European Medicines Agency

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Mandate of the Ad Hoc Pharmacovigilance Inspectors Working Group

Background note

A proposal for the establishment of an Ad Hoc Pharmacovigilance Inspectors Working Group was endorsed by the Heads of Medicines Agencies in January 2008, and agreed by the EMEA Management Board in April 2008, with 2 joint meetings per year (inspectors of medicinal products for Human use and of medicinal products for Veterinary use) and 2 meetings involving only inspectors of medicinal products for Human use. At that time it was agreed to operate the group as an Ad Hoc group for the first year and to come back to HMA and to this Management Board with a report on the first year of operation and a proposal for the continued functioning of the group.

The document attached is the mandate for the PhV IWG and is aligned with those previously adopted for the GCP IWG and GMP/GDP IWG. The document circulated now to this Management Board has been previously agreed in September 2008 by the Ad Hoc PhV IWG, in November 2008 by the Human & Veterinary PhV WPs, respectively, in November 2008 by the CHMP and in January 2009 by the CVMP. It has also been endorsed by the Head of Medicines Agencies in July 2009.

The PhV IWG is made up of inspectors from the EU/EEA MSs dealing with human and veterinary products. This mandate provides the background for the creation of this group, the objectives and the interaction with other parties, the composition of the group and the rules of the procedure (responsibilities, organization of the meetings, drafting groups etc.).

Matters for consideration

During its discussion at the HMA in July 2009 it was agreed to run all the group meetings as joint meetings of inspectors of medicinal products for Human use and of medicinal products for Veterinary use. The arrangement in the first year (with 2 joint and 2 Human product “only” inspection meetings) leads to disjointed development of processes and documents, missed opportunity for sharing of experience, and repetition of discussion of some issues, or delay in progression of some topics/documents. The mandate has been adapted in section IV to reflect this, but is otherwise the same text as that submitted to HMA in July 2009.

A report of the progress of the group in its first year is also circulated for information and there is also a public report on the first year of operation on the EMEA website.

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DRAFT MANDATE, OBJECTIVES AND RULES OF PROCEDURE FOR THE PHARMACOVIGILANCE INSPECTORS WORKING GROUP

I. GENERAL CONSIDERATIONS

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.

Since September 2006, the GCP IWG has dedicated one additional day from two of their regular quarterly meetings to the discussion of pharmacovigilance (PhV) inspection issues (i.e. one day each in Sep 2006 and Feb and Sep 2007). With the introduction of the revised pharmaceutical legislation and increasing use of pharmacovigilance inspection by regulators the inspectors recommended that a working group dedicated to pharmacovigilance inspection should be set up. A proposal for the establishment of an Ad hoc Pharmacovigilance Inspectors Working Group was endorsed by the Heads of Medicines Agencies in January 2008, and agreed by the EMEA Management Board in April 2008.

The guideline on monitoring of compliance with pharmacovigilance regulatory obligations and pharmacovigilance inspections for human medicinal products (chapter I.2 of Volume 9A of The Rules Governing Medicinal Products in the European Union) and for veterinary medicinal products (published as a standalone guideline under Volume 9B of The Rules Governing Medicinal Products in the European Union) describes the PhV inspection process and clearly indicates the involvement of the inspectors' group in sections 2.4 and 5, respectively:

2.4.11

"*The Agency will establish procedures for the administration and review of inspection requests and reports in conjunction with the CHMP and relevant Pharmacovigilance and Inspectors' Working Parties.*

2.4.12

Procedures for pharmacovigilance inspection will be prepared by the Good Clinical Practice (GCP) Inspection Services Group in association with pharmacovigilance inspectors and representatives of the Pharmacovigilance Working Party and will be updated as needed."

