EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Compliance and Inspection

# Work plan for the Pharmacovigilance Inspectors Working Group for 2016

## 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 human pharmacovigilance legislation, including the implementation of the common repository to further facilitate sharing of information on planned and conducted pharmacovigilance inspections, the implementation of pre-authorisation inspections, revision of existing guidance based on the experience gained to date, 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);
- continue the work on the risk-based inspection planning and follow-up processes (veterinary);
- inspectors and assessors collaboration and training;
- engage with stakeholders on topics of common interest.

## 2. Meetings

The following meetings are scheduled in 2016:

- 17-18 March 2016;

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- 09-10 June 2016;
- 22-23 September 2016;
- 24-25 November 2016.

Meetings include a joint session and two separate sessions, one dedicated to human and one to veterinary medicinal products only.

The following joint meetings will take place:

- joint meeting with stakeholders with focus on pharmacovigilance inspections and the implementation of the pharmacovigilance legislation in the last 3 years.

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

- human medicinal products:
  - *ad-hoc* teleconferences/meetings with Pharmacovigilance Risk Assessment Committee (PRAC) delegates/assessors will be scheduled (remote access provided), when necessary, in relation to the implementation of the pharmacovigilance legislation and specifically to discuss practical aspects (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 pharmacovigilance 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 2016 risk-based programme for routine pharmacovigilance inspections of marketing authorisation holders connected with human and veterinary centrally authorised products (CAPs).
- For cause inspections at the request of the scientific committees for human and/or veterinary medicinal products (PRAC, CHMP and CVMP).
- Continue with the 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

## *4.1. Procedures and guidance documents*

- Concerning human medicinal products, the group will focus on the preparation and/or completion of the following documents in 2016:

- in relation to the work on the implementation of the pharmacovigilance legislation, finalisation or revision and publication of GVP and Union pharmacovigilance inspection procedures as listed below:
  - Union guidance on pre-authorisation pharmacovigilance inspections,
  - Union guidance on routine pharmacovigilance inspection follow up (including corrective and preventive action (CAPA) follow up),
  - revision of GVP Module II on pharmacovigilance system master file, as necessary,
  - revision of GVP Module III on pharmacovigilance inspections, as necessary,
  - revision of the Union procedures on pharmacovigilance inspections, as necessary;

- Concerning veterinary medicinal products, the group will focus on:
  - finalisation of the triggers and risk factors for selection of sites/prioritisation for pharmacovigilance inspection and inclusion in existing guidance;
  - further harmonisation of pharmacovigilance inspections between Member States;
  - 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;
  - finalisation of an aide memoire for pharmacovigilance inspections for medicinal products for veterinary use conducted in the context of the centralised procedure.
- 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.

## *4.2. 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 2016, as necessary.
- 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 Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) Working Group(s) (WGs) 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 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 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 procedures and pharmacovigilance systems.
  - Contribution to the preparation of aide memoire for pharmacovigilance inspections for medicinal products for veterinary use conducted in the context of the centralised procedure.
  - 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 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 to the preparation of the revised legislation for veterinary medicinal products, 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:
  - Good Clinical Practice (GCP) and Good Manufacturing Practice/Good Distribution Practice Inspectors Working Group (GMDP IWG);
  - 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);
  - Strengthening Collaborations for Operating Pharmacovigilance in Europe (SCOPE) team of Work Package (WP) 7: Quality Management System, with focus on the area of interaction between assessors and inspectors, best practices, proposals for improvement and training requirements (WP 7.3);
  - external bodies, as appropriate.

# 8. International cooperation

- Development of contacts between EU and non-EU/EEA agencies on pharmacovigilance matters.
- Enforce the existing links with the PIC/S, facilitate joint visits when possible and work towards the development of guidance and harmonisation of standards in the field of pharmacovigilance inspections.