30 March 2010
EMA/INS/PhV/786484/2009
Compliance and Inspection

Work plan for the Pharmacovigilance Inspectors Working Group for 2010

Status: February 2010

1. Introduction

The Pharmacovigilance Inspectors Working Group (PhV IWG) has been established by the EMA within the scope of article 57(1)(i) of Regulation (EC) No. 726/2004. Following a report on the first year of operation, the PhV IWG Mandate has been endorsed by the Heads of Medicines Agencies on 18-19 May 2009 and by the EMA Management Board on 1 October 2009, thereby formally establishing the PhV IWG.

The PhV IWG focuses on harmonisation and co-ordination of PhV 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:

- Develop pre-defined queries from EudraVigilance Data Warehouse to support inspection preparation
- Procedures and processes to ensure harmonisation and mutual recognition
- Work jointly with assessors to identify triggers for inspection and to improve processes for inspection follow-up
- Develop international co-operation in the field of PhV inspection
- Inspectors and assessors training
- Preparation of Good PhV guidance

2. Meetings scheduled for 2010

- 23 February 2010
- 08 June 2010
- 23 September 2010
- 30 November 2010

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A number of subgroup meetings (e.g. PhV IWG - PhV WP) to discuss specific topics and draft documents 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

Development of PhV inspections relating to Centrally Authorised Products

This is an ongoing activity and includes planning of inspections on a risk based approach and coordination of inspections and re-inspections when needed.

Maintenance of the information on PhV inspections for Centrally Authorised Products.

To develop the PhV module of the Corporate GxP database for the coordination of PhV inspections for Centrally Authorised Products.

4. Harmonisation topics

Procedures and Guidance documents

To prepare or review, as applicable, inspection procedures and guidance for PhV inspections for medicinal products for human use conducted in the context of the Centralised Procedure and in particular:

- Triggers and risk factors for selection of sites for PhV inspection and its revision as required
- Guideline on communication of inspection findings and information sharing process after the completion of a PhV inspection
- Guideline on follow up and actions to be taken after the completion of a PhV Inspection
- EMA internal SOP on Coordination of post-approval PhV Inspections
- Other procedures as required

To prepare and publish inspection procedures and guidance for PhV, for veterinary medicinal products inspections conducted in the context of the Centralised Procedure and in particular:

- Triggers and risk factors for selection of sites for PhV inspection and its revision as required
- Guideline on communication of inspection findings and information sharing process after the completion of a PhV inspection
- Guideline on follow up and actions to be taken after the completion of a PhV Inspection
- EMA internal SOP on Coordination of post-approval PhV Inspections
- Pre-submission instructions and template for the “Detailed description of the PhV system” (DDPS) document for veterinary medicinal products
- Assessors’ checklist in relation to the DDPS document assessment
- Other procedures as required

Joint Inspections

To continue with joint inspections of sites involving inspectorates from more than one National Competent Authority.

Training and development

- Develop peer review of case studies
- Sharing and discussion of inspection reports, including grading of anonymised findings
- Develop and monitor opportunities for joint inspections
- Provision of on job training and a process for ensuring that all members gain experience through this
- 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
- Conduct a PhV IWG Training Course
- Conduct a EudraVigilance and Eudravigilance Data Analysis System training for PhV Inspectors

5. Pharmacovigilance topics

- Maintenance of the priority based strategy for the scheduling of inspections for medicinal products for human use and for veterinary use
- Preparation and monitoring of the yearly programme for routine PhV inspections, using the priority based strategy with focus on centrally authorised products but taking into account the relevance of these inspections to Mutual Recognition/Decentralized products as well
- Develop the processes for sharing information (what, when, how and what to do with it) in support of the inspection process and programme and for interaction between PhV inspectors and assessors and promote inspections via increased communication
- Provide recommendation to the PhV WP and PhV inspectors in relation to PhV inspection or related assessment issues
- Identification of training needs for PhV inspectors and assessors (e.g. gradings and interpretation of findings, assessment of the Detailed description of the PhV system…etc.)
- Support the development of guidelines for the assessment of the “Detailed description of the PhV system” (DDPS) that is submitted in Marketing Authorization Applications and suggest the relative input of assessors and inspectors to this process
- Preparation of pre-defined queries from Eudravigilance Data Analysis System to facilitate PhV inspection preparation

6. Collaboration with the European Commission

- Development and agreement by consensus of PhV inspections related guidelines for submission to the European Commission for adoption

- Development, agreement by consensus and maintenance of high-level procedures for the conduct of PhV 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 will as their follow-up. Agreed procedures will be submitted for adoption by the European Commission
- Discussions on practical implementation of PhV guidelines, common interpretation of guidelines and harmonisation of PhV inspection approaches in the EEA
- Development, implementation and monitoring of plans for implementation/operation of MRAs and other similar Community arrangements, if applicable
- Formulating advice and comment on issues related to PhV inspections including draft legislation to the European Commission
- Providing advice to and liaising with the human and veterinary PhV WPs for the development of implementing texts for PhV on matters relating to inspections
- Development and agreement by consensus of other documents within the framework of PhV guidelines and related documents in connection with inspections such as Reflection Papers and Questions and Answers to be published on the EMA website

7. Liaison with other groups

GCP and GMP IWG

- To maintain a dialogue with these two groups on areas identified of common interest

CHMP, CVMP and respective Pharmacovigilance Working Parties

- Advising on and developing procedures for the coordination of inspections requested by the Scientific Committees – these procedures are published by the EMA
- Formulating advice and comment on PhV related issues to the scientific committees and their working parties
- Liaison with the human and veterinary PhVWPs, CHMP and CVMP, and other EMA or scientific committee working parties as applicable on matters of mutual interest

Heads of Medicines Agencies

- When requested, formulating advice and comment on PhV inspections related issues to HMA and its working groups
- When requested, formulating advice and comment on PhV inspections related issues to the Coordination Groups for Mutual Recognition and De-centralised Procedures (CMD (h&v))
- Contribution to the development of the Benchmarking of European Medicines Agencies with respect to those elements related to PhV inspections
- Liaison and co-operation with the Working Group of Enforcement Officers (WG EO) on specific issues

Other Regulatory Agencies

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

External bodies

- Liaison and cooperation on matters of mutual interest with international bodies. In particular: The World Health Organisation (WHO), the Pharmaceutical Inspection Cooperation Scheme (PIC/S), and International Conference on Harmonisation (ICH) as well as MRA partners and key regulatory authorities
- Liaison with interested parties (EFPIA, EuropaBio, EGA, AESGP, ISPE, ISOP, IFAH-Europe, EGGVP and other specific interested groups)