5.11

"*The Agency will establish procedures for the administration and review of inspection requests and reports in conjunction with the CVMP and relevant Pharmacovigilance and Inspectors' working parties.*"

5.12

"*Procedures for pharmacovigilance inspection will be prepared in association with Pharmacovigilance inspectors and representatives of the Pharmacovigilance Working Party and will be updated as needed. These procedures will be adopted and published in line with the policies and procedures of the Agency on such documents.*"

Thus, the PhV IWG will address all matters related directly or indirectly to PhV inspections and carry out the tasks described under section II. The key to its role is the development and implementation of procedures and processes to ensure harmonisation and mutual recognition, within the EU, of a high standard of PhV inspection and harmonisation with the wider membership of the group.
The group will address inspection related pharmacovigilance issues in conjunction with the Pharmacovigilance Working Parties (human and/or veterinary, as applicable).

II. MANDATE AND OBJECTIVE

The PhV IWG provides input and recommendations on all matters relating directly or indirectly to the preparation, conduct and follow up of PhV inspections in the context of post-authorisation processes and irrespective of the marketing authorisation procedure. Its main goals are to promote an effective management of PhV inspections in the Community, to establish proficient communication and information exchange and to provide input into PhV legislation preparation.

Co-operation 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 the guideline on monitoring of compliance with pharmacovigilance regulatory obligations and pharmacovigilance inspections for veterinary medicinal products published as a standalone guideline under 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 well 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 or having an impact on PhV inspections including draft legislation to the European Commission.
- Providing advice to and liaising with the human and veterinary PhV Working Parties (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.

Co-operation with EMEA

- 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 GCP IWG, Good Manufacturing Practice (GMP) Inspectors Working Group, the human and veterinary PhV WPs, CHMP and CVMP, and other EMEA or scientific committee working parties as applicable on matters of mutual interest.

Co-operation with 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.

Training

- To promote and actively contribute to training of inspectors and the development of harmonised procedures and practices through training programmes and joint inspections.
- Increase shared experience through review of (anonymous) inspection reports and findings. Discussion of problem issues/case reports.

Co-operation with other 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), the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (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 Pharmacovigilance Inspectors Working Group 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.

III. COMPOSITION AND RULES OF PARTICIPATION

Chairmanship

Meetings will be chaired by a representative of EMEA inspections Sector or delegate. Members may request, for specific topics coming under the heading of cooperation with HMA that a co-chair is appointed from within the members. Appointment of the co-chair will be by consensus of the members or, if necessary, using the voting rules described in section VI.4.

Membership

Membership is composed of experts nominated by the relevant national authority for human and/or veterinary medicinal products with senior responsibility and broad experience in the area of PhV inspections. A replacement delegate, who would participate in those exceptional cases where the nominated member is unable to attend the meeting, may also be nominated.

Meeting documentation will be distributed by EMEA to all members and any nominated replacements.

There will be one member from each of the EEA Member States with one additional member from each Member State where there is a separate PhV inspectorate for human and for veterinary medicinal products. Members from EU Member States will be reimbursed for attendance at meetings. Additional staff of the authorities may attend with the chairman's agreement, in particular where their participation is needed for a specific topic. The European Commission – DG Enterprise and Industry will also be invited to send a representative to meetings.

The Executive Director of the Agency and members of EMEA secretariat may attend all meetings.

Observers

Observers may include the representatives of EU accession countries.

Specific confidentiality rules will apply to observers. Observers attend at the discretion of the chairman, in line with EMEA policy on observers, and may not be involved when particular items of concern to EU/EEA member states are discussed, product specific matters or other confidential matters.

Observers are encouraged to participate freely in discussions but shall not take part in any decision-making process.

Other observers may participate with the agreement of the chairperson in consultation with the group where possible, in line with EMEA policy on observers.

IV. MEETING FREQUENCY

The Pharmacovigilance Inspectors Working Group shall meet at least four times per year. Additional meetings may be held when planned for specific reasons such as training. The dates of the meetings shall be included in the work plan. Some meetings or parts of the meetings may involve joint activities with other working groups. Drafting groups will conduct the majority of their business by correspondence and teleconference but upon reasoned request meetings will be organised by EMEA usually in the margins of the plenary meeting of the Pharmacovigilance Inspectors Working Group.

