specific guidance, as applicable, in relation to:
    - handling of non-serious cases from non-interventional studies
    - patient support programmes and market research programmes reporting requirements
    - off-label use requirements
    - management of deviations and implementation of the associated corrective and preventive actions listed in the Pharmacovigilance System Master File (PSMF),
- **Veterinary medicinal products:**
  - inspections / pharmacovigilance systems,
  - contribution to the preparation of specific guidance on the use of EMA databases and IT systems in relation to:
    - pharmacovigilance inspection information sharing
    - categorisation of pharmacovigilance inspection findings identified in CVMP requested inspections coordinated by EMA for entry into the EMA Corporate GxP database.

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.
  - Contribute in the preparation for implementation of the revised legislation for veterinary medicinal products, expected to be published in 2014, in relation to pharmacovigilance inspections, as necessary.

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 (HMA),
  - 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, as appropriate.

8. International cooperation

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