European Medicines Agency
Veterinary Medicines and Inspections

EMEA WORKSHOP ON PHARMACOVIGILANCE
PHARMACOVIGILANCE SYSTEMS AND INSPECTIONS
4 DECEMBER 2007 AT 9:00-13:00
4TH FLOOR, ROOM 4A, EMEA, LONDON
Chairperson: K. Grein

REPORT

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The workshop on Pharmacovigilance Systems and Inspections concerning veterinary medicinal products was arranged by the Agency on 4 December 2007 following the publication of the Guideline on Monitoring of Compliance with Pharmacovigilance Regulatory Obligations and Pharmacovigilance Inspections for Veterinary Medicinal Products[1] by the European Commission in April 2007. The guideline has been developed to assist applicants and Marketing Authorisation Holders (MAHs) of veterinary medicinal products in understanding the expectations of competent authorities with regard to the format and content of the detailed description of the pharmacovigilance system (DDPS). The guideline also sets out criteria for the arrangement and conduct of pharmacovigilance inspections and other monitoring of compliance with their pharmacovigilance obligations under the current legal framework.

The aim of the workshop was to convene regulatory and industry experts in pharmacovigilance systems to express expectations on the implementation of the legal requirements and to share experiences to date. Furthermore, the workshop was designed to give an opportunity to clarify the scope of the legal provisions and the details of the guidance, as applicable.

Veterinary industry and the National Competent Authorities responded well to the open invitation[2] published on the Agency's website and promoted to the industry by the IFAH-Europe secretariat. The workshop convened a total number of 60 delegates, including Qualified Persons for Pharmacovigilance (QPPV).

The presentations on the guideline, current experiences in the veterinary pharmacovigilance field and the inspections of the pharmacovigilance (see programme[3]) were given by representatives of the Agency, MS competent authorities and IFAH-Europe[4]. These were followed by intense discussions amongst the delegates.

The issues raised during the discussion are summarised below.

- The guideline aims to clarify the necessary elements of a pharmacovigilance system, including the means for reporting adverse reactions and the required proof of the availability of the services of the QPPV. For centrally authorised products, results show that in 2007, approximately 30% (4 of 14) of the DDPSs were compliant with the guideline. The main deficiencies relate to the presentation of written procedures for pharmacovigilance activities and to the required MAH and QPPV statements, as well as the presentation on organisational issues and quality management systems.

- The DDPS should describe the pharmacovigilance system at MAH level for each MA application. Any product specific information may be collected in an appendix to the DDPS. Industry and authority representatives also expressed the wish to consider introducing a Master file concept that would be valid for all marketing authorisation applications.

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- In the current system all elements included in the DDPS become part of the Marketing Authorisation (MA). Therefore, all later changes to the DDPS would be subject to Type II variations under the current legal provisions for variations (See guideline). To reduce the need for these variations, the MAHs were advised to focus on the elements required by the regulations. A document that highlights the required elements and provides guidance regarding the level of required information was circulated during the meeting. A need for proportionality in legal requirements was stressed, in view of the current revision of the variation regulations.

- A proposal was made for more detailed guidance on the structure and contents of a DDPS, as well as for a harmonised checklist, for validation of the DDPS. This was with a view to facilitating the preparation of the DDPS and to assist in harmonising the optimal, but still adequate and practical, contents of a DDPS,. This would also contribute to harmonisation of the assessment of the DDPS across authorisation procedures, including central and national procedures.

- At present, less than 50% of NCAs conduct inspections on pharmacovigilance systems. Training has been organised for NCA inspectors within the scope of medicinal products for human use, with occasional attendance of veterinary inspectors.

- A need for clarification of the scope and objectives of inspections of the MAH's pharmacovigilance systems was identified, with the aim of reaching a harmonised understanding of these between stakeholders and within the European regulatory network. It was agreed that the objectives for GMP(GCP) and pharmacovigilance system inspections are different. However, when necessary during GMP (GCP) inspections, parts of pharmacovigilance systems may, however, be inspected.

- Regarding the more practical aspects relating to the conduct of inspections, there is a need for a common language for efficient communication between the MAHs and inspectors. Some MAHs felt that the differences in the size of their enterprises, in comparison to e.g. MAHs for medicinal products for human use, should be acknowledged in the expectations inspectors have for their pharmacovigilance systems.

- Concerning collaboration in inspections of pharmacovigilance systems, suggestions concerning opportunities for worksharing between NCAs were made. Another useful aspect would be the establishment of a procedure for sharing the inspection reports and the information on their outcomes.

In summary, the workshop was considered a fruitful and very positive experience by both the regulators and the industry delegates. The meeting facilitated a discussion between stakeholders, identifying a need for better guidance and harmonisation, as well as calls for proportionate legal requirements concerning changes of the details of the DDPS in the MA dossier after authorisation. A Master File concept would be considered useful. Meanwhile, a checklist for validation would be useful to ensure harmonised requests fro information by NCAs.
One additional message delivered at the meeting was the need to decrease the administrative burden on NCAs, the Agency and MAHs.

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[1] Guideline on Monitoring of Compliance with Pharmacovigilance Regulatory Obligations and Pharmacovigilance Inspections for Veterinary Medicinal Products
http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-9/pdf/2007_03%2027_vol9b_guidelines.pdf

[2] EMEA workshop on pharmacovigilance systems and inspections for veterinary medicinal products - Open invitation http://www.emea.europa.eu/pdfs/vet/phvwp/workshopannouncement.pdf

[3] EMEA workshop on pharmacovigilance systems and inspections 4 December 2007 - Programme
http://www.emea.europa.eu/pdfs/vet/phvwp/workshop.pdf

[4] IFAH-Europe is an organisation representing manufacturers of veterinary medicines, vaccines and other animal health products.