V. DURATION OF ACTIVITY

Not applicable.

VI. RULES OF PROCEDURE

1. Responsibilities of Chairperson
The Chairperson is responsible for the efficient conduct of the business of the Pharmacovigilance Inspectors Working Group and shall in particular:

- Plan the work of PhV Inspectors Working Group;
- Monitor that the rules of procedure are respected;
- Ensure that at the beginning of each meeting that any potential conflict of interest is declared regarding any particular item to be discussed;
- Aim to achieve consensus on issues discussed;
- Decide in exceptional cases, when a vote is necessary;
- Ensure, the regulatory and scientific consistency of recommendations;

- Co-ordinate the work of PhV Inspectors Working Group with that of the Agency's Scientific Committees, Working Parties and other relevant groups of EMEA, the Heads of Medicines Agencies or the European Commission;
- Report on the activities of PhV Inspectors Working Group to the Agency's Scientific Committees, Working Parties and other relevant groups of EMEA, the Heads of Medicines Agencies or the European Commission as appropriate.

2. Responsibilities of EMEA Secretariat

The EMEA Secretariat shall provide technical, scientific legal, regulatory and administrative support to the Pharmacovigilance Inspectors Working Group. This includes the following:

- Prepare for and co-ordinate the work of the PhV Inspectors Working Group;
- Organise meetings and ensure timely circulation of meeting documents;
- Facilitate the necessary contacts between the PhV Inspectors Working Group and other bodies;
- Ensure adequate co-ordination of the work carried out by the PhV Inspectors Working Group and other concerned groups;
- Contribute to the overall quality assurance and assurance of scientific and regulatory consistency of the documents/recommendations of the PhV Inspectors Working Group;
- Prepare the agenda, table of actions and summary records of meetings;
- Communicate, in a pro-active manner, any output of the PhV Inspectors Working Group to the interested parties;
- Transmit any recommendations of the PhV Inspectors Working Group to the relevant body for adoption and/or publication as appropriate.

3. Responsibilities of Members

Membership implies a commitment to actively participate in the work of the Pharmacovigilance Inspectors Working Group and to regularly attend the meetings.

- Members shall ensure that they communicate the views of the Member State, which they represent when contributing to discussions and decisions.
- Members shall ensure that all agreements are communicated within their Member State and should ensure that necessary steps are taken to act upon decisions as appropriate.
- Members may identify and propose topics for consideration by the PhV Inspectors Working Group. Any proposal should be supported by a problem statement or other adequate justification.
- Members tabling documents for discussion at meetings of the Pharmacovigilance Inspectors Working Group shall respect the guidelines prepared by the group for this purpose or the relevant Community guidelines.
- Members shall observe deadlines for the submission of documents to EMEA to allow for timely distribution of documents to other members in order to enable them to establish the position of the Member State that they represent.

4. Organisation of meetings

- The meetings will be held and meeting minutes prepared in English.
- The draft agenda for every meeting shall be circulated, together with the relating documents, by the EMEA Secretariat, in consultation with the chairperson, at least 14 calendar days before the meeting.
- When a Member of the PhV Inspectors Working Group is unable to participate in a meeting or a part of the meeting, or in a discussion topic due to a conflict of interest, he/she must inform the Secretariat in writing in advance.

- The PhV Inspectors Working Group shall prepare and agree an annual work plan. The work plan shall be reviewed regularly and updated as necessary.
- A quorum is required for all decisions or recommendations of the PhV Inspectors Working Group. This shall be reached when two thirds of the total members of the PhV Inspectors Working Group are present.
- Whenever possible, decisions or recommendations of the group shall be taken by consensus. If such a consensus cannot be reached, the chair or any member may propose a vote. Each Member State shall have 1 (one) vote. An absolute majority (i.e. favourable votes by at least half of the total number of members eligible to vote plus one) will be required. Divergent positions shall be mentioned in the summary record of the meeting.
- Prior to any vote the group will agree, depending on the nature of the topic, whether any members should not participate in the vote.

