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Veterinary Medicines and Inspections

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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

(CVMP)

CONCEPT PAPER FOR USE OF DATA IN EUDRAVIGILANCE VETERINARY

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1. INTRODUCTION

Article 76(1) of Directive 2001/82/EC of the European Parliament and of the Council, as amended, states that the Agency[1] in collaboration with Member States and the European Commission (EC) shall set up a data-processing network to facilitate the exchange of pharmacovigilance information regarding veterinary medicinal products marketed in the Community in order to allow the competent authorities to share the information at the same time.

In accordance with Article 51 of Regulation (EC) 726/2004 of the European Parliament and of the Council, the Agency in collaboration with Member States and the European Commission (EC) shall set up a data-processing network for the rapid transmission of data between the competent Community authorities in the event of an alert, relating to faulty manufacture, serious adverse reactions and other pharmacovigilance data regarding veterinary medicinal products marketed in the Community.

A database has now been developed called Eudravigilance Veterinary as a joint effort between the European Commission, the Member States and the European Medicines Agency with the first test version released in 2002 and a revised production version 2.2.0 released in November 2005.

In accordance with Article 53 of Regulation (EC) 726/2004, the Agency and the Member States' competent authorities shall cooperate to develop pharmacovigilance systems and approaches that maximise use of resources available within the Community.

In accordance with Article 57(1)(c) of Regulation (EC) 726/2004, the Agency shall coordinate the supervision, under practical conditions of use, of medicinal products which have been authorised within the Community and the provision of advice on the measures necessary to ensure the safe and effective use of these products, in particular by evaluation, coordination of the implementation of pharmacovigilance obligations and the monitoring of such implementation.

For this purpose, this concept paper is the initial step in defining and harmonising the evaluation of data contained in EudraVigilance Veterinary.

In accordance with Article 57(1)(d) of Regulation (EC) 726/2004, the Agency shall ensure the dissemination of information on adverse reactions to medicinal products authorised in the Community, by means of a database permanently accessible to all Member States. Health-care professionals, marketing authorisation holders and the public shall have appropriate levels of access to these databases. This concept paper excludes considerations on such dissemination of information.

EudraVigilance Veterinary is a key component in supporting the Member States and the EMEA within its Scientific Committees in the co-ordination of the supervision, under practical conditions of use, of veterinary medicinal products which have been authorised within the EEA and the provision of advice on the measures to ensure the safe and effective use of these products, in particular by evaluating and making available through a pharmacovigilance database information on adverse reactions to the veterinary medicinal products in question.

2. PROBLEM STATEMENT

With all involved parties (the Agency, Member States and Industry) reporting into EudraVigilance Veterinary, a high amount of reports and pharmacovigilance data are already available for use and together with future reports coming in, it is essential to have a harmonised strategy throughout the European Regulatory Authorities on how to use the data in EudraVigilance Veterinary.

[1] The Agency is defined as the European Medicines Agency

Furthermore, at the Eudravigilance Veterinary webpage it is stated regarding the Data warehouse that it allows for user-friendly analysis and publication of data, which indicate to the public that evaluation and publication are foreseen.

Therefore, a strategy for use and procedures for evaluation of data in EudraVigilance Veterinary are needed.

3. DISCUSSION (ON THE PROBLEM STATEMENT)

Many issues have to be considered before development of a guideline on use of Eudravigilance Veterinary data is possible, as there are many stakeholders and common problems involved.

- The purpose of using the pharmacovigilance data within the EU has to be clarified as well as the scope of the guideline. In the light of the increased role of the Pharmacovigilance Working Party for veterinary medicinal products (PhVWP-V) with a task for surveillance of **all** veterinary medicinal products within the EU predominantly based on the reporting of serious adverse reaction reports to EudraVigilance Veterinary, the guideline should encompass the use of the data on the level of the EU as well as on the level of the individual member states. In that respect it could be considered to rename the title to 'Guideline to surveillance of veterinary medicinal products within the EU',

- Depending on the specifications of the access policy to the data within EudraVigilance Veterinary there should be clarification with regard to the responsibilities of the different stakeholders towards the use of the data. The roles of the competent authorities, the marketing authorisation holders, the EMEA with its Committees (and the PhVWP-V), the coordination group (CMD-V), the Commission and the general public in the use of the data should be clarified. The question on sharing the responsibility of surveillance of products or product groups should also be considered together with benefits from work sharing between Authorities.

