European Medicines Agency
Inspections

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WORK PLAN FOR

AD HOC PHARMACOVIGILANCE INSPECTORS WORKING GROUP (PhV IWG) FOR 2009

STATUS: March 2009

1. INTRODUCTION

The Ad hoc Pharmacovigilance Inspectors Working Group (PhV IWG) has been established by the EMEA in 2008, within the scope of article 57(1)(i) of Regulation (EC) No. 726/2004.

The PhV IWG will address all matters related directly or indirectly to Pharmacovigilance (PhV) inspections and the priorities of the group will be mainly focus on the following areas also indicated in section 3 and 4 of this document:

- Procedures and processes to ensure harmonisation and mutual recognition
- Communication of inspection findings
- Exchange of information
- Inspectors training

2. MEETINGS SCHEDULED FOR 2009

- 11 March 2009
- 16 June 2009
- 23 September 2009
- 08 December 2009

A number of subgroup meetings (e.g. Ad Hoc Pharmacovigilance Inspectors Working Group or Pharmacovigilance Working Party) 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 meetings or teleconferences will be organised.

3. INSPECTIONS CONDUCTED IN SUPPORT OF THE CENTRALISED PROCEDURE

Development of Pharmacovigilance inspections relating to centralised 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 Pharmacovigilance inspections for Centrally Authorised Products.

To develop a new database to enter the information on PhV inspections for Centrally Authorised Products (CAPs).

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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:

- Procedure on triggers and risk factors for selection of sites for PhV inspection and its revision as required.
- Guideline on communication of inspection findings and the actions to be taken after the completion of a PhV inspection.
- 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:

- Procedure for coordinating PhV inspections requested by CVMP.
- Procedure for conducting PhV inspections requested by CVMP.
- Procedure for reporting PhV inspections requested by CVMP.
- Procedure for the preparation of a risk-based programme for routine PhV inspections of MAHs connected with CAP products.
- Guideline on triggers and risk factors for selection of sites for PhV inspection and its revision as required.
- Guideline on communication of inspection findings and the actions to be taken after the completion of a PhV inspection.
- 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.

5. PHARMACOVIGILANCE TOPICS

- Maintenance of the priority based strategy for the scheduling of inspections for medicinal products for human use.
- Preparation of a priority based strategy and inspection programme for veterinary medicinal products.
- 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 for promoting inspections via increased communication.
- Provide recommendation to the PhV WP and PhV IWG in relation to PhV inspection or related assessment issues.
- Preparation of pre-assessment instruction and template for the requirements of the DDPS for MAHs of veterinary medicinal products.
- Support the development of guidelines for the assessment of the "Detailed description of the PhV systems" that is submitted in Marketing Authorization Applications and suggest the relative input of assessors and inspectors to this process.
- 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.).

6. COLLABORATION WITH 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 EMEA website.

7. LIAISON WITH OTHER GROUPS

GCP and GMP IWG

- To maintain a dialogue with GCP and GMP Inspectors on areas identified of common interest.

CHMP, CVMP and respective PhV WPs

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

Heads of Medicines Agencies (HMAs)

- 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 third 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) and Veterinary Use (VICH) 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).

Communication with the public and external bodies

- The PhV IWG will regularly communicate details of its work to external organisations and the general public using appropriate vehicles including in particular the EMEA and HMA websites. Appropriate opportunities will be taken through international training courses and conferences to communicate on PhV inspections.