5. Drafting Groups

When further consideration is required in order to prepare proposals on specific topics drafting groups may be convened constituted of members of the PhV Inspectors Working Group or other experts, as appropriate.

The drafting group will report to the PhV Inspectors Working Group.

Rules of procedure for drafting groups will be developed.

6. Guarantees of independence

The members of the PhV Inspectors Working Group and experts referred to above shall not have any direct interests in the pharmaceutical industry that could affect their impartiality. They shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of their financial interests. All indirect interests, which could relate to the pharmaceutical industry, shall be entered in a register held by the Agency, which is accessible to the public, on request at the Agency's office.
Members and experts attending meetings shall declare at the beginning of each meeting any specific interests, which could be considered to be prejudicial to their independence with respect to the points of the agenda. These declarations shall be made available to the public.

The specific provisions for handling declarations of interests and confidentiality undertakings as defined in the EMEA Policy on the Handling of Conflicts of Interests for Committee Members and Experts, adopted by the Management Board (EMEA/H/31653) are applicable to members of the PhV Inspectors Working Group and experts participating in the activities of the PhV Inspectors Working Group.

7. Code of conduct

Members of the PhV Inspectors Working Group and experts participating in EMEA's activities shall abide by the principles set out in the EMEA Code of Conduct.

8. Contacts with Interested Parties

- Where relevant, the PhV Inspectors Working Group will establish contacts, on an advisory basis, with parties concerned with the manufacture and control of medicinal products.
- The pharmaceutical industry, health care professionals, patients/consumers or other interested parties have the opportunity to comment in writing on draft guidelines and general regulatory developments during the public consultation of the documents.

- When considered appropriate by the PhV Inspectors Working Group, oral or written presentations by interested parties can be made during meetings at earlier stages of development of the guidelines. The PhV Inspectors Working Group may also meet with interested parties to discuss general matters or specific issues.
- In any case, the PhV Inspectors Working Group shall neither conduct any deliberations nor reach any formal decisions in the presence of members of interested parties.
- Before any consultation session, interested party representatives and the PhV Inspectors Working Group members will communicate to the EMEA Secretariat points they would like to discussed, so that a session agenda can be prepared for agreement by Chairperson and circulation by EMEA secretariat.

9. General Provisions

Members of the PhV Inspectors Working Group as well as the observers and all experts shall be bound, even after the cessation of their duties, not to disclose any information, which, by its nature, must be covered by individual professional secrecy. When participating in international or other forums on behalf of the PhV Inspectorss Working Group, members shall ensure that the views expressed are those of the PhV Inspectors Working Group. When participating in international or other forums not specifically on behalf of the PhV Inspectors Working Group, members shall make clear that the views expressed are their own views, or those of the National Competent Authority, independent of the views of the PhV Inspectors Working Group.

AD HOC PhV INSPECTORS WORKING GROUP REPORT ON FIRST YEAR OF OPERATION

1. MEETINGS

The plenary meetings of the Ad Hoc PhV IWG[1] held during the reporting time were in the following dates:

- 11 March 2008 (H&V)
- 20 June 2008 (H)
- 9 September 2008 (H&V)
- 05 December 2008 (H)
- 11 March 2009 (H&V)

The March and September plenary meetings were joint meetings involving inspectors dealing with human medicinal products and inspectors dealing with veterinary medicinal products. The June and December meetings were only human.

The Ad Hoc PhV IWG-PhV WP[2] subgroup did not meet in 2008, however some delegates from the Human and Veterinary PhV WP attended the plenary meetings. A workplan of the this subgroup for 2009 has been agreed by the plenary group in the 2009 March meeting and included as an attachment for information.

