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ANNUAL REPORT OF THE AD HOC PHARMACOVIGILANCE INSPECTORS WORKING GROUP 2008

Adopted by the PhV IWG on 11 March 2009

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1. INTRODUCTION

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

The Ad Hoc PhV IWG focuses on harmonisation and co-ordination of PhV related activities at Community level. The group's role and activities are described in more detail in its Workplan. The group supports the co-ordination of the provision of PhV inspection related advice and provides a link with other groups such as CHMP[2], CVMP[2], and PhVWP (H+V)[3].

The Ad Hoc PhV IWG has decided to publish Annual Reports as part of the process of improving transparency. This document is the first report from this group and is set out in line with the format and objectives of the 2008 Workplan.

2. MEETINGS

The plenary meetings of the Ad Hoc PhV IWG were held in the following dates:

- 11 March 2008
- 20 June 2008
- 9 September 2008
- 05 December 2008

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 subgroup did not meet this year, however some delegates from the Human and Veterinary PhV WP attended the plenary meetings.

3. INSPECTIONS CONDUCTED IN SUPPORT OF THE CENTRALISED PROCEDURE

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 MS[5] in whose territory the MAH's[4] QPPV[5] is located and applicable Pharmacovigilance and Inspectors' Working Parties, will determine a programme for inspection in relation to CAPs[6]. 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[7]. These inspections

[1] Ad Hoc Pharmacovigilance Inspectors Working Group
[2] Committee for Medicinal Products for Human Use
[2] Committee for Medicinal Products for Veterinary Use
[3] Pharmacovigilance Working Party (Human + Veterinary)
[5] Member State
[4] Marketing Authorisation Holder
[5] Qualified Person
[6] Centrally Authorised Products
[7] European Economic Area

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.

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 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 CAPs

	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**

It should be noted that this total (24) is just a part of the total number of PhV inspections conducted in 2008 in EU/EEA (approximately 275 inspections).

B) Medicinal products for veterinary use

The Veterinary PhV inspection programme will be implemented in 2009. However approximately 30 national inspections have been already performed in 2008 in EU/EEA outside of the risk-based programme for routine PhV inspections of MAHs connected with veterinary CAPs.

4. HARMONISATION TOPICS

4.1. Procedures and Guidance documents

A) Medicinal products for human use

The Ad Hoc PhV IWG has finalized and published the following documents in the EMEA external website:

- Procedure for coordinating pharmacovigilance inspections requested by the CHMP
- Procedure for conducting pharmacovigilance inspections requested by the CHMP
- Procedure for reporting pharmacovigilance inspections requested by the CHMP

The Ad Hoc PhV IWG has finalized and in the process to publish the following documents in the EMEA external web site:

- 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.

B) Medicinal products for veterinary use

The Ad Hoc PhV IWG has finalized and in the process to publish the following documents in the EMEA external web site:

- Procedure for coordinating 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 are included in the 2009 Workplan of the group:

a) In preparation since 2008:

- Procedure for conducting PhV inspections requested by CVMP.
- Procedure for reporting PhV inspections requested by CVMP.

b) Outstanding:

- 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.

4.2. 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 MS.

B) Medicinal products for veterinary use

No CVMP PhV inspections were requested this year.

4.3. Training and development

During the Ad Hoc PhV IWG meetings held in 2008, 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.

5. 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 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 CAPs.

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

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

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.

6. COLLABORATION WITH THE EUROPEAN COMMISSION

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

7. LIAISON WITH OTHER GROUPS

CHMP, CVMP and respective PhV WPs

- Some delegates from the PhV WP have attended the plenary meetings of the Ad Hoc 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.