- A signal detection strategy has to be defined. A proposal would be to transpose some or all of the trigger points from the 'Guideline on a strategy for triggering pharmacovigilance investigations preceding regulatory actions by EU competent authorities' (EMEA/CVMP/900/03), to the EU data gathering model of EudraVigilance Veterinary. Together with trigger points, identification of risk products that would need closer surveillance would also be relevant. E.g. the first two years a new product is on the market or high-risk vaccines. The format of documents for evaluation of detected signals needs to be discussed, together with the reporting lines back to the relevant authorities including the different routes of action that could lead to appropriate regulatory measures.

- Considering the current underreporting and the continuous accumulation of data within EudraVigilance Veterinary, the area of pharmacovigilance on the scale of the EU is relatively new. It will therefore be important to set realistic targets in relation to the overall development of the science of the use of pharmacovigilance data for veterinary medicinal products. The science on the analysis and the use of pharmacovigilance data for medicinal products has been established further and will be exemplary; however continuous development of the guidance should be foreseen and be based on the day to day experience with the data becoming available within EudraVigilance Veterinary.

- The importance of continuous feedback and collaboration between the authorities and the relevant pharmaceutical industry partners on issues under consideration should be highlighted. Any issues triggered should be checked and validated carefully in collaboration with all stakeholders in order to ensure that scientific conclusions be based on the widest expertise and most complete information available.

- In reference to the access to data policy (to be finalised), the document should describe the levels of transparency with regard to the proceedings and communication routes with certain professional groups (e.g. vets / breeders) and the general public.

4. RECOMMENDATION

The Pharmacovigilance Working Party recommends drafting a guideline on surveillance of veterinary medicinal products within the EU from data in EudraVigilance Veterinary. Points to be addressed will be:

Purpose of using data, involved parties, how to detect signals from data, how to transform this knowledge into regulatory measures and information to the public.

As discussions on how data in EudraVigilance Veterinary will be used in the future for surveillance purposes are still ongoing, it is recommended that the issue will be discussed at future PhVWP-V meetings. As stated earlier, discussions with the European Surveillance Strategy group (ESS)[2] for responsibility and work sharing clarification are needed and possibly discussions with the Joint Implementation Group (JIG)[3] for implementing tools for signal detection would also be needed.

5. PROPOSED TIMETABLE

- Q2/Q3 2006: Adoption of concept paper and consultation period
- Q3/Q4 2006: Initial discussions on guideline in PhVWP-V together with first draft of the guideline
- Q1/Q2 2007: Draft guideline for discussion with adoption and release for 6 months consultation
- Q1 2008: Adoption of guideline

6. RESOURCE REQUIREMENTS FOR PREPARATION

- A Rapporteur and Co-Rapporteurs are needed for drafting of a guideline.
- Discussions at least at two meetings of the PhVWP-V.
- Discussions with the Joint Implementation Group (JIG), the European Surveillance Strategy (ESS) Working Group and Heads of Medicines Agency – Veterinary (HMA-V).

7. IMPACT ASSESSMENT (ANTICIPATED)

The use of the data in Eudravigilance Veterinary for a harmonised surveillance of veterinary medicinal products in Europe will be of benefit for the public, the Authorities and Industry. A surveillance strategy for veterinary medicinal products generated from Eudravigilance Veterinary data will ensure that the data are used and evaluated in a coordinated manner and workload is shared between authorities in the evaluation procedure. However, a better use of the available pharmacovigilance resources in member states and EMEA will be necessary.

Furthermore, the transparency to the public and the Industry on pharmacovigilance information will be increased.

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[2] The European Surveillance Strategy is a regulatory authority initiative and has been established by the HMA-V to develop pharmacovigilance in the EU. The Agency participates as a member of the group.

[3] The Joint Implementation Group (JIG) is a working group consisting of representatives from the Agency, the National Competenet Authorities and the pharmaceutical industry, with the objective to discuss and decide on the concepts for the development of EudraVigilance Veterinary.

8. INTERESTED PARTIES

Regulatory authorities, the Agency, Industry and public.

Furthermore, the European Surveillance Strategy (ESS) Group, Heads of Medicines Agencies–Veterinary (HMA-V) and the Joint Implementation Group (JIG) will also have interest in such a guideline.

9. REFERENCES TO LITERATURE, GUIDELINES ETC

- Guideline on a strategy for triggering pharmacovigilance investigations preceding regulatory actions by EU competent authorities (EMEA/CVMP/900/03).