2. INSPECTIONS CONDUCTED IN SUPPORT OF THE CENTRALISED PROCEDURE

Development of PhV inspections relating to centralised products

A) Medicinal products for human use

According to the Volume 9A and the guideline on monitoring of compliance with PhV regulatory obligations and PhV inspections of veterinary medicinal products in volume 9B, the CHMP and CVMP, respectively, in conjunction with the Competent Authority of the Member State (MS) in whose territory the MAH's QPPV is located and applicable Pharmacovigilance and Inspectors' Working Parties, will determine a programme for inspection in relation to centrally authorised products (CAPs). These inspections will be prioritised based on the potential risk to public health, the nature of the products, extent of use, number of products that the MAH has on the EEA market and other risk factors.

The focus of these inspections is to determine whether the MAH has the personnel, systems and facilities in place to meet their regulatory PhV obligations for CAPs in the EEA. These inspections will be requested as system inspections with one or more specific products selected as examples, for which specific information can be traced and verified through the various processes. This shall provide a practical evidence for the functioning of the MAH's PhV system in the Community and their compliance with the regulatory requirements.

[1] Pharmacovigilance Inspectors Working Group

[2] Pharmacovigilance Working Party

In general, it is anticipated that national inspection programmes will fulfil the need for the routine inspections of this programme and therefore it is expected that the inspection programme will be achieved mainly through the national programmes. However there will be situations where these inspections might be specifically requested by the CHMP or CVMP, as applicable, (e.g. global PhV sites in third countries). Targeted inspections are also reflected in this programme as they may replace the need for a routine inspection.

The results presented in Table 1 show the number of inspections requested in relation to the 2008 risk-based programme for routine PhV inspections of MAHs connected with human centrally authorised products (CAPs) and split by the type of site inspected, being most of them requested as part of the national programmes and few ones requested by the CHMP.

Table 1- PhV inspections requested in relation to the 2008 risk-based programme for routine PhV inspections of MAHs connected with human centrally authorised products

	QQPV (MAH) site	Global PhV site	QPPV Subcontractor site	Subcontractor site	Total
CHMP Requested	2	5	0	1	8*
National Inspection Programmes	16	0	0	0	16
Total	18	5	0	1	24

*** Note: Inspection of 2 sites requested by CHMP in 2008 will be conducted in 2009**

B) Medicinal products for Veterinary use

The Veterinary PhV inspection programme will be implemented in 2009.

3. HARMONISATION TOPICS

Procedures and Guidance documents

A) Medicinal products for human use

The Ad Hoc PhV IWG has finalized and published the following documents:

- Procedure for coordinating pharmacovigilance inspections requested by the CHMP
- Procedure for conducting pharmacovigilance inspections requested by the CHMP
- Procedure for reporting of pharmacovigilance inspections requested by the CHMP
- Procedure for the preparation of a risk-based programme for routine pharmacovigilance inspections of MAHs connected with human Centrally Authorised Products (CAPs)

The following documents are still pending and will be included in the 2009 Workplan of the group:

- Guideline on triggers and risk factors for selection of sites for PhV inspection and its revision as required.

- Procedure on the actions to be taken after the completion of a PhV inspection.

B) Medicinal products for Veterinary use

The Ad Hoc PhV IWG has finalized and published the following documents:

- 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 CAPs.

The following documents are still pending and will be included in the 2009 Workplan of the group:

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

Joint Inspections

A) Medicinal products for human use

The 8 CHMP PhV inspections requested by the CHMP (see Table 1 in section 2) have been joint inspections involving more than one Member State.

B) Medicinal products for Veterinary use

No CVMP PhV inspections were requested this year.

Training and development

During the Ad Hoc PhV IWG meetings held in the reporting period, discussions on the following topics have taken place:

- Develop peer review of case studies.
- Sharing and discussion of inspection findings.
- Develop and monitor opportunities for joint inspections.

A training course for PhV inspectors has not taken place this year but scheduled for 2009.

4. PHARMACOVIGILANCE TOPICS

A) Medicinal products for human use

The Ad Hoc PhV IWG has prepared and is maintaining the following programme on PhV inspections, which is not publicly available as it contains confidential information:

- Risk-based programme for routine PhV inspections of MAHs connected with human centrally authorised products (CAPs).

The Ad Hoc PhV IWG has also prepared the following documents:

a) For the use of the inspectors

- Preparation of a list of headings for categorization of findings of PhV inspections.

b) In the process to be published in the EMEA external web site:

- Template for the detailed description of the PhV System.

PhV inspectors have also provided recommendation to the PhV WP and Ad Hoc PhV IWG in relation to PhV inspections or related assessment issues.

B) Medicinal products for Veterinary use

The Ad Hoc PhV IWG has prepared and is maintaining the following programme on PhV inspections, which is not publicly available as it contains confidential information:

- Risk-based programme for routine PhV inspections of MAHs connected with veterinary centrally authorised products (CAPs).

The Ad Hoc PhV IWG has also prepared or has under preparation the following documents:

- Preparation of a list of headings for categorization of findings of PhV inspections
- Pre-submission Instructions and Template on the Detailed Description of the Pharmacovigilance System (under preparation)

C) Medicinal products for Human and Veterinary use

The following documents are still pending and will be included in the 2009 Workplan of the group:

- 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.
- 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.

5. COLLABORATION WITH THE EUROPEAN COMMISSION

- The Ad Hoc PhV IWG through the PhV IWG-PhV WP subgroup has contributed to the Detailed Variation Classification Guideline in relation to the classification of variation for the Detailed description of the PhV system.

6. LIAISON WITH OTHER GROUPS

CHMP, CVMP and respective PhV WPs

- Some delegates from the PhV WP have attended the plenary meetings of the PhV IWG in order to improve the communication and interaction between both groups.
- PhV Inspectors (human) have provided recommendations to the PhV WP (human) and attended the PhV WP meetings when needed to explain and discuss inspections findings and further recommendations.

Heads of Medicines Agencies (HMAs)

- The proposal for the establishment of an Ad hoc PhV IWG was endorsed by the Heads of Medicines Agencies in January 2008, and agreed by the EMEA Management Board in April 2008.

Communication with the public and external bodies

- Delegates from the Ad Hoc PhV IWG have participated and given presentations on behalf of the group in different European Conferences, covering different topics of public interest.

For the details of the activities of the Ad Hoc PhV IWG see the Workplan for 2009.

ATTACHMENT 1- SUBGROUP PhV IWG-PhV WP 2009 WORKPLAN

WORK PLAN FOR SUBGROUP OF PhV WP AND PhV INSPECTORS FOR 2009

CHAIRPERSON: Fergus Sweeney

STATUS: March 2009

1. MEMBERSHIP

Membership is composed of 6 PhV inspectors from the PhV Inspectors Working Group (3 Human and 3 Veterinay inspectors) and 6 experts from the Pharmacovigilance Working Party(3 h-PhV WP and and 3 V-PhV WP) with senior responsibility and broad experience in the area of PhV inspections or assessment. A replacement delegate may participate in those exceptional cases where the nominated member is unable to attend the meeting.

Meeting documentation will be distributed by EMEA to all members and any nominated replacements.

2. MEETING FREQUENCY

This sub group will have 1 face to face meeting, which will be organised by EMEA usually in the margins of the plenary meetings of the PhV IWG meetings, and 2 teleconferences per year. Additional meetings or teleconferences may be arranged if needed. Additional preparation and review work will be carried out by email.

Proposals and documents developed by the group should be forwarded for adoption to the PhVWP and/or Inspectors' Working Group as appropriate.

3. TASKS TO BE DEVELOPED BY THE SUBGROUP

- Preparation of a procedure on triggers and risk factors for selection of sites for PhV inspections.
- Procedure for the communication on PhV inspection and findings and on the actions to be taken after the completion of a PhV inspection.